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, 2019
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 No. 001-38959

BridgeBio Pharma, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**84-1850815**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
421 Kipling Street, Palo Alto, CA	**94301**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(650) 391-9740**

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	BBIO	The Nasdaq Global Select Market

SECURITIES REGISTERED PURSUANT TO SECTION 12(g) OF THE ACT: **NONE**

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

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

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 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, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant based upon the closing price of the registrant's Common Stock on The Nasdaq Global Select Market on June 28, 2019 was $0 since the registrant had not issued any shares as of that date.

On February 24, 2020, there were 123,765,465 shares of the registrant's Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Specified portions of the registrant's definitive Proxy Statement to be issued in conjunction with the registrant's 2020 Annual Meeting of Stockholders, which is expected to be filed not later than 120 days after the registrant's fiscal year ended December 31, 2019, are incorporated by reference into Part III of this Annual Report. Except as expressly incorporated by reference, the registrant's Proxy Statement shall not be deemed to be a part of this Annual Report on Form 10-K.

BRIDGEBIO PHARMA, INC.
2019 Form 10-K Annual Report

Table of Contents

		Page
	PART I	
Item 1.	Business	1
Item 1A.	Risk Factors	58
Item 1B.	Unresolved Staff Comments	120
Item 2.	Properties	120
Item 3.	Legal Proceedings	120
Item 4.	Mine Safety Disclosures	120
	PART II	
Item 5.	Market for the Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	121
Item 6.	Selected Financial Data	123
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	124
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk	140
Item 8.	Financial Statements and Supplementary Data	141
Item 9.	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	199
Item 9A.	Controls and Procedures	199
Item 9B.	Other Information	200
	PART III	
Item 10.	Directors, Executive Officers and Corporate Governance	201
Item 11.	Executive Compensation	201
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	201
Item 13.	Certain Relationships and Related Transactions, and Director Independence	201
Item 14.	Principal Accountant Fees and Services	201
	PART IV	
Item 15.	Exhibits and Financial Statement Schedules	202
Item 16.	Form 10-K Summary	203
Exhibits		203
Signatures		207

Special Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the "Securities Act"). Such forward-looking statements involve substantial risks, uncertainties and assumptions. All statements in this Annual Report on Form 10-K, other than statements of historical fact, including, without limitation, statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans, intentions, expectations, goals and objectives may be forward-looking statements. The words "anticipates," "believes," "could," "designed," "estimates," "expects," "goal," "intends," "may," "objective," "plans," "projects," "pursuing," "will," "would" and similar expressions (including the negatives thereof) are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. The forward-looking statements in this report include, but are not limited to, statements about:

- *the success, cost and timing of our clinical development of our product candidates, including the progress of, and results from, our ongoing and planned Phase 3 clinical trials of BBP-265 and our clinical trials of BBP-831;*
- *our ability to initiate, recruit and enroll patients in and conduct our clinical trials at the pace that we project;*
- *the timing of our submissions to the FDA and any review or comments on data that we will need to generate to file our NDAs;*
- *our plans to implement certain development strategies;*
- *our ability to obtain and maintain regulatory approval of our product candidates, and any related restrictions, limitations or warnings in the label of any of our product candidates, if approved;*
- *our ability to compete with companies currently marketing or engaged in the development of treatments that our product candidates are designed to target;*
- *our reliance on third parties to conduct our clinical trials and to manufacture drug substance for use in our clinical trials;*
- *the size and growth potential of the markets for BBP-265, BBP-831, BBP-631, BBP-454 and any of our current product candidates or other product candidates we may identify and pursue, and our ability to serve those markets;*
- *our ability to identify and advance through clinical development any additional product candidates;*
- *the commercialization of our current product candidates and any other product candidates we may identify and pursue, if approved, including our ability to successfully build a specialty sales force and commercial infrastructure to market our current product candidates and any other product candidates we may identify and pursue;*
- *our ability to retain and recruit key personnel;*
- *our ability to obtain and maintain adequate intellectual property rights;*
- *our expectations regarding government and third-party payor coverage and reimbursement;*
- *our estimates of our expenses, ongoing losses, capital requirements and our needs for or ability to obtain additional financing;*
- *our expectations regarding the time during which we will be an emerging growth company under the JOBS Act;*
- *our financial performance; and*
- *developments and projections relating to our competitors or our industry.*

We may not actually achieve the plans, intentions, expectations or objectives disclosed in our forward-looking statements and the assumptions underlying our forward-looking statements may prove incorrect. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. Therefore, you should not place undue reliance on our forward-looking statements, and you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. Actual results or events could differ materially from the plans, intentions, expectations and objectives disclosed in the forward-looking statements that we make. Important factors that we believe could cause actual results or events to differ materially from our forward-looking statements include, but are not limited to, those listed under "Risk Factors" in Item 1A of Part I, "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Item 7 of Part II and elsewhere in this Annual Report on Form 10-K. Our forward-looking statements in this Annual Report on Form 10-K are based on current expectations as of the date hereof and we do not assume any obligation to update any forward-looking statements on account of new information, future events or otherwise, except as required by law.

PART I

ITEM 1. BUSINESS

Overview

We are a team of experienced drug discoverers, developers and innovators working to create life-altering medicines that target well-characterized genetic diseases at their source. We founded BridgeBio in 2015 to identify and advance transformative medicines to treat patients who suffer from Mendelian diseases, which are diseases that arise from defects in a single gene, and cancers with clear genetic drivers. Our pipeline of over 20 development programs includes product candidates ranging from early discovery to late-stage development. Several of our programs target indications that we believe present the potential for our product candidates, if approved, to target portions of market opportunities of at least $1.0 billion in annual sales. We have initiated a rolling NDA submission for one of our product candidates, and have three product candidates in clinical trials that, if positive, we believe could support the filing of an application for marketing authorization.

We focus on genetic diseases because they exist at the intersection of high unmet patient need and tractable biology. Our approach is to translate research pioneered at academic laboratories and leading medical institutions into products that we hope will ultimately reach patients. We are able to realize this opportunity through a confluence of scientific advances, including: (i) identification of the genetic underpinnings of disease as more cost-efficient genome and exome sequencing becomes available; (ii) progress in molecular biology; and (iii) the development and maturation of longitudinal data and retrospective studies that enable the linkage of genes to diseases. We believe that this early-stage innovation represents one of the greatest practical sources for new drug creation.

We believe we have developed a sustainable and scalable product platform that supports the continued growth of our company and the advancement of our pipeline. Leveraging our product platform, we have a goal of adding two to three programs to our pipeline each year going forward.

Our Platform

Our platform is distinguished by several key elements:

- **World class discovery and development talent:** Our team has previously submitted over 30 INDs and 15 NDAs, in aggregate. Our operations are overseen by a Management Committee that is comprised of renowned leaders in cancer and rare disease drug development.
- **Disciplined approach to target identification and prioritization:** We pair a systematic mapping of the genetic disease landscape with a proprietary set of over 10 criteria to narrow our focus on diseases with attractive attributes for drug development. We look for diseases with high unmet need and well-characterized mechanisms that present opportunities to address the root cause of disease.
- **Opportunistic approach to drug candidate selection:** We seek the best science and drug mechanisms of action, wherever they can be found. We accept programs that meet our standards at any stage of development, and we are agnostic to therapeutic area. However, we only pursue programs with treatment modalities that we believe are biologically suited to address the target disease.
- **Focus at the level of each program:** We maintain a decentralized structure wherein each program is housed in its own subsidiary. This allows us to build a team of experts and specialists tailored to the needs of each program, and who are economically incentivized at the program level. We enable our subsidiary leaders to make certain operational decisions outside of a centralized management hierarchy, as we fundamentally believe that those operators who have the most intimate program knowledge are best positioned to make key operational decisions.
- **Operational efficiency:** We aim to rapidly and decisively advance our product candidates to objective critical decision points. At each stage of research, discovery, or development, we direct resources toward the opportunities that we believe are the most promising, and we discontinue programs that do not meet performance thresholds. We field a minimum viable team for each asset, with the goal of ensuring that each program has sufficient personnel to fit its purpose while reducing excess overhead costs. We accomplish this by hiring the best talent, centralizing and sharing certain support functions across various programs, and leveraging external providers where appropriate. This enables us to minimize traditionally fixed costs at the program level.

- **Portfolio breadth and diversification:** We have built a broad and diversified portfolio with over 20 programs that vary across stage of development, therapeutic category and modality. We believe that our programs are biologically uncorrelated, covering different diseases, different targets, and different modalities, such that the results of one program will not impact the development of others. Further, the breadth of our portfolio mitigates the impact of failure of any single program. As a result, we can be objective about each of our programs and allocate capital efficiently, delivering staged funding across our portfolio based on each program's scientific merits.
- **Optimized ownership for each program:** When we believe that we are best suited to continue a program's development, we will continue to fund it internally. If we believe a strategic partner is better suited to progress a program, we will consider externalizing development at economically attractive terms.

Our Pipeline

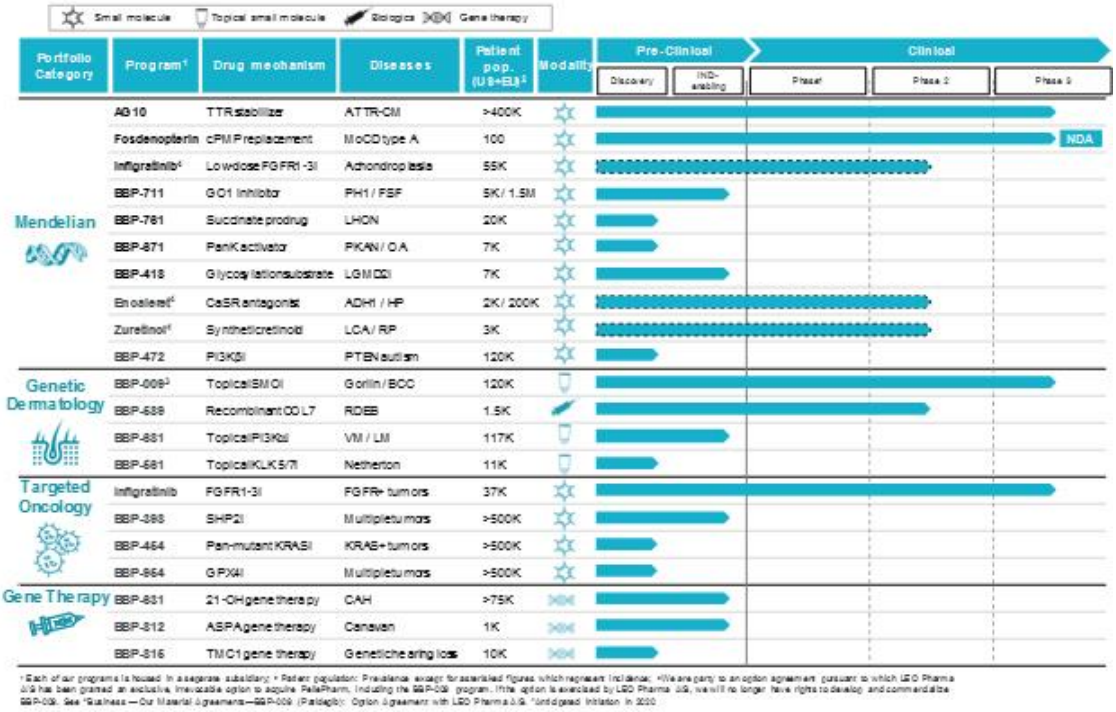
Our product platform supports the advancement of our current pipeline, which includes over 20 development programs that can be divided into four key categories:

- **Mendelian:** Ten small molecule product candidates, in stages of development ranging from preclinical to rolling NDA submission. Several of our product candidates in this category target some of the most prevalent Mendelian diseases, including ATTR and achondroplasia. One of our programs in this category has received breakthrough therapy designation from the FDA.
- **Genetic Dermatology:** Four small molecule and protein replacement product candidates, in stages of development ranging from preclinical to Phase 3. One of our programs in this category has received breakthrough therapy designation from the FDA.
- **Targeted Oncology:** Four targeted oncology programs, in stages of development ranging from preclinical to Phase 3, that address key oncogenic pathways including FGFR, KRAS and SHP2. These programs have potentially broad applicability across a number of solid tumor types with high unmet patient need.
- **Gene therapy:** Three programs focused on Mendelian diseases that are particularly suited to gene therapy, all of which are in preclinical development. Our gene therapy programs are led by executives who have substantial domain expertise and are recognized leaders in this field, and we are actively building our gene therapy capabilities.

Of our development programs, we believe the following, which we refer to as our key value drivers, have the greatest potential to drive significant value for our company due to a combination of factors, including their stage of development, potential availability of expedited development pathways, degree of unmet medical need and potential market size in the applicable target indication:

- BBP-265 (also known as AG10, under development at our subsidiary, Eidos Therapeutics, Inc.), a small molecule stabilizer of TTR that is in an ongoing Phase 3 clinical trial for the treatment of ATTR-CM.
- Infigratinib (also known as BBP-831), a small molecule selective FGFR1-3 inhibitor being developed for the treatment of FGFR-driven cancers and achondroplasia, for which we intend to submit an NDA in 2020 for the treatment of CCA as a second-line or later therapy.
- BBP-631, an AAV5 gene transfer product candidate in preclinical development for the treatment of CAH, driven by 21OHD.
- BBP-454, a preclinical development program for small molecule inhibitors of KRAS for the treatment of pan-mutant KRAS-driven cancers, which act via two novel binding pockets.

The following table summarizes our significant development programs, their estimated patient populations, their therapeutic modalities and their development status:



[1] Each of our programs is housed in a separate subsidiary. [2] Patient population: Prevalence except for asterisked figures which represent incidence. [3] We are party to an option agreement pursuant to which LEO Pharma A/S has been granted an exclusive, irrevocable option to acquire PellePharm, including the BBP-009 program. If the option is exercised by LEO Pharma A/S, we will no longer have rights to develop and commercialize BBP-009. See "Business—Our Material Agreements—BBP-009 (Palidagib): Option Agreement with LEO Pharma A/S." [4] Undisclosed indication in 2020.

KEY VALUE DRIVERS

BBP-265/AG10 (Eidos): TTR Amyloidosis

Summary

We are developing BBP-265, also known as AG10, an oral small molecule TTR, stabilizer, for the treatment of TTR amyloidosis, or ATTR, including both cardiomyopathy and polyneuropathy manifestations, or ATTR-CM and ATTR-PN, respectively. A Phase 3 clinical trial in ATTR-CM, known as the ATTRibute study, is currently ongoing, and we anticipate initiating a Phase 3 clinical trial in ATTR-PN in the first-half of 2020. We anticipate reporting of 12-month 6MWD data from the Phase 3 ATTRibute study in patients in ATTR-CM in 2021.

Disease Overview

ATTR is a disease caused by destabilization of TTR tetramers resulting in amyloid deposition. TTR is a protein that occurs naturally in the form of a tetramer, which is a molecular structure consisting of four identical subunits, or monomers, and performs multiple physiologic roles, including the transport of essential hormones and vitamins. In ATTR, TTR tetramers become destabilized due to a mutation in the TTR gene or as part of the natural aging process. Destabilized TTR dissociates into monomers, self-aggregates and assembles into fibrils which are deposited, predominantly in the heart and nervous system, driving disease pathophysiology.

ATTR is commonly categorized by its genotypic cause and primary clinical manifestation: wild-type ATTR cardiomyopathy, or ATTRwt-CM, which results from an age-related process; mutant ATTR cardiomyopathy, or ATTRm-CM; and ATTR polyneuropathy, or ATTR-PN, which is only associated with TTR mutants. All three forms of the disease are progressive and fatal. ATTRwt-CM and ATTRm-CM patients generally present with symptoms later in life (older than 50) and have median life expectancies of three to five years from diagnosis. ATTR-PN presents either in a patient's early 30s or later (older than 50), and results in a median life expectancy of five to ten years from diagnosis. Progression of all forms of the disease causes significant disability, impacts productivity and quality of life, and creates a significant economic burden due to the costs associated with patient need for supportive care. As the disease progresses, ATTRwt-CM and ATTRm-CM patients may require frequent hospitalizations and repeated interventions. ATTR-PN patients experience gradual loss of the ability to walk without assistance, and autonomic nervous system function affecting digestion and blood pressure.

The worldwide estimated prevalence of ATTRwt-CM, ATTRm-CM, and ATTR-PN is approximately 400,000, 40,000, and 10,000, respectively. However, we believe that the cardiomyopathic forms of the disease are significantly underdiagnosed. For example, recent literature has suggested that between 12% to 19% of patients diagnosed with heart failure with preserved ejection fraction may, in fact, have undiagnosed ATTR-CM. This single segment represents approximately half of the 6.0 million to 7.0 million estimated people with heart failure in the United States alone. With the increasing availability of disease modifying therapeutics, disease awareness is heightened.

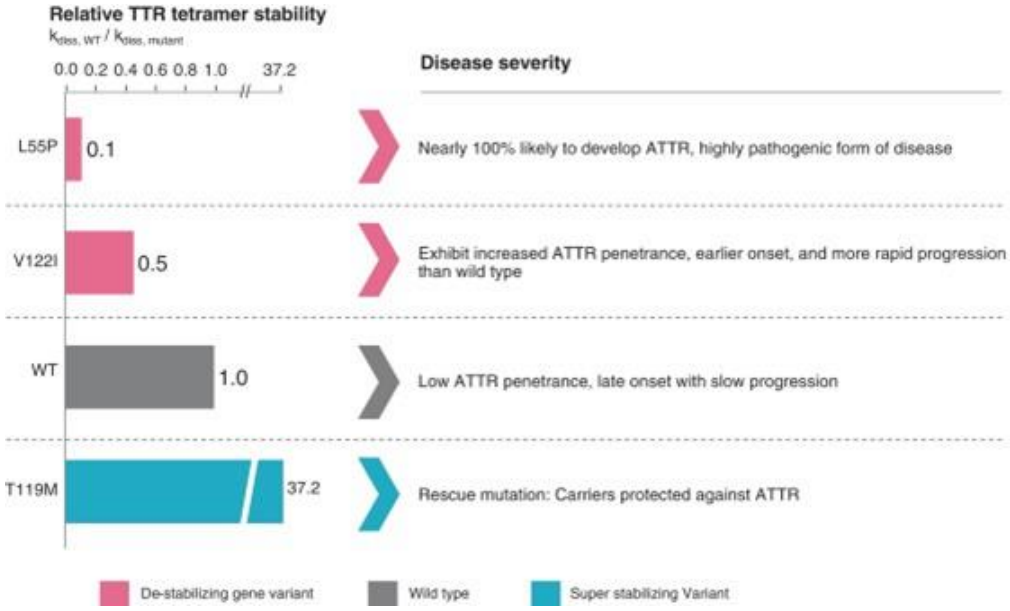
We believe the population of diagnosed ATTR-CM patients is also growing rapidly due to the shift to an accurate and reliable non-invasive diagnostic imaging technique. Historically, a heart biopsy was required to make a diagnosis of ATTR-CM. Recently, however, it has been shown that scintigraphy with technetium-labelled radiotracers is a highly accurate, non-invasive and cost effective method for ATTR-CM diagnosis. We believe that both increased disease awareness and availability of this non-invasive diagnostic imaging technique are allowing for earlier diagnosis of ATTR-CM patients and the identification of previously misdiagnosed patients.

Our Product Concept

BBP-265 is a clinical-stage orally-administered, small molecule TTR stabilizer being developed to treat ATTR at its source by reducing the level of amyloid formation through TTR stabilization. This has been shown in preclinical studies and clinical trials to prevent the dissociation of tetrameric TTR into monomers, and in preclinical studies, to reduce the rate of amyloid fibril formation. In addition, BBP-265 has been shown to lead to increased circulating levels of tetrameric TTR. BBP-265 has been designed to bind TTR in a way that causes TTR's conformational structure to mimic that of the well-characterized T119M variant, a naturally occurring rescue mutation which super stabilizes the TTR tetramer. T119M has been observed to prevent the dissociation of TTR tetramers into monomers; T119M tetramers dissociate 40-fold more slowly than wild-type tetramers in biochemical assays. Known as a trans-allelic trans-suppressor, individuals who coinherit the T119M rescue mutation along with a TTR-destabilizing mutation, are protected against the development of ATTR.

In third party clinical trials of tafamidis and diflunisal, interventional approaches that increased TTR stabilization led to improved outcomes in this disease and were correlated with increases in serum TTR. Further, based on genetic data, there is a correlation between the level of TTR stabilization, serum TTR levels, and disease severity. As a result, we believe that serum TTR is a predictive biomarker for disease prognosis and that there may be a relationship between more effective TTR stabilization, serum TTR levels, and improved clinical outcomes. Based on head-to-head preclinical data, we believe that BBP-265 has the potential to stabilize TTR to a greater extent than other TTR stabilizers.

Human genetics suggest TTR stability is associated with disease severity



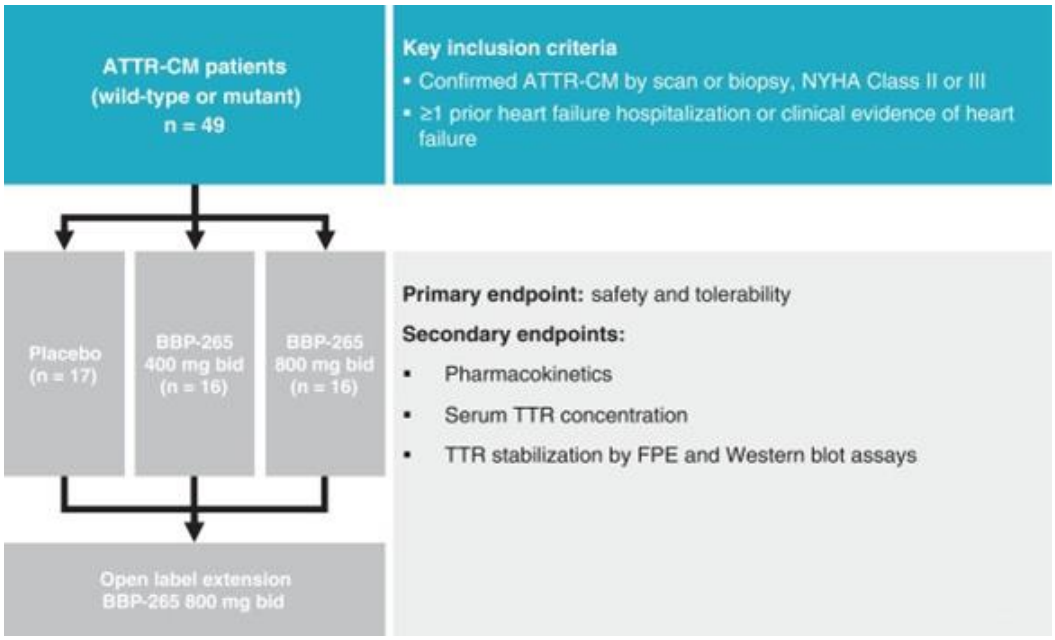
The above chart shows the correlation between TTR stability, as assessed using recombinant protein in vitro, and disease severity in ATTR patients. Patients with TTR variants that result in highly destabilized TTR are nearly 100% likely to develop the disease, like those with the L55P gene variant. Patients who have super-stabilized TTR, as in the case of individuals with the T119M gene variant, are protected against ATTR and cerebrovascular diseases.

We believe that TTR is an important plasma protein as evidenced by the fact that it is highly evolutionarily conserved, existing in high concentrations in all vertebrates. We believe that therapies that increase serum TTR are likely to result in better clinical outcomes than therapies that decrease TTR serum levels, assuming similar levels of monomer reduction. This hypothesis is further supported by two prospective studies of 68,602 participants in Denmark over an average 32 years of clinical follow-up, which showed that individuals who inherited the T119M mutation in the absence of a TTR pathogenic gene had higher circulating TTR concentrations, had a lower range of cerebrovascular events, especially fatal or debilitating stroke, and had a five-to-ten year increase in life expectancy relative to the general population. Additionally, data from a retrospective study at Boston University, suggests a correlation between serum TTR changes and mortality in ATTRwt-CM patients.

Clinical Data

Phase 2 Data

In April 2018, we initiated our Phase 2 randomized, placebo-controlled, dose-ranging clinical trial of BBP-265 in 49 patients with symptomatic ATTR-CM, of which 14 had ATTRm-CM. Eligible patients were randomized in a 1:1:1 ratio to placebo or 400 mg or 800 mg of BBP-265 twice daily. The primary objective of the trial was to evaluate the safety and tolerability of BBP-265 administered to adult subjects with symptomatic ATTR-CM. The secondary objectives were to characterize the pharmacokinetics, or PK, of BBP-265 in symptomatic ATTR-CM subjects and to describe the pharmacodynamics, or PD, properties of BBP-265, as well as the PK-PD relationship of BBP-265. The PD assessments of TTR stabilization were measured by fluorescent probe exclusion, Western blot and serum prealbumin (TTR). The trial design is depicted below:



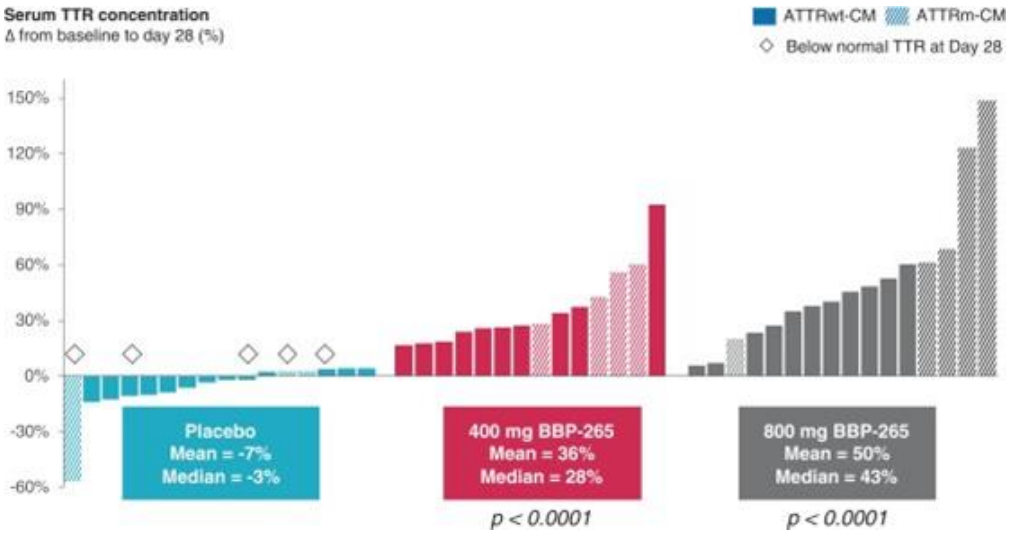
Enrolled symptomatic ATTR-CM subjects ranged in age from 60 to 86 years of age, with a mean age of 74.1, and 92% of subjects were male. In this trial, we enrolled subjects exclusively with advanced disease, with 29% of subjects presenting with New York Heart Association (NYHA) Class III heart failure symptoms and a high baseline NT-proBNP with a mean of 3,368 pg/mL. Additionally, on average, subjects had relatively low TTR at baseline with a mean of 22.0 mg/dL. The laboratory reference range for serum TTR is 20mg/dL to 40 mg/dL in healthy individuals. Both high NT-proBNP and low TTR are biomarkers of disease severity. The subject disposition and baseline characteristics are shown below.

Characteristic	Placebo (n = 17)	BBP-265 400 mg (n = 16)	BBP-265 800 mg (n = 16)	Total (n = 49)
Age, mean (range)	73.2 (60-5)	73.8 (60-83)	75.4 (67-86)	74.1 (60-86)
Male, n (%)	17 (100%)	14 (88%)	14 (88%)	45 (92%)
ATTRm-CM, n (%)	3 (18%)	6 (38%)	5 (31%)	14 (29%)
NYHA Class III, n (%)	5 (29%)	6 (38%)	3 (19%)	14 (29%)
Race, n (%)				
White	13 (76%)	10 (62%)	12 (75%)	35 (72%)
Black	3 (18%)	4 (25%)	3 (19%)	10 (20%)
Other	1 (6%)	2 (13%)	1 (6%)	4 (8%)
NT-proBNP (pg/mL)[1]	3151 ± 2705	3589 ± 3020	3377 ± 2806	3368 ± 2789
Troponin I (ng/mL)[2]	0.17 ± 0.30	0.22 ± 0.24	0.10 ± 0.06	0.16 ± 0.22
TTR (mg/dL)[3]	23.4 ± 5.5	23.2 ± 5.7	19.5 ± 4.2	22.0 ± 5.4

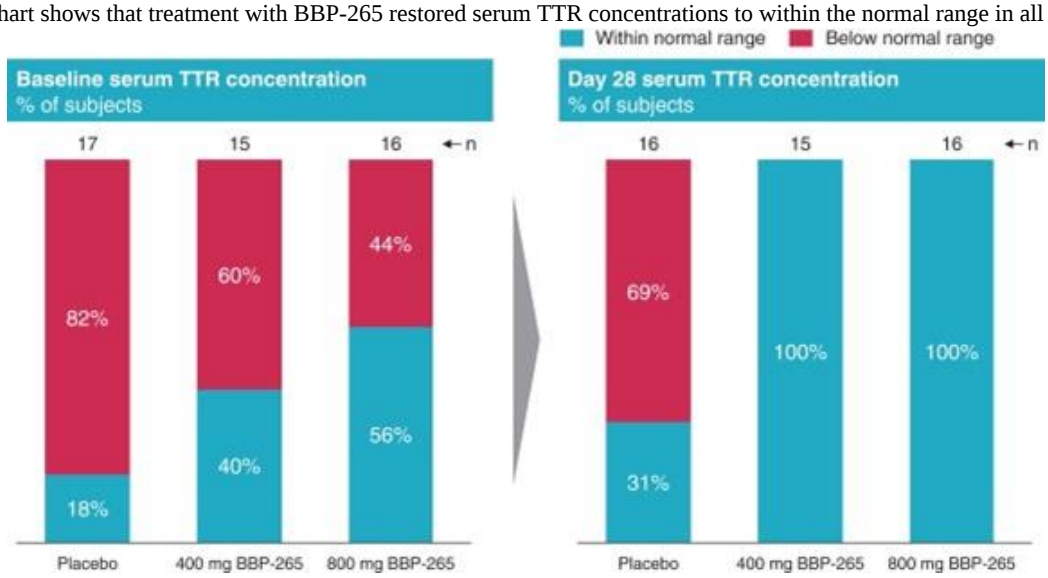
1 NT-proBNP normal range = 0 – 449 pg/mL; NT-proBNP = N-Terminal pro B-type Natriuretic Peptide
2 Troponin I normal range = 0 – 0.02 ng/mL
3 TTR normal range = 20 – 40 mg/dL

Overall, BBP-265 was well-tolerated in symptomatic ATTR-CM subjects with no lab safety signals of potential clinical concern attributed to study drug. In this trial, 88% of subjects administered placebo experienced AEs and 63% and 69% of subjects administered 400 mg and 800 mg BBP-265 experienced AEs, respectively. In both the placebo and active treatment groups, most of the AEs were mild to moderate in severity. The most commonly observed AEs, occurring in four or more subjects across the treatment and placebo groups, were atrial fibrillation, constipation, diarrhea and muscle spasms. Three subjects reported SAEs during this study. One placebo-treated subject experienced two SAEs of atrial fibrillation and congestive heart failure and another placebo-treated subject experienced cellulitis in their lower extremity. One BBP-265 treated subject experienced an SAE of shortness of breath on study, which was considered unlikely to be related to study drug.

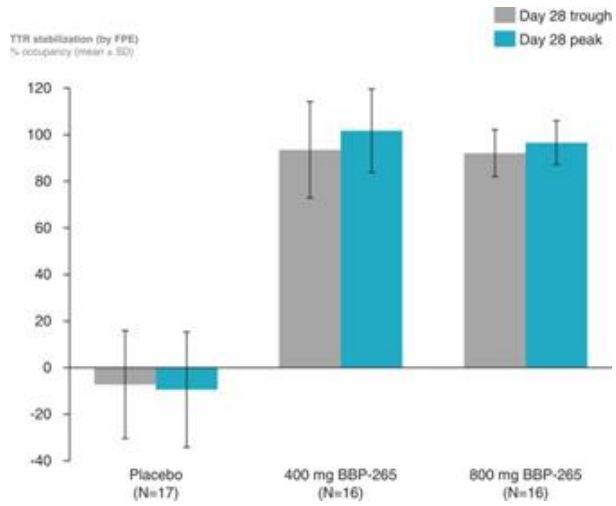
As shown in the chart below, subjects in the placebo group experienced a mean 7% reduction in the circulating tetrameric TTR concentrations compared to baseline. Conversely, subjects administered either 400 mg or 800 mg BBP-265 showed a dose-dependent statistically significant mean increase in circulating TTR of 36% and 50%, respectively, compared to baseline. Compared to placebo, both the 400 mg and 800 mg BBP-265 arms demonstrated statistically significant increases in mean circulating TTR ($p<0.0001$ for both arms). p-value is a statistical calculation that relates to the probability that the difference between groups happened by chance, with a p-value of less than 0.05 (i.e., less than 5% probability that the difference happened by chance) generally being used as the threshold to indicate statistical significance. There was a greater observed treatment effect in subjects with mutant ATTR-CM as compared to subjects with wild-type ATTR-CM, which we believe can be explained, in part, by the lower absolute serum TTR of mutant ATTR-CM subjects at baseline.



The following chart shows that treatment with BBP-265 restored serum TTR concentrations to within the normal range in all subjects at Day 28.



Ex vivo stabilization assays demonstrated near-complete TTR stabilization by BBP-265, with greater than 90% average tetramer stabilization across subjects treated with 400 mg and 800 mg BBP-265 as shown in the chart below. The stabilization response was consistent across mutant and wild-type TTR carriers and replicates previously reported clinical and preclinical TTR stabilization data.

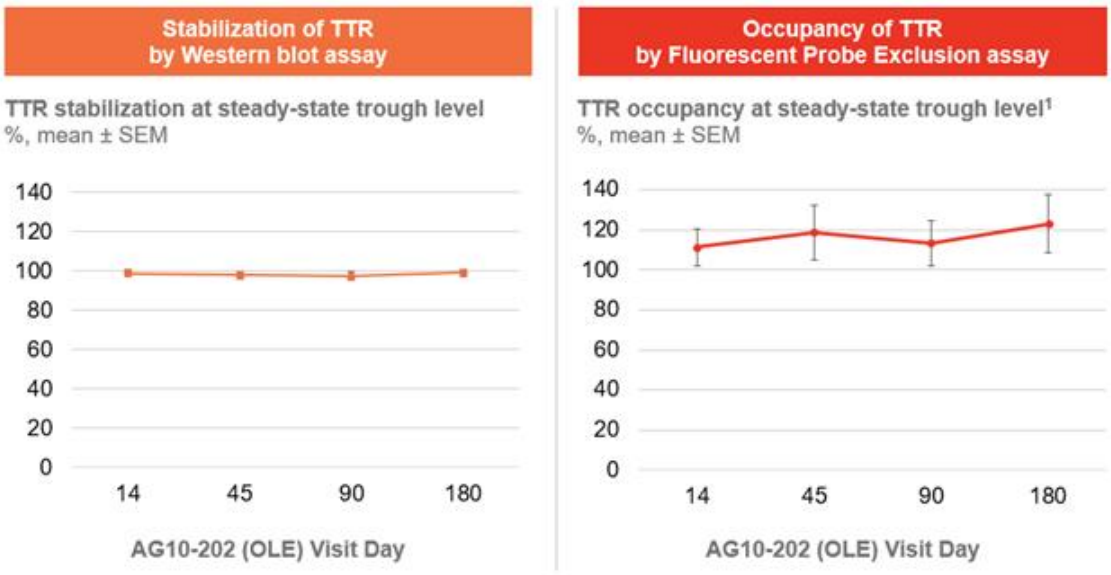


Interim analysis of the ongoing Phase 2 open label extension, or OLE, study was completed on August 31, 2019 in conjunction with annual regulatory reporting and review, at which time 41 participants remained in the study. Three (6.4%) participants in the OLE had died, two due to disease progression and one due to cervical cancer. Three (6.4%) additional patients enrolled in the study had discontinued treatment, including one participant who underwent cardiac transplantation for their disease.

Adverse events reported in the OLE study were generally consistent with the underlying ATTR-CM disease state and no safety signals of potential clinical concern were associated with the administration of AG10 in the study. Forty-six (97.9%) patients experienced a treatment-emergent adverse event reported during the study, with falls, congestive cardiac failure, dyspnea, and acute kidney injury the most commonly reported adverse events. Nineteen (40.4%) participants experienced a treatment-emergent serious adverse event reported during the study, with congestive cardiac failure (10.6%) and acute kidney injury (8.5%) the most commonly reported serious adverse events.

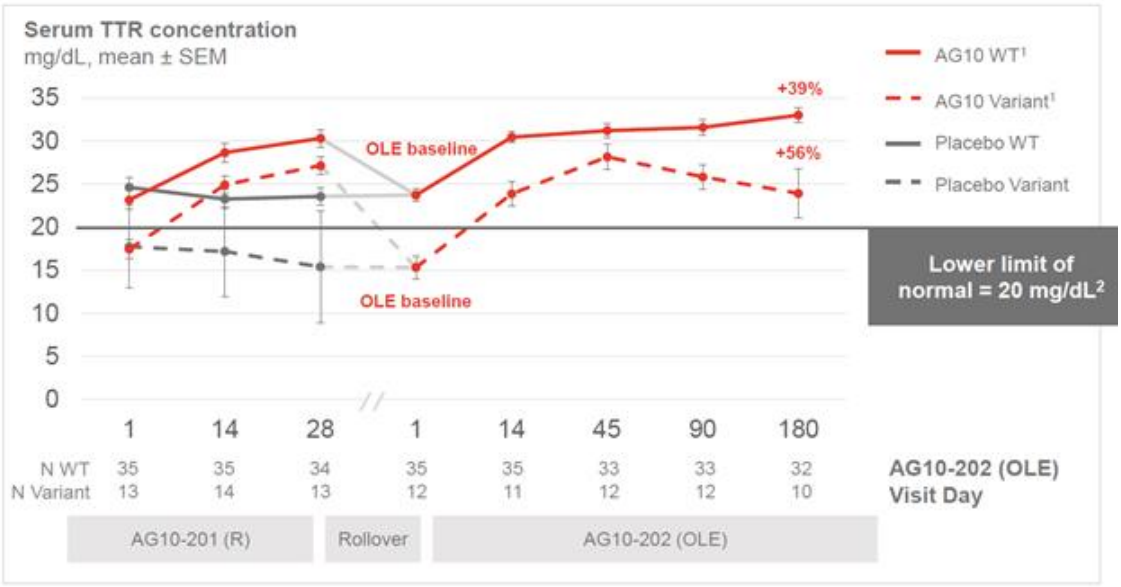
The rate of all-cause mortality (including either death or cardiac transplantation, 8.5%) and cardiovascular-related hospitalizations (25.5%) observed in an exploratory analysis of participants in this study following a median of 15 months since Phase 2 initiation were lower than those observed at 15 months in placebo-treated patients in the ATTR-ACT study (all-cause mortality including death or cardiac transplantation, 15.3%; cardiovascular-related hospitalizations, 41.8%).

Stabilization of TTR, as measured using established ex vivo assays, was maintained >90% on average at all study visits in actively treated patients.



(1) Reported occupancy >100% caused by background protein fluorescence.

Mean serum TTR levels, a prognostic indicator of survival in a published cohort of wild-type ATTR-CM patients, were elevated upon AG10 treatment and were maintained in the normal range throughout the study duration. Mean serum TTR levels were increased from baseline by 39% and 56% in wild-type and variant-carrying ATTR-CM patients, respectively, at OLE Visit Day 180.



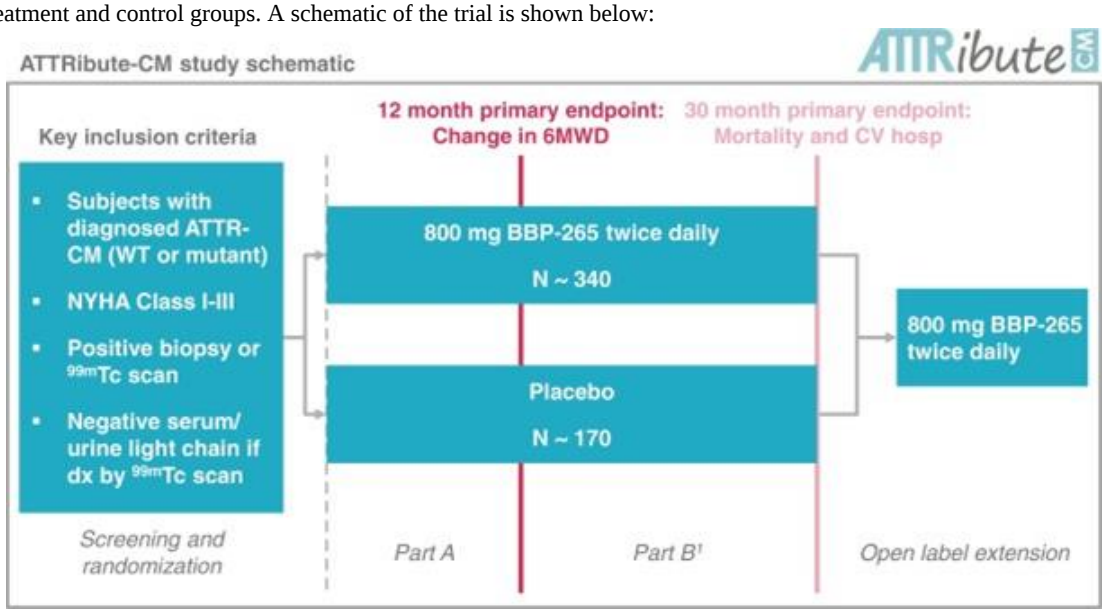
1 400mg and 800mg BID AG10 groups pooled during randomized portion

2 Defined as the lower limit of the reference interval for the serum prealbumin (TTR) clinical laboratory assay

Cardiac biomarkers and echocardiographic parameters were stable during the OLE study. NT-proBNP and TnI were unchanged throughout the course of the study. Echocardiographic parameters, including left ventricular mass and left ventricular stroke volume index, were unchanged during the study.

Clinical Development Plan

In November and December of 2018, we met with the FDA to discuss a potential regulatory path for BBP-265 in ATTR-CM. Following these discussions, we initiated a randomized, global Phase 3 study of BBP-265 in ATTR-CM patients (ATTRibute-CM). ATTRibute-CM will enroll approximately 510 subjects with symptomatic ATTR-CM, including both wild-type and mutant TTR carriers with New York Heart Association Class I-III symptoms. Subjects will be randomized 2:1 between treatment (AG10 800 mg twice daily) and placebo. In Part A, change in six-minute walk distance (6MWD) at 12 months will be compared between treatment and placebo groups as a potential registrational endpoint. We anticipate reporting 12-month 6MWD data from Phase 3 ATTRibute study in patients with ATTR-CM in 2021. If the change in 6MWD is highly statistically significant, we anticipate submitting an NDA for ATTR-CM. In Part B, the study will continue for a total duration of 30 months, at which point all-cause mortality and cardiovascular hospitalizations will be compared between treatment and control groups. A schematic of the trial is shown below:



Secondary endpoints include: Kansas City Cardiomyopathy Questionnaire, serum TTR, TTR stabilization
As local standard of care evolves, concomitant use of approved, indicated therapies may be allowed

6MWD = Six minute walk distance; NYHA = New York Heart Association;
99mTc = Technetium labeled pyrophosphate (PYP) or bisphosphonate (e.g., DPD); dx = diagnosis;
CV hosp = cardiovascular-related hospitalizations

We believe the safety and tolerability data of BBP-265 in healthy volunteers and in ATTR-CM patients will also be relevant for the ATTR-PN patient population. We anticipate initiating a Phase 3 clinical trial of BBP-265 in ATTR-PN in 1H 2020. Our Phase 3 study in ATTR-PN (ATTRibute-PN) is expected to enroll approximately 145 subjects with symptomatic ATTR-PN. Eligible subjects will be randomized in a 2:1 ratio to AG10 800 mg or matching placebo administered twice daily. The primary endpoint of the study is to evaluate the efficacy of AG10 based on the difference between the AG10 and placebo groups in Modified Neuropathy Impairment Score + 7 at 18 months of treatment relative to baseline.

Market Opportunity

We believe that the total market for ATTR therapeutic interventions will continue to grow for the foreseeable future as the population of diagnosed patients increases as a result of heightened disease awareness and the adoption of non-invasive diagnostic techniques. As such, if BBP-265 is approved, we believe that there could be a significant population of newly diagnosed patients who can be treated with BBP-265 who have not previously been treated with a disease-modifying therapy.

If approved, we believe that BBP-265 could have meaningful commercial potential. Further, we believe that BBP-265, if approved, has the potential to demonstrate benefit as a best-in-class stabilizer for the treatment of ATTR.

Competition

In the area of ATTR, we expect to face competition from competitors targeting three distinct mechanisms of action: TTR stabilization, TTR knockdown, and TTR clearance, each of which is expected to compete with BBP-265, if approved.

Among TTR stabilizers, we will face competition from Pfizer Inc.'s tafamidis, an oral TTR stabilizer that is approved for ATTRwt-CM and ATTRm-CM in the United States, Europe, and Japan and is marketed as VYNDAQEL and VYNDAMAX. Tafamidis is also approved in select geographies outside of the United States for Stage 1 (early stage) ATTR-PN. Corino Therapeutics Inc./SOM Innovation Biotech, S.L. is developing SOM0226 (tolcapone, CRX-1008), an oral, small molecule TTR stabilizer for ATTR and has completed a Phase 2a trial in ATTR-PN. Tolcapone is a generic drug that is FDA-approved for the treatment of Parkinson's disease. Diflunisal, a generic, non-steroidal anti-inflammatory drug (NSAID) indicated for mild to moderate pain and arthritis, may also be considered a competitor, having been shown to significantly slow development of ATTR-PN in a randomized Phase 2/3 trial. Diflunisal's label contains a boxed warning for cardiovascular, renal and gastrointestinal risks.

Potentially competitive TTR knockdown approaches are being pursued by multiple companies. In 2018, Alnylam Pharmaceuticals Inc., or Alnylam, received marketing authorization from both the FDA and EMA for Onpattro (patisiran), an intravenously administered RNAi therapeutic for the treatment of hereditary ATTR with polyneuropathy. Alnylam is also developing ALN-TTRsc02 (vutrisiran), a subcutaneously administered RNAi therapeutic for ATTR. Alnylam has reportedly completed a Phase 1 clinical trial of ALN-TTRsc02 in healthy volunteers and initiated a Phase 3 trial in patients with hereditary ATTR with polyneuropathy. Ionis Pharmaceuticals Inc./Akcea Therapeutics, Inc. received marketing approval from both the FDA and EMA in 2018 for Tegsedi (inotersen), an antisense oligonucleotide (ASO) drug, for hereditary ATTR with polyneuropathy. Both Alnylam and Ionis/Akcea have initiated Phase 3 trials in ATTR-CM. Intellia's program is currently in preclinical development.

Therapeutics targeting TTR clearance may also be competitive to BBP-265. Prothena Therapeutics plc is developing PRX004, a monoclonal antibody, for ATTR that is currently in a Phase 1 clinical trial. Neurimmune Holding AG is developing NI006, a monoclonal human antibody for ATTR that is in Phase 1 clinical trial. Proclara Biosciences, Inc. is developing NPT189, an immunoglobulin fusion, for ATTR and amyloid light chain amyloidosis and has completed a Phase 1a clinical trial.

BBP-831/Infigratinib: FGFR-Driven Cancers

Summary

We are developing infigratinib, an oral FGFR1-3 selective tyrosine kinase inhibitor, or TKI, for the treatment of FGFR-driven cancers. Specifically we are developing infigratinib in three oncologic indications: (i) cholangiocarcinoma, or CCA, with FGFR2 fusions or translocations, (ii) urothelial carcinoma, or UC, with FGFR genomic alterations, and (iii) other cancers with FGFR fusions or translocations.

We are currently preparing an NDA submission in advanced CCA, as a second-line or later therapy and have initiated a Phase 3 clinical trial in advanced CCA as a first-line therapy as well as an Investigator-initiated trial in certain cancers involving FGFR fusions or translocations. We received Fast Track Designation in adults with first-line advanced or metastatic cholangiocarcinoma and Orphan Drug Designation for infigratinib for treatment of cholangiocarcinoma.

We anticipate submitting an NDA for the treatment of advanced CCA as a second-line or later therapy in 2020. We also anticipate enrolling our first patient in a Phase 3 clinical trial in adjuvant UC in 2020.

Disease Overview

FGFRs are a family of genes that regulate multiple biological processes including cell proliferation, angiogenesis, and tissue repair. Amplifications, mutations, and fusions/translocations in FGFR genes are present in multiple cancers, and it is believed that they are key drivers in certain cancer types. FGFR genomic alterations have been shown to be present in approximately 7% of cancers. FGFR fusions or translocations, more specifically, have been shown to be present in approximately 0.6% of solid tumors.

Below is a table showing the frequency of certain FGFR genomic alterations in different tumor types:

Tumor type	Incidence (U.S. and EU)	Estimated Occurrence of FGFR genomic alterations*	Most common alteration(s)
Cholangiocarcinoma	20,000	15-20%	FGFR2 fusions or translocations
Urothelial carcinoma	200,000		
Non-muscle invasive bladder cancer	130,000	35-60%	FGFR3 mutations
Muscle invasive bladder cancer	41,000	15-20%	FGFR3 mutations
Non-invasive upper tract urothelial carcinoma	13,000	80-90%	FGFR3 mutations
Invasive upper tract urothelial carcinoma	19,500	50-60%	FGFR3 mutations
Gastric adenocarcinoma	40,000	10%	FGFR2 amplifications, FGFR2 fusions or translocations
Glioma	10,000	5%	FGFR3 fusions or translocations, FGFR1 amplifications
Head and neck squamous cell carcinoma	90,000	15%	FGFR1 genomic alterations
Carcinoma of unknown primary	20,000	5-10%	FGFR2/3 fusions or translocations
Endometrial adenocarcinoma	125,000	10-15%	FGFR2 fusions or translocations

* Approximate percentages

Cholangiocarcinoma

CCA is a rare and aggressive epithelial malignancy of the bile ducts of the liver. Approximately 20,000 new cases are diagnosed each year in the United States and European Union. The majority of newly diagnosed cases are non-resectable, meaning the malignancy cannot be removed completely through surgery. CCA, including resectable and non-resectable cases, has a median overall survival, or OS, between 20 and 28 months from diagnosis, and a five-year survival rate of approximately 25%.

Currently, no product has been specifically approved for the treatment of non-resectable CCA. Standard of care in locally advanced (i.e., non-resectable) and/or metastatic disease for first-line treatment is platinum-based chemotherapy, which has median with a progression-free survival, or PFS, of approximately eight months and an OS of approximately 12 months. Approximately 85% of these patients will move on to receive a second-line of treatment.

Second-line treatment for advanced and/or metastatic CCA is alternative single or combination agent chemotherapy; however, second-line chemotherapy has shown only single-digit response rates on average. In a comprehensive review of 25 studies, median PFS was 3.2 months and overall response rate, or ORR, was 7.7% for patients receiving second-line treatment. As a result, the National Comprehensive Cancer Network, or NCCN, guidelines for the treatment of CCA currently do not recommend any specific regimen for second-line treatments. Further, there are currently no targeted therapies approved for the treatment of CCA.

Urothelial Carcinoma

UC is a cancer of the lining of the urinary tract with approximately 200,000 new cases diagnosed each year in the United States and European Union.

UC can be categorized as bladder cancer, or BC, and upper tract urothelial carcinoma, or UTUC. In BC, patients are typically segmented into muscle-invasive, or MIBC, and non-muscle invasive, or NMIBC disease. UTUC, in turn, can be classified as invasive or non-invasive disease. We are initially focused on developing infigratinib for the 45,000 MIBC and 15,000 invasive UTUC cases that occur annually in the United States and European Union.

Patients that present with MIBC or invasive UTUC are typically candidates for surgical resection, specifically radical cystectomy or radical nephroureterectomy, respectively, as an initial treatment. However, upon resection, approximately 50% of cases will recur within two years of surgery. Following surgical resection there is no standard of care for adjuvant treatment, especially for cisplatin ineligible patients. There are limited clinical data suggesting that cisplatin-based adjuvant regimens may increase disease-free survival. And, as renal function is impaired in many patients due to age and surgical removal of the bladder, ureter and/or kidney, many patients are not candidates for cisplatin-based therapy. Data suggests that approximately 40% to 50% of MIBC patients and 70% to 80% of invasive UTUC patients are cisplatin ineligible after radical cystectomy and radical nephroureterectomy, respectively.

Our Product Concept

Signaling via FGFR genes is thought to be a key driver of certain cancers, including CCA and UC. As an FGFR1-3 specific inhibitor, infigratinib abrogates signaling via the FGFR1-3 pathways, interfering with oncogenic signaling and cancer growth.

Infigratinib has shown clinical activity in advanced and/or metastatic CCA with FGFR2 fusions or translocations, with an ORR of 26.9%, in a Phase 2 clinical trial as described below. In advanced and/or metastatic CCA, limited treatment options make FGFR-directed therapies particularly attractive potential treatment options.

Infigratinib has also shown clinical activity in advanced and/or metastatic UC with FGFR3 genomic alterations in a Phase 1 expansion cohort, with an ORR of 25.4%, as described below. The majority of patients with invasive UC undergo surgical resection; however, there is no standard of care for adjuvant treatment post-surgery, especially for cisplatin-ineligible patients. While there is limited evidence for the use of cisplatin-based chemotherapy as an adjuvant treatment, many patients are cisplatin ineligible due to poor renal function. We believe that infigratinib could play a meaningful role as an adjuvant treatment for patients with UC driven by FGFR3 genomic alterations.

Clinical Data

Infigratinib has been studied in fifteen clinical trials that include eight Phase 1 clinical trials in healthy volunteers, one mass balance and exertion study, three Phase 1 clinical trials in cancer patients, and three Phase 2 clinical trials in certain cancer patients, and has demonstrated clinical proof of concept in CCA and UC. To date, infigratinib has been tested in over 700 subjects, including healthy volunteers and cancer patients, and has demonstrated acceptable tolerability.

In the studies described below, the following revised RECIST guideline version 1.1, or RECIST 1.1, criteria, which are the accepted criteria by the scientific community for the tumor type discussed, were used to define responses:

- ORR, which is defined as the proportion of patients with a best overall response of partial response, or PR, plus those with complete response, or CR.
- Response duration, which is measured from the time of initial response until documented tumor progression.
- Disease control rate, or DCR, which is defined as the proportion of patients who have achieved a best overall response of CR, PR, or stable disease, or SD.
- Progression free survival, or PFS, which is defined as the time from randomization/start of treatment until objective tumor progression or death, whichever occurs first.
- Overall survival, or OS, which is defined as the time from randomization until death from any cause.

CCA Phase 2 Clinical Trial

Infigratinib is being studied in an open-label, single-arm, Phase 2 clinical trial in patients with advanced and/or metastatic CCA. The study initially enrolled patients with any FGFR genomic alterations and was later amended to enroll only patients with FGFR2 fusions or translocations, who represented patients showing the strongest response. To date, we have reported interim data in 71 CCA patients with FGFR2 fusions or translocations, who had previously received a cisplatin-and gemcitabine-containing regimen, or a gemcitabine-containing regimen (for those who are considered intolerant to cisplatin) and are continuing to enroll patients in the trial. Patients received infigratinib 125 mg once daily for 21 days followed by seven days off in 28-day cycles until disease progression. The primary endpoint of the study is ORR. Secondary endpoints include PFS, best overall response, or BOR, DCR, OS, safety and PK. The median age of enrolled subjects is 53 years, 62.0% are female, 100.0% are FGFR2 fusion or translocation positive, and 7.0% have co-existing FGFR2 mutations. A significant majority of patients enrolled in the trial were pretreated, with 65.1% having received at least two prior lines of antineoplastic therapy.

At an interim analysis based on a data cut-off date of August 8, 2018, we observed the following results for FGFR2 fusion or translocation positive patients. The data presented in the table below are based on patients with potential for confirmation (n=67; patients who had completed or discontinued prior to six cycles). All responses were investigator-assessed.

ORR, % (95% CI)	26.9 (16.8-39.1)
ORR in patients receiving prior lines of treatment, %	
≤ 1 (n=28)*	39.3
≥ 2 (n=39)	17.9
BOR ‡ (confirmed and unconfirmed PRs)*, %	32.8
DCR, % (95% CI)	83.6 (72.5-91.5)
Median duration of response, months (95% CI)	5.4 (3.7-7.4)
Median PFS, months (95% CI)	6.8 (5.3-7.6)
Median OS, months (95% CI)	12.5 (9.9-16.6)

***** Three patients received no prior systemic therapy for advanced or metastatic CCA

‡ BOR defined per RECIST1.1: patients with one scan with greater than 30% change from baseline in target lesions, without confirmation from a second scan

The ORR as of the interim analysis was observed to be higher in the subsegment of patients who had received only one prior line of therapy (39.3% versus 26.9% for all patients).

Urothelial Carcinoma Phase 1 Clinical Trial Expansion Cohort

In a Phase 1 open-label, single arm expansion cohort of the '2101 study, patients with UC harboring FGFR3 genomic alterations (n=67) received infigratinib 125 mg once daily for 21 days followed by seven days off in 28-day cycles until progression. Patients enrolled in the trial had a median age of 67 years, and 68.7% were male. 92.5% of patients had FGFR3 mutations and 7.5% had FGFR3 fusions or translocations. The primary objective of the '2101 study was to determine the maximum tolerated dose, or MTD, and thus the recommended Phase 2 clinical trial dose and schedule of single agent oral BGJ398 in patients with advanced solid tumors. The key secondary objective of the expansion cohort in this study was to assess preliminary anti-tumor activity in patients treated with infigratinib. Other secondary objectives included safety, tolerability and PK analyses. Patients enrolled in the trial were heavily pre-treated, 70% of enrolled patients having received two or more prior lines of therapy. The endpoint assessment of patients from this trial follows:

ORR, %	25.4 (15.5-37.5)
BOR (confirmed and unconfirmed PRs), %	41.8
DCR, %	64.2 (51.5-75.5)
Median duration of response, months (95% CI)	5.6 (2.3-11.0)
Median PFS, months (95% CI)	3.8 (3.1-5.4)
Median OS, months (95% CI)	7.8 (5.7-11.9)

Of the 67 patients treated in this expansion cohort, eight were diagnosed as having UTUC. In these eight patients, ORR was 50% and DCR was 100%.

Safety Data

Infigratinib has been studied in over 700 subjects to date, including 222 healthy volunteers, 433 oncology patients treated with infigratinib monotherapy, and 62 oncology patients treated with infigratinib in combination with BYL719, a phosphoinositide 3-kinase, or PI3K inhibitor. To date, at the dose of 125mg daily (three weeks on, one week off), the dose being used in our ongoing and planned Phase 2 and Phase 3 clinical trials, infigratinib has shown acceptable tolerability with expected on-target class effects. The table below show safety data for all oncology patients (n=433) exposed to infigratinib monotherapy across all studies, dosing levels, and dosing schedules, and provides a summary of the most frequently observed AEs in ≥ 25.0% of oncology patients:

	Hyperphos-phatemia	Fatigue	Constipation	Stomatitis	Decreased appetite	Nausea	Diarrhea	Alopecia
All Grades	61.2%	40.4%	36.7%	34.9%	29.8%	28.9%	27.0%	26.8%
Grade 3+	6.7%	5.5%	<1.0%	4.8%	2.8%	2.8%	2.1%	0.0%

The most commonly reported treatment emergent adverse event of any grade was hyperphosphatemia, occurring in 61.2% of patients. Hyperphosphatemia is an on-target AE based on FGFR1 inhibition. Other frequently reported AEs included fatigue (40.4%), constipation (36.7%), stomatitis (34.9%), decreased appetite (29.8%), nausea (28.9%), diarrhea (27.0%), and alopecia (26.8%). Other Grade 3+ AEs occurring in >5% of patients included hypophosphatemia (7.6%), hyponatremia (6.9%), and increased lipase (6.2%).

In total, 37.9% (n=164/433) of oncology patients across all trials with monotherapy treatment experienced SAEs. SAEs occurring in greater than 1.0% of patients included pyrexia (2.8%), dyspnea (2.3%), general physical health deterioration (2.1%), pyrexia (2.1%), sepsis (2.1%), vomiting (2.1%), abdominal pain (1.8%), anemia (1.8%), hypercalcemia (1.8%), pneumonia (1.8%), , acute kidney injury (1.4%), constipation (1.4%), dehydration (1.4%), nausea (1.4%), and urinary tract infection (1.4%).

In healthy volunteers (n=222), no SAEs were reported.

Clinical Development Plans

Advanced CCA

We intend to file an NDA with the FDA for second line and later advanced CCA with FGFR2 fusions or translocations in 2020 with the data that have been generated to date from clinical trials of infigratinib, after meetings with the FDA in 2019, including a pre-submission meeting with the Center for Drug Evaluation and Research and the Center for Devices and Radiological Health to discuss analytical validation and clinical bridging to support the marketing authorization pathway for the companion diagnostic we are developing with FMI. We believe that approval of this companion diagnostic via the premarket approval, or PMA, pathway will be required for approval of an NDA for infigratinib; however, based on our interactions with the FDA to date, we do not expect to have to perform any additional clinical work specifically related to the companion diagnostic we are developing with FMI. We have fully enrolled the cohort that will be used for the primary efficacy analysis to support our planned NDA submission.

First-line CCA

A Phase 3 randomized, open-label clinical trial of infigratinib as a first-line therapy for CCA compared to gemcitabine and cisplatin in advanced and/or metastatic CCA with FGFR2 fusions or translocations is currently enrolling. The trial has a target enrollment of approximately 384 patients globally.

Adjuvant Urothelial Carcinoma

We anticipate enrolling the first patient in a Phase 3 randomized, double-blind, placebo controlled clinical trial in cisplatin-ineligible adjuvant UC with FGFR3 genomic alterations in 2020.

Other Cancers with FGFR Fusions or Translocations

We are exploring potential clinical development paths for infigratinib in additional FGFR fusion or translocation-driven cancers, as we believe that fusions or translocations are the most likely FGFR genomic alterations to be sensitive to infigratinib monotherapy, based on available data. To date, infigratinib has shown responses in FGFR fusion or translocation-driven CCA and UC, as well as gallbladder cancer, carcinoma of unknown primary, and glioblastoma. An investigator initiated trial has been initiated at the Ohio State University to study infigratinib in patients with multiple tumor types exhibiting FGFR fusions or translocations to further explore the activity of infigratinib in FGFR fusion or translocation-driven solid tumors.

Key Competitors

There are six other FGFR targeted assets currently known to be in clinical development. These product candidates have not been compared with infigratinib in head-to-head studies. However, efficacy and tolerability data of competitive compounds appears to be in-line with the data from clinical studies of infigratinib.

Key competitors include pemigatinib, an FGFR TKI under Phase 2 and Phase 3 clinical development by Incyte Corporation, futibatinib (TAS-120), an FGFR TKI under Phase 2 clinical development by Taiho Oncology, Inc., derazantinib, an FGFR TKI under Phase 2 and Phase 1/2 clinical development by ArQule, Inc. in collaboration with Basilea Pharmaceutica International Limited, erdafitinib (BALVERSA), an FGFR TKI under development by Janssen Pharmaceuticals, Inc., which has been approved by FDA for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma that has susceptible FGFR3 or FGFR2 genetic alterations and who have progressed during the following at least one line of prior platinum-containing therapy, vofatamab, an FGFR3 monoclonal antibody under Phase 1/2 clinical development by Rainier Therapeutics, Inc. and rogaratinib, an FGFR TKI under Phase 2/3 clinical development by Bayer AG.

BBP-831/Infigratinib: Achondroplasia

Summary

We are developing infigratinib, an oral FGFR1-3 selective TKI for the treatment of achondroplasia at a significantly lower dose than those doses studied in our oncology programs for infigratinib. We are currently enrolling patients in PROPEL, a prospective observational study in children with achondroplasia. We anticipate both initiating our Phase 2 PROPEL 2 trial in Australia and submitting our IND to the FDA in 2020 to expand the study to the United States.

Condition Overview

Achondroplasia is the most frequent cause of disproportionate short stature, and FGFR3 mutations have been shown to be the molecular source of the condition. Achondroplasia has a prevalence of greater than 55,000 in the United States and European Union, and an estimated worldwide incidence of one in 10,000 to 30,000 live births. The condition leads to a disproportionate short stature with anomalies in bone development and potential for foramen magnum stenosis, spinal stenosis, cardiovascular complications and obesity. The average height is approximately 4’4” for a male and 4’1” for a female with achondroplasia. Lifespan and intelligence are most often normal.

Achondroplasia is an autosomal dominant condition caused by a gain-of-function point mutation in the FGFR3 gene. Approximately 97% of cases are due to G380R substitution and 80% of cases are the result of de novo mutations. FGFR3 is expressed in osteoblasts and chondrocytes where it plays a critical role in regulating bone growth through the MAPK pathway, which drives hypertrophic differentiation, and through the STAT1 pathway, which drives chondrocyte proliferation. Apart from growth hormones, which are approved in Japan, we are not aware of any other medicines approved for marketing by the FDA or the EMA for the treatment of achondroplasia.

Our Product Concept

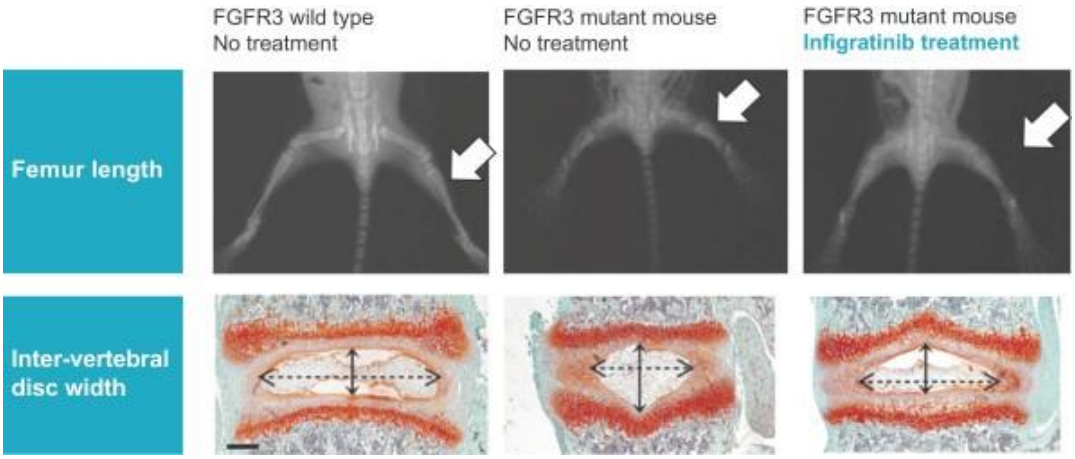
FGFR3 gain-of-function mutations are the driver behind the pathophysiology of achondroplasia. As an FGFR1-3 inhibitor, we believe that infigratinib has the potential to decrease pathologic signaling downstream of FGFR3 and treat achondroplasia at its source. Unlike potentially competitive CNP mimetic approaches, which only inhibit MAPK signaling, our approach also inhibits STAT1 signaling.

Preclinical proof of concept has been demonstrated in an achondroplasia mouse model at dose levels as low as 2% of those used in our oncology trials. In our Phase 1 dose escalation clinical trials of infigratinib, we saw acceptable tolerability, including no instances of hyperphosphatemia, at three to six times the expected dose level in our achondroplasia trials. Based on these results, we do not expect significant tolerability issues at the proposed dose level in the clinic.

Preclinical Data

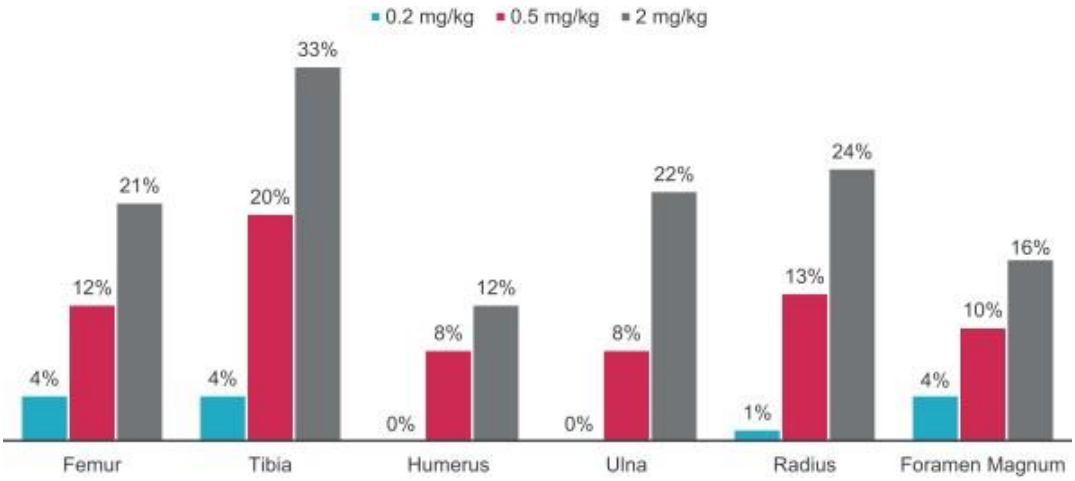
Infigratinib has been studied preclinically in a mouse model of achondroplasia that recapitulates anomalies of the growth plates, vertebrae, and intervertebral discs. Investigators observed that infigratinib rescued *ex vivo* bone growth of mutant mouse embryo femurs after six days of treatment. Further, 15 days of treatment showed *in vivo* bone growth, which mimics human achondroplasia in many respects. Effects on both appendicular and axial skeletal parameters were observed in this study.

Below are figures demonstrating the extent of femur growth and intervertebral disc width rescue in wild-type, untreated model, and infigratinib treated (2 mg/kg) model mice:



In vivo bone growth was further demonstrated at lower doses (0.2 mg/kg and 0.5 mg/kg) by the same laboratory. Together, preclinical studies at all doses have demonstrated meaningful increases in skeletal growth parameters between treated and untreated mutant mice, as follows:

lncrease in length compared to non-treated mouse (%)



Notably, treatment with infigratinib did not modify the expression of FGFR1 in the hypertrophic zone of the growth plate. The effects seen were mainly due to FGFR3 inhibition, with no other gross side effects being observed in these preclinical studies. Furthermore, survival was improved after 15 days in infigratinib treated mice, regardless of dose, as compared to untreated mice.

Clinical Development Plan

We are currently enrolling patients in PROPEL, a prospective observational study in children with achondroplasia. The study will establish annualized growth velocity (AGV) for each child of a minimum period of six months. PROPEL is designed to provide baseline measurements for children that we anticipate enrolling in PROPEL 2, a planned Phase 2 study of low-dose infigratinib, that we anticipate initiating in 2020. We anticipate that we will report initial data from PROPEL 2 in 2021.

PROPEL 2 is designed as an open-label, dose-escalation and expansion trial in children with achondroplasia prior to growth plate closure. The primary objective of this study will be to assess safety and tolerability in children with achondroplasia. Secondary objectives will include PK analyses, change in growth velocity, and assessment of quality of life.

Key Competitors

Infigratinib is the only oral direct FGFR1-3 inhibitor that has been publicly disclosed in development for the treatment of achondroplasia. There are three other identified companies developing compounds for the treatment of achondroplasia using alternative mechanistic approaches: BioMarin Pharmaceutical Inc. (vosoritide), Ascendis Pharma A/S (TransCon CNP), and Pfizer Inc. (recifercept).

BBP-631: Congenital Adrenal Hyperplasia

Summary

We are developing BBP-631, a preclinical AAV, gene transfer product candidate, for the treatment of CAH, caused by 21OHD. BBP-631 was granted orphan drug designation from both FDA for the treatment of congenital adrenal hyperplasia 21-hydroxylase deficiency and EMA for the treatment of congenital adrenal hyperplasia in 2018. We are currently conducting GLP toxicity studies and anticipate submitting an IND to the FDA in 2020.

Disease Overview

CAH is a debilitating and life-threatening disease with no available cure, despite newborn screening for the disease being conducted in every U.S. state. The disease is defined by an inability to produce cortisol and aldosterone, and an excess production of testosterone. Lack of cortisol disrupts glucose metabolism and the body’s normal response to stress, leading to potentially fatal adrenal crises, while lack of aldosterone disrupts sodium retention, resulting in low blood pressure, arrhythmia and dehydration. Additionally, excess testosterone causes virilization in females, often leading to ambiguous genitalia and masculinizing features at birth. Hormonal changes during puberty compound the CAH deficiencies. Females often suffer from limited fertility and require intensive treatment before, during, and after pregnancy, and up to 40% of adult males will have adrenal rest tumors which can lead to gonadal dysfunction and infertility, occasionally requiring surgery.

Over 90% of CAH cases are caused by 21OHD, a genetic defect in the CYP21A2 gene coding for the enzyme 21OH. Mutations resulting in loss of enzymatic activity of 21OH prevent conversion of progesterone into 11-deoxycorticosterone and 17-hydroxyprogesterone (17OHP) into 11-deoxycortisol, which are the precursors to aldosterone and cortisol, respectively.

CAH patients with 21OHD can be divided into two categories depending on the type of genetic mutation: classic and non-classic. We are primarily focused on treating classic patients, who have the more severe phenotype and that can be categorized into simple virilizing (approximately 25% of patients) and salt-wasting (approximately 75%) by the severity of aldosterone deficiency and level of residual 21OH enzyme activity. Patients with the salt-wasting form of disease have residual enzyme activity of 0-1% of normal and patients with the simple virilizing phenotype have 1-10% enzyme activity. All patients with the classic form require treatment at birth, as cortisol deficiency can lead to adrenal crisis as early as one to four weeks of life and can quickly lead to death. The salt-wasting form has an incidence of one in 20,000 births, while the simple virilizing form has an incidence of one in 60,000 births. Together, these translate to an estimated 600 classic patients born in the United States and Europe per year. We estimate there are more than 75,000 patients in the United States and Europe in the total addressable patient population.

Current standard of care treatments do not cure patients, but replace missing glucocorticoids, such as cortisol and mineralocorticoids, such as aldosterone, as well as reduce excessive androgen secretion. Although glucocorticoids are the mainstay of CAH therapy, individuals respond in varying ways, and chronic use of glucocorticoids in children and adults requires careful management because of the well-known side effects of these drugs, such as Cushingoid features, metabolic disease, obesity, hypertension, growth retardation, glucose intolerance, electrolyte disturbance, bone demineralization/increased risk of fracture and delayed puberty. Clinical management of classic CAH is often a very difficult balance between hyperandrogenism and hypercortisolism.

Our Product Concept

BBP-631 is a preclinical intravenously administered AAV5 gene transfer product candidate designed for the treatment of CAH due to 21OHD by replacing the 21OH enzyme in the adrenal cortex. Replacement of enzyme function has the potential to normalize flux through the pathway, simultaneously addressing the lack of cortisol and aldosterone, as well as the excess of testosterone and other androgens. Genotype-phenotype correlation studies in CAH suggest that non-classic patients, who are often asymptomatic and do not require treatment, have enzyme activity that is a little as 10% to 20% of normal individuals. We believe that an AAV gene therapy may be able to restore this level of enzymatic activity in CAH patients with both simple virilizing and salt-wasting forms of disease, providing substantial clinical impact and potentially eliminating the need for treatment with exogenous steroids. BBP-631 was granted both FDA and EMA orphan drug designation in 2018 for the treatment of CAH caused by 21OHD.

Development Status

Initial preclinical activity was explored in a Cyp21 knockout mouse model using AAVrh10. An IV injection of vector genomes was observed to improve multiple disease-related factors over a 15-week duration window, including an increase in body weight, a decrease in urinary progesterone (the main substrate of 21OH), and an increase in renin expression (signaling an increased capacity for salt retention).

A study in nonhuman primates (NHP) comparing evaluated AAV serotypes 1, 5, and 6 identified AAV5 as the optimum serotype. We observed significant transfection in the adrenals where 21OH is synthesized. Additionally, AAV5 has relatively low seroprevalence in the human population limiting potential immunogenicity issues.

We have completed two sets of NHP studies, designed to evaluate durability of expression, dosing/transgene expression relationships, and preliminary safety. In the first set of experiments, which evaluated a lower dose of 3x10 12 vector genomes per kilogram, we observed sustained increases in Cyp21 mRNA levels up to six months out. We did not observe rapid decreases in vector genome counts and mRNA levels due to adrenal cell turnover between 1.5 and six months, providing preliminary support for sustained transgene expression.

In a second set of experiments, a total of 20 non-human primates (NHPs) were treated with BBP-631 at one of three intravenous (IV) doses. Vector copy number and transgene mRNA expression in the adrenal glands were analyzed at 4 and 12 weeks post-dosing in the low- and medium-dose arms and at 12 and 24 weeks post-dosing in the high-dose arm. No dose-related adverse events were observed at any of the doses tested at any time point.

Overall, treatment with BBP-631 resulted in high vector copy number (VCN) and mRNA expression in the adrenal gland, suggesting strong tropism and uptake of BBP-631 for the adrenal gland. In the high-dose arm, VCNs were maintained between 12 and 24 weeks. Furthermore, mRNA levels increased between 4 and 12 weeks for the medium dose arm and were consistent between 12 and 24 weeks for the high dose arm. Researchers also saw dose-dependent increases in both VCNs and mRNA levels across the three doses tested.

Subject to the successful outcome of ongoing toxicology studies, we anticipate filing an IND for BBP-631 in 2020.

Key Competitors

There are two alternative therapeutic mechanisms being investigated for treatment of CAH. The first are corticotropin-releasing factor type 1 (CRF1) receptor antagonists. CRF1 receptor antagonists regulate the release of adrenocorticotropic hormone (ACTH) from the pituitary gland, which stimulates androgen and cortisol synthesis in the adrenal gland. In healthy individuals, endogenous cortisol provides negative feedback to the release of ACTH, which keeps androgen synthesis well regulated. Because this negative feedback is severely impaired in CAH patients, supraphysiologic doses of exogenous steroids are required to normalize androgen synthesis in these patients. While CRF1 receptor antagonists may regulate androgen synthesis, they do not address the lack of cortisol or aldosterone production in these patients. Therefore, steroid supplementation is still required with CRF1 receptor antagonists. Two CRF receptor antagonists, NBI-74788 (under development by Neurocrine Biosciences, Inc.) and SPR001 (under development by Spruce Biosciences, Inc.), are currently in Phase 2 clinical trials.

The second alternative therapeutic mechanism is acetyl-coenzyme A acetyltransferase 1 (ACAT-1) inhibition. Inhibition of this metabolic enzyme induces targeted cell death in the adrenal gland, reducing steroid production and secretion. However, like CRF1 receptor antagonists, ACAT-1 inhibitors do not address the lack of cortisol or aldosterone production in these patients. ATR-101, an ACAT1 inhibitor, is currently in Phase 2 clinical development by Millendo Therapeutics, Inc.

While these alternative therapeutic mechanisms attempt to address meaningful aspects of the disease by potentially reducing the need for exogenous steroids, neither is able to address the disease at its source by targeting the complete set of features that define the disease. In particular, these mechanisms cannot obviate the need to administer steroids because they do not address the body’s inability to synthesize cortisol and aldosterone. In contrast, we believe enzymatic replacement by gene therapy has the potential to simultaneously address all facets of the disease by restoring proper flux through the hormonal pathways, reducing androgen production by providing alternative pathways for the precursor molecules to be converted into cortisol or aldosterone.

BBP-454 : KRAS-Driven Cancers

Summary

We are advancing BBP-454, a preclinical development program focused on novel approaches to inhibit KRAS, for the treatment of KRAS-driven cancers. BBP-454 is currently in the lead optimization stage of preclinical development.

Pathway Overview

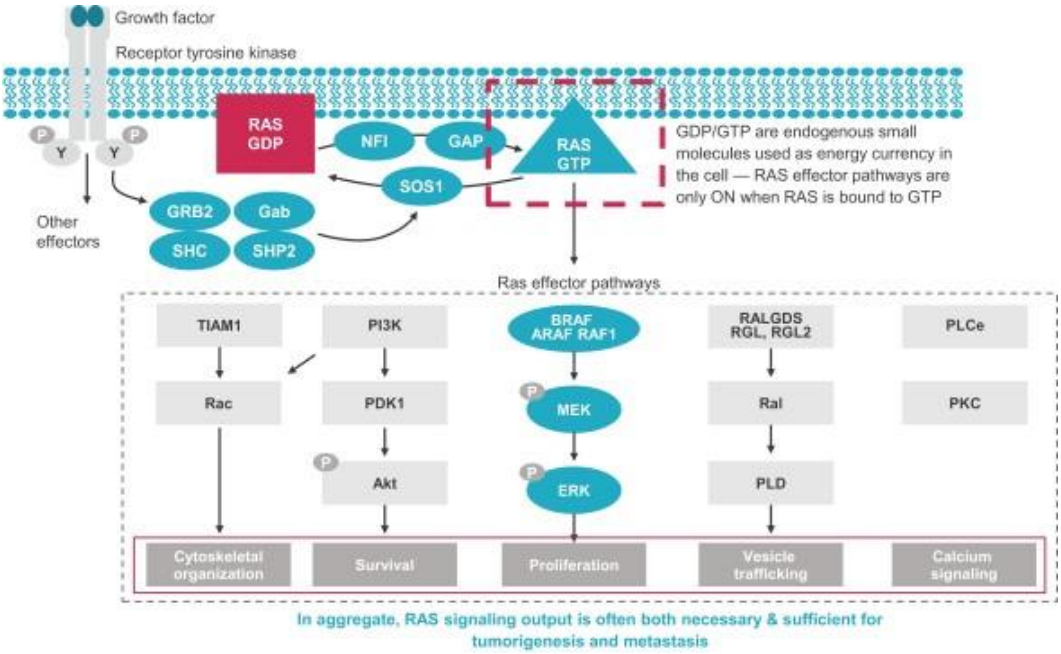
KRAS is a member of the RAS family of oncogenes, which also includes HRAS and NRAS, and together comprises some of the most well-known monogenic drivers of cancer. Mutations in NRAS are frequently found in leukemia and melanoma, while HRAS is frequently mutated in bladder, thyroid, and head and neck squamous cell carcinoma. KRAS mutations are a frequent driver of a number of the largest cancer indications with high unmet medical need, including 30% of non-small cell lung cancers, 98% of pancreatic adenocarcinomas, and 45% of colorectal adenocarcinomas. The most common KRAS mutations involve a change from glycine at position 12 in the protein to aspartic acid (G12D, 36% of all KRAS mutations), valine (G12V, 24%), and cysteine (G12C, 15%) but also include mutations at glycine 13 and glutamine 61. In aggregate, over 500,000 patients in the United States and Europe are diagnosed with KRAS-driven cancers, annually.

KRAS is a G protein, meaning that it cycles between ON and OFF states when bound to GTP or GDP, respectively. When active, KRAS interacts with multiple proteins that initiate a series of reactions that collectively cause cells to grow and divide. Because of its critical position atop multiple pathways, aberrant KRAS activation is a potent driver of unwanted cell growth, resulting in tumors. Normal KRAS is kept almost entirely in its inactive state by GTPase-activating proteins (GAPs), which cause KRAS to quickly convert GTP into GDP. All forms of mutant KRAS are insensitive to GAPs and remain bound to GTP long enough to drive oncogenic signaling. In order to initiate signaling, KRAS is required to be both localized to the cell membrane and bound to GTP. Historically, KRAS has been viewed as an undruggable target, due to the lack of a clear binding pocket to drug.

KRAS localization to the cell membrane is facilitated by modification to KRAS on the HVR. This modification consists of addition of a farnesyl or geranylgeranyl group to the cysteine residue at position 185 (C185) by farnesyl transferase or geranylgeranyl transferase. KRAS can only be modified when the hypervariable region is "open" and accessible to the transferring enzymes. When the hypervariable region is "closed," KRAS cannot be modified, preventing its association with the cell membrane and subsequent downstream signaling.

An earlier therapeutic strategy inhibiting farnesyl transferase, which transfers farnesyl group onto HRAS to allow membrane association, has generated effective clinical responses in tumors driven by mutant HRAS. Though these molecules proved ineffective in KRAS, which has an adaptive capability to utilize an alternative modification (geranylgeranylation), these results for mutant HRAS provide a proof of concept for using a single agent disrupting localization of an oncogenic RAS mutant to treat RAS-driven tumors.

The RAS Signaling Pathway



Our Product Concept

KRAS-mutant cancers are driven by active, GTP-bound KRAS located at the cell membrane. We are developing two different strategies that target KRAS through novel, mutation-agnostic mechanisms. The first involves preventing modification of C185 in the HVR, disrupting the membrane localization process that is required for KRAS signaling. The second directly reduces concentration of active GTP-bound KRAS by targeting a novel residue to induce degradation.

Frank McCormick, one of our co-founders and leader of the NCI RAS initiative, characterized a novel druggable binding pocket involved in positioning of the HVR on KRAS. Molecules that bind this eponymous "McCormick" pocket were confirmed to stabilize the KRAS HVR in a "closed" state, where C185 is not accessible for modification to localize KRAS to the membrane, thereby preventing oncogenic signaling. This mechanism is independent of the specific mutation causing KRAS tumors and is expected to apply to all oncogenic KRAS mutants. We have identified compounds that bind at this new pocket and covalently modify C185, thus preventing farnesylation and geranylgeranylation and thereby blocking membrane association.

The second approach is another pan-mutant KRAS drug which targets the histidine residue at position 95 (H95), an amino acid unique to KRAS located in the G-domain. Initial preclinical data have demonstrated that our initial series of compounds are able to downregulate KRAS signaling by degrading GTP-KRAS and thereby reducing the concentration of GTP-bound KRAS. We believe that degrading fully processed, active KRAS at the plasma membrane is the most direct strategy for eliminating oncogenic signaling across all mutant KRAS cancers. We believe our approach compares favorably with several other identified competitive approaches, which bind GDP-bound KRAS, which exists only transiently in mutant KRAS cancers. This mechanism is mutation agnostic, in contrast to competitive molecules, which only target a single mutation.

Development Status

We are advancing our KRAS research program through collaborations with the NCI RAS initiative and with Lawrence Livermore National Labs, where we are utilizing one of the most powerful supercomputers in the world to conduct molecular dynamics simulations. We blend the knowledge and experimental capabilities of our collaborators with BridgeBio's drug development expertise to prosecute these targets.

Key Competitors

Due to its high prevalence in cancer, we expect to face competition from other small molecule KRAS inhibitors as well as other modalities, including mRNA vaccines, that target KRAS mutations. The majority of these product candidates focus on a single version of mutant KRAS, G12C. This form is particularly accessible for drug development due to the reactivity of the mutant cysteine residue. However, both compounds we are developing will target a broader set of cancers by pursuing mutation-agnostic mechanisms. In particular, our competitors may include:

- MRTX849, a KRAS inhibitor that only targets KRAS harboring a G12C mutation. Mirati Therapeutics, Inc., or Mirati, has dosed its first patient in a Phase 1/2 clinical trial enrolling patients with solid tumors harboring a KRAS G12C mutation. Additionally, Mirati is currently developing a KRAS G12D inhibitor through preclinical testing.
- AMG-510, a KRAS inhibitor that only targets KRAS harboring a G12C mutation, is in Phase 1 clinical development by Amgen Inc.
- mRNA-5671, an mRNA vaccine targeting the four most common KRAS mutations, is currently under joint development by Moderna, Inc. and Merck & Co., Inc. The rationale is to induce a neoantigen response causing T-cells to attack tumors with KRAS mutations.
- ARS-1620, a G12C-specific covalent small molecule, is currently in preclinical development by Wellspring Pharmaceutical Corporation in collaboration with Janssen Pharmaceuticals, Inc.
- Revolution Medicines, Inc. is in the hit-to-lead phase of discovery for small molecule inhibitors of KRAS mutations G12C, G12D, and G13C acquired from Warp Drive Bio, Inc.

OTHER DEVELOPMENT PROGRAMS

MENDELIAN PORTFOLIO

BBP-870 / fosdenopterin: MoCD Type A

We are developing BBP-870, also known as fosdenopterin, an IV formulation of synthetic cyclic pyranopterin monophosphate, or cPMP, for the treatment of molybdenum cofactor deficiency, or MoCD, Type A. Fosdenopterin received breakthrough therapy designation from the FDA in 2013 for MoCD, orphan drug designation from the FDA in 2009 and EMA in 2010 for the treatment of MoCD Type A, and rare pediatric disease designation for the treatment of MoCD Type A in June 2017. We have initiated a rolling NDA submission of fosdenopterin with the FDA in late 2019.

MoCD Type A is an ultra-rare autosomal recessive inborn error of metabolism caused by disruption in molybdenum cofactor (MoCo) biosynthesis which results in deficiencies in multiple enzyme activities, including sulfite oxidase (SOX) and leads to uncontrolled sulfite toxicity in the brain. The disease typically presents very early in life (median presentation at first day of life). The disease is characterized by severe and rapidly progressive acute sulfite-related neurological damage and associated heterogeneous neurological sequelae including seizures, feeding difficulties and in most cases death with the median survival estimated to be approximately three years. Incidence is estimated to be one in 100,000 to 200,000 live births worldwide, with MoCD Type A accounting for approximately two-thirds of all cases. There are no available treatments approved for any form of MoCD. Supportive care and anti-convulsant therapy may be used to manage symptoms.

BBP-671 : PKAN and Organic Acidemias

BBP-671 is an oral, small molecule, allosteric activator of pantothenate kinases, that we are developing for the treatment of Pantothenate Kinase Associated Neurodegeneration, or PKAN, and Organic Acidemias, or OAs. BBP-671 is currently in preclinical development.

PKAN is a rare genetic disorder with progressive neurodegeneration. Early onset patients typically demonstrate motor deficits with possible visual problems from retinal degeneration within six years of age. Later onset disease is heterogeneous, with psychiatric symptoms and progressive parkinsonism developing in late childhood to adulthood. The prevalence of PKAN is approximately one in 1,000,000, with between 800 to 850 patients in the United States and European Union. There are currently no approved treatments for PKAN.

Organic acidemias are caused by mutations in enzymes that disrupt amino acid metabolism leading to acute decompensations requiring hospitalization, as well as long term complications involving multiple organ systems, such as the heart, pancreas, kidney, liver, and brain. The incidence of OAs are approximately 5 in 100,000 births. The standard of care includes dietary restriction and supplementation, but unmet need remains high due to metabolic decompensations and long-term complications.

BBP-711: Primary Hyperoxaluria and Frequent Stone Formers

BBP-711 is an oral, small molecule inhibitor of glycolate oxidase, or GO, that we are developing for the treatment of primary hyperoxaluria and patients who experience frequent kidney stone formation. BBP-711 is currently in preclinical development.

Primary hyperoxaluria, or PH1, is a rare, autosomal-recessive inborn error of metabolism driven by a defect in the AGXT gene, which codes for the enzyme alanine-glyoxylate aminotransferase, or AGXT. Deficiencies in the AGXT enzyme translate into the incapacity of PH1 patients to detoxify glyoxylate into glycine. As a result, glyoxylate is oxidized into oxalate which cannot be metabolized by humans. Elevated oxalate levels form calcium oxalate crystals, and subsequently kidney stones, which damage the kidneys, culminating in renal dysfunction.Prevalence for PH1 is estimated to be 5,000 patients in the United States and EU. Due to heterogeneous symptom presentation and similarity with other diseases, we believe that the disease is underdiagnosed. Prevalence for FSF is estimated to be 1.5 million in the United States and European Union. Standard of care involves symptomatic management through supplementation with vitamin B6, increased fluid intake, and citrate, to intensive dialysis and lithotripsy. Ultimately, the only curative treatment is a combined liver and kidney transplant.

BBP-761: Leber’s Hereditary Optic Neuropathy

BBP-761 is a preclinical program focused on developing succinate pro-drugs for the treatment of Leber’s Hereditary Optic Neuropathy, or LHON.

LHON is a rare mitochondrial disease of the eye, which manifests as rapidly progressive and severe loss of central vision predominantly in young adults. Onset occurs most frequently in a single eye and is followed by the second eye, while bilateral presentation occurs in approximately 25% of cases. Most patients reach legal blindness several months after disease onset. LHON is caused by mutations in subunits of Complex I of the electron transport chain, a key protein complex for energy metabolism found in mitochondria, which results in mitochondrial dysfunction. Prevalence is approximately 20,000 patients in the United States and European Union and annual incidence is estimated at approximately 500 new patients.

There are currently no treatments for the disease approved in the United States. Idebenone (Santhera) was approved in the European Union for LHON in 2015 under exceptional circumstances, as its pivotal trial did not meet its primary endpoint

BBP-418 : Limb Girdle Muscular Dystrophy type 2i (LGM2i)

BBP-418 is an orally administered ribitol replacement therapy we are developing for the treatment of Limb Girdle Muscular Dystrophy type 2i (LGDM2i). BBP-418 is currently in preclinical development.

LGMD2i is an inherited rare progressive genetic disorder characterized by lower-limb weakness and loss of ambulation, in addition to potential pulmonary and cardiac dysfunction. LGMD2i has an estimated prevalence of ~4.5 per 1M. There is no disease modifying treatment available. Standard of care for FKRP dystroglycanopathies is supportive care to alleviate end organ dysfunction.

BBP-305 / encaleret: Autosomal Dominant Hypocalcemia Type 1 and Hypoparathyroidism

Encaleret is an oral small molecule antagonist of the calcium sensing receptor that we are developing for the treatment of Autosomal Dominant Hypocalcemia Type 1, or ADH1 and hypoparathyroidism, or HP. Our IND application for the treatment of ADH1 became effective in late 2019.

HP is a disease in which the parathyroid gland secretes no or abnormally low levels of parathyroid hormone, or PTH, which results in hypocalcemia, causing symptoms including muscle cramps, tingling and seizures. ADH1 is a rare form of HP caused by gain-of-function mutations of the Calcium Sensing Receptor (CaSR), and which is characterized by increased sensitivity of the CaSR to calcium level. Symptoms due to hypocalcemia can be more severe than in other forms of HP, and include severe muscle cramping, seizures and kidney damage resulting from hypercalcuria. ADH1 has a prevalence of approximately 2,000 in the US and EU. Hypoparathyroidism has a larger patient group of approximately 200,000 in the US and EU. No FDA or EMA approved therapies for ADH1 currently exist, although hypocalcemia is typically managed with calcium and vitamin D supplementation. Natpara (parathyroid hormone) was FDA approved in 2015 as an adjunct to calcium and vitamin D to control hypocalcemia in patients with hypoparathyroidism, and has a boxed warning for potential risk of osteosarcoma.

BBP-551 / - Zuretinol acetate – Inherited Retinal Disease (Retinitis Pigmentosa and Leber's Congenital Amaurosis) due to autosomal recessive RPE65 or LRAT mutations

We are developing zuretinol acetate, an oral, small molecule synthetic retinoid as a treatment for inherited retinal disease, or IRD, associated with autosomal recessive mutations in Retinal Pigment Epithelium Protein, or RPE65, or Lecithin: Retinol Acyltransferase, or LRAT. We anticipate initiating a Phase 2/3 clinical trial for BBP-551 in 2020. BBP-551 has been granted Orphan Drug Designation in the United States for the treatment of Leber congenital amaurosis (LCA) due to inherited mutations in RPE65 or LRAT genes and for the treatment of retinitis pigmentosa and in the European Union for the treatment of retinitis pigmentosa and for the treatment of Leber's congenital amaurosis. BBP 551 has also received Fast Track Designation in the United States for the treatment of LCA due to inherited mutations in LRAT and RPE65 genes, and for the treatment of autosomal recessive RP due to inherited mutations in LRAT and RPE genes.

IRDs, including RP and LCA, are a group of genetically driven retinal degenerations that are characterized by progressive photoreceptor and retinal pigment epithelial cell (RPE) death and dramatic vision loss. It is estimated that there are approximately 2,000-4,500 people in the US and EU with IRDs due to RPE65 and LRAT mutations. No FDA or EMA approved therapies for LRAT-associated IRDs currently exist. Luxturna, a subretinally administered gene therapy, has received FDA approval for the treatment of patients with confirmed biallelic RPE65 mutation-associated retinal dystrophy.

BBP-472 – PI3KB Inhibitor for Autism-Spectrum Disorder characterized by loss of PTEN protein

BBP-472 is a series of small molecule PI3KB inhibitors being designed to balance kinase signaling in the brain for the treatment of children with autism-spectrum disorders (ASD) characterized by loss of the PTEN protein. BBP-472 is currently in preclinical development.

GENETIC DERMATOLOGY

BBP-009/Patidegib (PellePharm): Gorlin Syndrome and High Frequency Basal Cell Carcinoma

BBP-009 is a topical gel formulation of patidegib, a hedgehog inhibitor, that we are developing for the treatment of Gorlin Syndrome and High-Frequency Basal Cell Carcinoma, or HF-BCC. We are currently conducting a Phase 3 clinical trial of BBP-009 in Gorlin Syndrome and a Phase 2b clinical trial of BBP-009 in HF-BCC. We have received breakthrough therapy designation from the FDA, as well as orphan drug designation from both the FDA and EMA for BBP-009 for the treatment of Gorlin Syndrome.

Basal Cell Carcinomas, or BCCs, a form of skin tumor, are universally driven by overactivation of the hedgehog pathway. Gorlin Syndrome is caused by a genetic mutation in Patched1, or PTCH1, the primary inhibitor of the hedgehog signaling pathway. Uninhibited hedgehog signaling can cause tumorigenesis, leading to the formation of BCCs, particularly on the face and sun-exposed regions. HF-BCC is the presentation of more than nine BCCs over a period of three years, without having the genetic mutation present in Gorlin Syndrome. Gorlin Syndrome has a prevalence of approximately 1/31,000 individuals worldwide, approximately 10,000 patients in the United States and 17,000 in the European Union. HF-BCC has a larger patient group of approximately 1/9,000 individuals, approximately 35,000 patients in the United States and 57,000 in the European Union. No FDA or EMA approved therapies for Gorlin Syndrome currently exist. Current treatments involve surgical resection of BCCs, or topical 5-FU or imiquimod, which are effective only in treating superficial BCCs.

In November 2018, through our investment in PellePharm, Inc., or PellePharm, we entered into a partnership with LEO Pharma, pursuant to which LEO has acquired a minority stake in PellePharm and has agreed to provide additional non-dilutive capital to fund the development of topical patidegib, including our planned Phase 3 clinical trial. LEO also acquired an option to purchase all shares in PellePharm at a later date. See "—Our Material Agreements —BBP-009 (Patidegib): Option Agreement with LEO Pharma A/S."

BBP-589/PTR-01: Recessive Dystrophic Epidermolysis Bullosa (RDEB)

Summary

We are developing BBP-589, an IV-administered recombinant collagen type VII, or rC7, protein replacement therapy, for the treatment of recessive dystrophic epidermolysis bullosa, or RDEB. BBP-589 received orphan drug designation from the FDA and EMA in 2014 for the treatment of dystrophic epidermolysis bullosa, or DEB, and we received fast track designation from the FDA in 2019 for the treatment of dystrophic epidermolysis bullosa (DEB).

We are currently conducting a Phase 1/2 clinical trial of BBP-589 in RDEB patients, and anticipate that data readout from this study will occur in 2020.

Disease Overview

DEB is a genetic condition caused by mutations in the COL7A1 gene encoding the protein collagen type VII, a type of collagen protein that plays an important structural function. Collagen type VII resides in the basement membrane beneath stratified squamous epithelia and forms anchoring fibrils that hold layers of the epithelium together, most notably the epidermal and dermal layers of the skin. In DEB patients, mutations of the COL7A1 gene lead to deficient anchoring fibrils, resulting in normal physical touch or friction upon the epithelium causing severe blistering, wounds, and scarring of the skin as well as the mucous membranes and gastrointestinal tract, which are lined with epithelial cells. These patients can also suffer from joint contractures and pseudosyndactyly as a result of this condition as well as many other comorbidities, and they experience a shortened life expectancy often due to squamous cell carcinomas.

RDEB is a subtype of DEB that tends to have more severe symptoms and clinical outcomes. At present, there is no approved therapy for RDEB. All of the current standard of care treatment approaches rely on protective or palliative interventions. These include bandaging and disinfecting of wounds, nutritional supplementation and pain management none of which address the underlying cause of the disease. We believe there is a significant unmet need for a therapeutic option that can potentially address the cause of disease systemically and offer respite from the effects of the disease.

Our Product Concept

DEB is caused by dysfunctional collagen type VII protein. BBP-589 is a recombinant version of collagen type VII that is intended to take the place of the patient's defective protein and reverse the DEB phenotype by forming the anchoring fibrils needed to hold the dermis and epidermis together. We have successfully generated a Chinese Hamster Ovary, or CHO, cell line to produce rC7 protein for use in further development. BBP-589, also referred to as PTR-01, has received orphan drug designation for the treatment of DEB in both the United States and European Union, respectively. As a systemic protein replacement therapy candidate, rC7 is intended for intravenous delivery, a modality that has proven effective at delivering rC7 to the skin's basement membrane in preclinical animal models.

Preclinical Data

Preclinical studies have shown that rC7 distributes to the basement membrane of the skin. In COL7A1 knockout mouse models, treatment with intravenously delivered rC7 was observed to restore anchoring fibrils, promote healing and improve survival.

Immunogold electron microscopy of skin obtained from COL7A1 knockout mice injected with rC7 showed formation of anchoring fibrils in the correct location. A single IV administration of rC7 to neonatal COL7A1 knockout mice was associated with a statistically significant improvement in survival compared to vehicle-treated controls.

In single bolus dose toxicity studies conducted in rats and non-human primates, or NHP, rC7 was shown to be well-tolerated. In PD studies, the rC7 administered product was detectable at up to four weeks in the tissue of COL7A1 knockout mouse while the serum half-life ranged from one to five hours in mouse, rat, and NHP. A 28-day repeat dose rat toxicology study and two 28-day NHP repeat-dosing IV toxicology studies included histopathology observations consistent with immune complexes and/or compound deposition. The NOAEL was determined at 4 mg/kg for NHP only, which was used to inform the starting dose of the Phase 1/2 clinical trial.

Clinical Development Plan

We are studying BBP-589 in a Phase 1/2 randomized, saline-controlled, single-blind, multiple ascending dose, dose-escalation trial that was initiated in the first quarter of 2019. This first-in human study in adult RDEB patients is evaluating ascending doses of BBP-589 over four cohorts administering a total of three doses of BBP-589 and three doses of saline control IV to all patients in a cross-over design over a 10-week period. The primary objective of the trial is to evaluate the safety, tolerability and PK of BBP-589 in RDEB patients. Additionally, the trial will assess the proof of biologic activity through skin biopsy evaluation of C7, and formation of anchoring fibrils. Wound healing and clinically meaningful patient reported outcomes will also be evaluated at multiple timepoints. We expect to complete the trial in 2020. BBP-589 received fast track designation from the FDA in 2019 for the treatment of DEB.

Key Competitors

A number of companies are developing potentially competitive products for RDEB. Krystal Biotech, Inc. is developing KB103, a topical HSV-1 gene therapy currently in a Phase 1/2 clinical trial. Abeona Therapeutics, Inc. is developing EB-101, a topical therapy consisting of *ex vivo* autologous gene-corrected keratinocytes which has completed a Phase 1/2 clinical trial. ProQR Therapeutics N.V. is developing QR-313, an RNA oligonucleotide therapy for DEB exon 73. Fibrocell Science, Inc., acquired by Castle Creek, is developing FCX-007, a COL7A1 gene therapy which has completed a Phase 1/2 clinical trial.

BBP-681: Venous and Lymphatic Malformations

BBP-681 is a transdermal PI3K inhibitor that we are developing for the treatment of cutaneous venous and lymphatic malformations. BBP-681 is currently in preclinical development.

Venous malformations, or VMs, are large, disorganized veins that can cause significant morbidity due to functional impairment, pain, bleeding, and disfigurement. Lymphatic malformations, or LMs, involve the lymphatic vessels and cause functional impairment and pain similar to VM, lymphatic leakage and disfigurement. The prevalence of VMs and LMs is greater than 75,000 and 42,000, respectively, in the United States and EU in the skin. Standard of care is generally non-disease-modifying and invasive and ranges from compression bandages and aspirin, to laser ablation, surgical resection, and sclerotherapy.

BBP-561: Netherton Syndrome

BBP-561 is a topical KLK5/7 inhibitor that we are developing for the treatment of Netherton Syndrome. BBP-561 is currently in preclinical development.

Netherton Syndrome is a devastating genetic disease characterized by skin breakdown complicated by risk of sepsis, severe malnutrition, and dehydration in affected neonates. It can additionally lead to chronic problems including allergy, infection, and inflammation. The prevalence is approximately 4,000 – 17,000 patients in the United States and European Union. No disease-modifying therapy exists. Palliative and preventative treatments are used to manage symptoms.

TARGETED ONCOLOGY

BBP-398: Targeting Multiple Oncology Indications

BBP-398 is a small molecule inhibitor of SHP2 that we are developing as a potential treatment of cancers driven by hyperactive receptor tyrosine kinase, or RTK, or MAPK signaling. BBP-398 is currently in preclinical development.

SHP2 is a phosphatase that acts downstream of receptor tyrosine kinases in the MAPK signaling pathway. SHP2 is critical in signaling in these pathways. Increased MAPK signaling is a hallmark of a number of cancer types, including: cancers driven by RTK genetic alterations, cancers with RTK fusion mutations, and cancers with constitutively active MAPK signaling. Additionally, SHP2 is implicated as a downstream mediator of PD-1 signaling, a key target of immuno-oncology treatment.

BBP-954 : Multiple Oncology Indications

BBP-954 is a preclinical discovery program for irreversible inhibitors of glutathione peroxidase 4, or GPX4, for the treatment of solid and hematological cancers.

Ferroptosis is a form of oxidative programmed cell death that cancer cells must avoid in order to survive and form tumors. GPX4 is an enzyme that protects cancer cells from ferroptosis by neutralizing toxic lipid free radicals. By inhibiting GPX4, we aim to trigger ferroptosis in cancer cells. Preclinical data generated by us and third parties suggest many of the most common cancers are sensitive to GPX4 inhibition, both in monotherapy and combination with standard anti-cancer agents such as kinase inhibitors and chemotherapy. We believe that GPX4 may be potentially applicable to a number of common solid and hematologic cancers, including: non-small cell lung cancer, breast cancer, melanoma, pancreatic adenocarcinoma, renal cell carcinoma and Non-Hodgkin’s lymphoma, among others.

GENE THERAPY

BBP-812: Canavan Disease

BBP-812 is an AAV gene therapy product candidate that we are developing for the treatment of Canavan Disease that is designed to deliver the ASPA gene, which is defective in patients with Canavan disease. BBP-812 is currently in preclinical development.

Canavan Disease is a fatal, progressive neurodegenerative disorder that begins in infancy. The disease is a leukodystrophy, caused by degradation of white matter in the brain. Patients typically miss developmental milestones, have a rapidly increasing head circumference, progressive lack of motor control, and often do not live past their mid-teens. The incidence of Canavan Disease is approximately one in 100,000 births worldwide. No treatments are approved for Canavan Disease; care is focused on symptom management.

BBP-815: TMC1-related Hearing Loss

BBP-815 is an AAV gene therapy product candidate that we are developing for the treatment for nonsyndromic hearing loss caused by recessive mutations in the TMC1 gene. Mutations in the TMC1 gene prevent sound from eliciting the appropriate electrical response in the hair cells, resulting in moderate to severe hearing loss, often present early in life. BBP-815 is currently in preclinical development.

Additional Program-Related Information

Manufacturing

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We currently depend on third-party contract manufacturing organizations ("CMOs"), for all of our requirements of raw materials, drug substance and drug product for our preclinical research and our ongoing clinical trials of our product candidates. Aside from a manufacturing agreement that we entered into in December 2019 through our subsidiary, BridgeBio Gene Therapy, LLC, we have not entered into long-term agreements with our current CMOs. We intend to continue to rely on CMOs for later-stage development and commercialization of our product candidates, including any additional product candidates that we may identify. Although we rely on CMOs, we have personnel and third-party consultants with extensive manufacturing experience to oversee the relationships with our contract manufacturers. Several of our development candidates have or are in the near term expected to have redundant and overlapping drug substance and drug product supply chains.

Sales and Marketing

We intend to begin building a commercial infrastructure in the United States and selected other territories to support the commercialization of each of our product candidates when we believe a regulatory approval in a particular territory is likely. Because most of our target indications are rare diseases with a concentrated prescribing audience and a small number of key opinion leaders who influence the treatments prescribed for the relevant patient population, we currently believe that we can effectively address each market using our own targeted, specialty sales and marketing organization supported by internal sales personnel, an internal marketing group and distribution support.

We intend to evaluate our commercialization strategy as we advance each product candidate through clinical development. In any core markets outside of the United States that we may identify, where appropriate, we may utilize strategic partners, distributors or contract sales forces to expand the commercial availability of our product candidates. We currently do not expect that we will require large pharmaceutical partners for the commercialization of any of our product candidates, although we may consider partnering in certain territories or indications or for other strategic purposes.

Intellectual Property

Overview

We strive to protect the proprietary technology that we believe is important to our business through a variety of methods, including seeking and maintaining patents and patent applications intended to cover our product candidates and compositions, their methods of use and processes for their manufacture, our platform technologies and any other aspects of inventions that are commercially important to the development of our business. We seek to obtain domestic and international patent protection and, in addition to filing and prosecuting patent applications in the United States, we may file counterpart patent applications in additional countries where we believe such foreign filing is likely to be beneficial, including Australia, Canada, Europe, China, Japan, and Mexico. We have entered

into various license agreements to obtain the rights to use certain patents for the development and commercialization of our product candidates. See "—Our Material Agreements." We also rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection.

Our success will depend on our ability to obtain and maintain patent and other proprietary rights protecting our commercially important technology, inventions and know-how related to our business, defend and enforce our current and future issued patents, if any, preserve the confidentiality of our trade secrets and operate without infringing the valid and enforceable patents and proprietary rights of third parties. We continually assess and refine our intellectual property strategy in order to best fortify our position, and file additional patent applications when our intellectual property strategy warrants such filings. We also rely on know-how, continuing technological innovation and potential in-licensing opportunities to develop and maintain our intellectual property portfolio. We seek to obtain domestic and international patent protection, and endeavor to promptly file patent applications for new commercially valuable inventions.

The patent positions of biopharmaceutical companies like us are generally uncertain and involve complex legal, scientific and factual questions. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and patent scope can be reinterpreted by the courts after issuance. Moreover, many jurisdictions permit third parties to challenge issued patents in administrative proceedings, which may result in further narrowing or even cancellation of patent claims. We cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any patents, if issued, will provide sufficient protection from competitors.

Because patent applications in the United States and certain other jurisdictions are maintained in secrecy for 18 months or potentially even longer, and since publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain of the priority of inventions covered by pending patent applications. Moreover, we may have to participate in interference proceedings or derivation proceedings declared by the United States Patent and Trademark Office, or USPTO, to determine priority of invention.

As of February 28, 2020, our intellectual property portfolio is composed of over 33 issued patents and over 56 patent applications that we license from academic and research institutions and other third parties, and over 37 issued patents or pending patent applications that we own, including through our subsidiaries. These patents and patent applications generally provide us with the rights to develop our product candidates in the United States and worldwide. Our intellectual property portfolios for each of the programs that we consider to be our key value drivers are further described below.

QED Therapeutics, Inc.

For our subsidiary, QED Therapeutics, Inc., we license rights from Novartis to two issued U.S. patents, and related pending and issued foreign patents and patent applications in Australia, Canada, China, Europe, Japan and Mexico, as well as in other countries in Asia and in South America, that are directed to compositions of matter of BBP-831. The issued U.S. patents are expected to expire between 2026 and 2029, which takes into account patent term adjustments granted by the USPTO. The foreign patents and patent applications, if issued, are expected to expire between 2025 and 2030.

We also license rights from Novartis to one issued U.S. patent, one pending U.S. patent application, and related pending and issued foreign patents and patent applications in Australia, Canada, China, Europe, Japan and Mexico, as well as in other countries in Asia and in South America, that are directed to pharmaceutical formulations containing BBP-831. The issued patents and patent applications, if issued, are expected to expire in 2034.

We also license rights from Inserm Transfert ESA and Assistance Publique-Hôpitaux de Paris to one issued U.S. patent and one pending U.S. patent application, and one granted patent in Europe, that are directed to methods of treating achondroplasia using BBP-831. The issued U.S. patent, granted patent in Europe, and the pending patent application, if issued, are expected to expire in 2032.

Eidos Therapeutics, Inc.

For our subsidiary Eidos Therapeutics, Inc., we license rights from the Board of Trustees of the Leland Stanford Junior University, or Stanford, to six issued U.S. patents with claims directed to composition of matter and methods of use relating to BBP-265. These patents are expected to expire in 2031 or 2033. We also license rights from Stanford to two pending U.S. patent applications, one issued European patent, one pending European patent application, and one issued Japanese patent with claims directed to composition of matter and methods of use relating to BBP-265. These patents and patent applications, if issued, are expected to expire in 2031 or 2033.

In addition, we own one issued U.S. patent, two pending U.S. patent applications, a pending PCT patent application, and over 12 related foreign patent applications pending in various jurisdictions, including Australia, Canada, Europe, China, Japan, and Mexico with claims directed to salt and solid forms, methods of manufacturing, dosing methods, and formulations relating to BBP-265. The issued U.S. patent is expected to expire in 2038. The pending U.S. patent applications, any patent applications claiming the benefit of and priority to the PCT patent application, and the foreign patent applications, if issued, are expected to expire in 2038 or 2039.

Adrenas Therapeutics, Inc.

For our subsidiary Adrenas Therapeutics, Inc., we own one pending PCT patent application with claims directed to recombinant AAV vectors relating to BBP-631. Any patent applications claiming the benefit of this PCT patent application, if issued, are expected to expire in 2039.

Phoenix Tissue Repair, Inc.

For our subsidiary Phoenix Tissue Repair, Inc., we license rights from the University of Southern California, or USC, to one issued U.S. patent with claims directed to polypeptides comprising functional fragments of collagen 7, and five pending U.S. patent applications with claims directed to methods of use, including treating epidermolysis bullosa with collagen 7. The issued U.S. patent is expected to expire in 2035 and the pending U.S. patent applications, if issued, are expected to expire between 2027 and 2035. We also license rights from USC to over four related foreign patents issued in various jurisdictions including Australia, Europe and Japan, and over seven related foreign patent applications pending in various jurisdictions including Australia, Canada, Europe, and Japan. The foreign patents and patent applications, if issued, are expected to expire between 2027 and 2035.

We also own an issued U.S. patent with claims directed to collagen 7 modification for enhancing the degradability of collagen, and related issued patents in the United Kingdom, France and Germany. These issued patents are expected to expire in 2022.

We also own one pending U.S. patent application with claims directed to methods of treating epidermolysis and chronic skin wounds with collagen 7, with one related issued patent in Australia, and over three related foreign patent applications pending in various jurisdictions including Australia, Canada, and Europe. The issued patent and related patent applications, if issued, are expected to expire in 2033.

We also own a pending U.S. patent application with claims directed to formulations comprising collagen 7 and over seven related foreign patent applications pending in various jurisdictions, including Canada, China, Europe, Japan, and Mexico. These patent applications, if issued, are expected to expire in 2036.

TheRas, Inc.

For our subsidiary TheRas, Inc., we license rights from The Regents of the University of California, or the University of California, and Leidos Biomedical Research, Inc., or Leidos, to two pending U.S. patent applications with claims directed to modulators of K-RAS, which include claims to the modulators as composition of matter and their use in therapy, including the treatment of cancer, and over twenty related foreign patent applications pending in various jurisdictions, including Australia, Canada, China, Europe, Japan, and Mexico. The U.S. patent application and foreign patent applications, if issued, are expected to expire in 2036 and 2038. We also co-own with, and license rights from, the University of California and Leidos, three pending PCT applications. If issued, any patent applications claiming the benefit of these PCT applications are expected to expire in 2039.

Our Material Agreements

BBP-265

License Agreement with Alexion

In September 2019, through our subsidiary Eidos Therapeutics, Inc., or Eidos, we entered into a license agreement (the "Alexion License Agreement") with Alexion Pharma International Operations Unlimited Company, a subsidiary of Alexion Pharmaceuticals, Inc. (together, "Alexion") to develop and commercialize BBP-265 in Japan. Additionally, in September 2019, Eidos entered into a stock purchase agreement with Alexion, pursuant to which Eidos sold to Alexion 556,173 shares of its common stock for aggregate cash proceeds of $25.0 million. Under the terms of the Alexion License Agreement, Eidos granted Alexion an exclusive license to certain of our intellectual property rights to develop, manufacture and commercialize BBP-265 in Japan. In consideration for the license grant, Eidos received an upfront payment of $25.0 million, with the potential for an additional one-time payment of $30.0 million subject to the achievement of a regulatory milestone. In addition, Eidos is entitled to receive royalties in the low double-digits on net sales by Alexion of BBP-265 in Japan. The royalty rate is subject to reduction if Alexion is required to obtain intellectual property rights from third parties to develop, manufacture or commercialize BBP-265 in Japan, or upon the introduction of generic competition into the market.

License Agreement with the Board of Trustees of the Leland Stanford Junior University

In April 2016, through Eidos, we entered into an exclusive license agreement with Stanford for rights relating to novel transthyretin aggregation inhibitors. Under our agreement, Stanford has granted us an exclusive worldwide license to make, use and sell products that are covered by the licensed patent rights. This license grant expires when the last licensed patent expires. The patent rights exclusively licensed to us under the license are described in more detail above under the heading "—Intellectual property— Eidos Therapeutics, Inc."

Stanford retains the right, on behalf of itself and all other non-profit academic research institutions, to practice under the patent rights for any non-profit purpose, including sponsored research and collaborations. We may grant sublicenses to third parties so long as we are actively pursuing the development or commercialization of products covered by the patent rights. We may also be required to sublicense our rights under the agreement at Stanford's request under certain conditions, including if we are unwilling or unable to serve a potential market or territory and there is a third party willing to be a sublicensee in such market or territory.

We are obligated to pay to Stanford a yearly license maintenance fee during the term of the agreement, but we may offset the maintenance fee against earned royalty payments due on net sales occurring in that year. Stanford is entitled to receive a royalty as a percentage of net sales of licensed products, in the low single digits. We have agreed to pay Stanford a percentage of non-royalty revenue we receive from our sublicensees, with the amount owed decreasing annually for three years based on when we enter into the applicable sublicense agreement. In addition, we are obligated to pay Stanford up to approximately $1.0 million upon the achievement of specific intellectual property, clinical and regulatory milestone events. In the event of a change of control transaction with respect to Eidos, we are obligated to pay Stanford a change of control fee of $250,000 in connection with the assignment of the license agreement to the acquirer of Eidos.

Under the license agreement with Stanford, we are obligated to use commercially reasonable efforts to develop, manufacture, and commercialize at least one licensed product; to develop markets for such licensed products; and to meet certain development milestones as agreed upon between us and Stanford.

Subject to the expiration of the license grant described above, the agreement does not have a specified term. We may terminate the agreement by providing prior written notice to Stanford, and Stanford has the right to terminate the agreement if we fail to achieve certain milestones or make payments under the agreement, or are not actively pursuing development of a licensed product, or if we otherwise materially breach the agreement and fail to cure such breach within a specified grace period.

BBP-831: License Agreement with Novartis International Pharmaceutical Ltd.

In January 2018, through our subsidiary QED Therapeutics, Inc., or QED, we entered into a license agreement with Novartis International Pharmaceutical Ltd., or Novartis, for certain intellectual property rights, including patents and know-how, related to BBP-831 for the treatment of patients with FGFR-driven diseases, including CCA, UC and achondroplasia. We refer to this agreement as the Novartis License.

Pursuant to the Novartis License, we obtained a license to research, develop, make, have made, use, import, offer for sale, sell, have sold and otherwise commercialize BBP-831, as well as therapeutic products incorporating BBP-831 that would, but for the license grant, infringe Novartis' license patent rights, or that were developed using or that incorporate or embody Novartis' licensed know-how, in all fields of use worldwide. The license grant to us includes the right to sublicense through multiple tiers. We also have certain rights to intellectual property licensed to Novartis' affiliate under a materials transfer agreement with a third party.

The Novartis License is subject to Novartis' existing obligations to supply a third party with BBP-831 to support the third party's clinical trials, and we have an ongoing obligation to inform Novartis of our or our sublicensees' intent to seek regulatory approval for and commercialize BBP-831 for various indications, with potential reversionary rights to Novartis in the event of a subsequent decision not to seek regulatory approval and commercialization, or a determination by Novartis that we have failed to sufficiently pursue regulatory approval and commercialization, for Novartis to grant such third party limited rights to develop and commercialize BBP-831.

Under the terms of the Novartis License, we made a one-time payment of $15.0 million to Novartis and agreed to issue shares of Series A preferred stock of QED valued at approximately $1.7 million in the aggregate to Novartis. In addition, we are obligated to make contingent milestone payments totaling $60.0 million upon achievement of certain regulatory milestones. We are also obligated to make contingent milestone payments totaling $35.0 million upon achievement of certain sales milestones for therapeutic products incorporating BBP-831. QED also agreed to pay Novartis tiered low double-digit royalties on net sales of therapeutic products incorporating BBP-831.

Under the Novartis License, we are required to use commercially reasonable efforts to develop BBP-831, and to obtain regulatory approval for and commercialize BBP-831 in the United States and the European Union.

We may terminate the Novartis License in its entirety or on a product-by-product or country-by-country basis at any time with 60 days' prior written notice to Novartis. Novartis may terminate if QED ceases to function as a going concern, is the subject of certain bankruptcy or similar proceedings, or otherwise winds down or discontinues its business. Either party may terminate for material breach that is not cured by the other party within a specified time period of receiving notice of such material breach. Otherwise, the Novartis License terminates on a product-by-product and country-by-country basis on the latest of the expiration of licensed patent rights, the expiration of regulatory exclusivity, or the tenth anniversary of the first commercial sale in such country.

BBP-870: Asset Purchase Agreement with Alexion Pharma Holding Unlimited Company

In June 2018, through our subsidiary Origin Biosciences, Inc., we entered into an asset purchase agreement with Alexion Pharma Holding Unlimited Company, or Alexion, pursuant to which we acquired Alexion's right, title and interest in certain assets relating to fosdenopterin, including patents and other intellectual property rights.

In the event that a Priority Review Voucher, or PRV, is granted to us by the FDA, we have agreed to pay Alexion a percentage in the mid-teens of any proceeds received by us from our sale of the PRV to a third party. If we do not sell the PRV to a third party within 180 days after our receipt of the PRV, we are obligated to pay Alexion $18.8 million, which amount is creditable against any amounts otherwise due to Alexion in accordance with the preceding sentence upon any future sale by us of the PRV. We are obligated to make contingent milestone payments totaling $3.0 million upon achievement of certain development milestones and $17.0 million upon achievement of certain sales milestones for products containing the fosdenopterin molecule. We also agreed to pay Alexion tiered royalties ranging from the low-to mid-teens on net sales of products containing the fosdenopterin molecule.

We are obligated to use commercially reasonable efforts to obtain a PRV, achieve specified milestone events and commercialize at least one product containing the fosdenopterin molecule after receipt of regulatory approval.

BBP-009 (Patidegib): Option Agreement with LEO Pharma A/S

In November 2018, through PellePharm, Inc., or PellePharm, we entered into an option agreement with LEO Pharma A/S, or LEO Pharma, and LEO Spiny Merger Sub, Inc., pursuant to which LEO Pharma was granted an exclusive, irrevocable option to acquire PellePharm. The option is exercisable by LEO Pharma on or before the occurrence of certain events relating to PellePharm's clinical development programs, and in no event later than July 30, 2021. As consideration for the option, LEO Pharma paid to PellePharm exclusivity payments totaling approximately $27.9 million in the aggregate and purchased a minority equity interest in PellePharm for approximately $5.1 million. In addition, LEO Pharma has agreed to pay additional exclusivity payments to PellePharm in an amount not to exceed $37.0 million in the aggregate under certain circumstances.

Pursuant to the option agreement, we have agreed to conduct the business of PellePharm in the ordinary course and in accordance with applicable laws, comply with the terms of our organizational documents, and use commercially reasonable efforts to operate the business of PellePharm in accordance with a mutually agreed budget and to complete a Phase 2 clinical trial of patidegib for HF-BCC and a Phase 3 clinical trial of patidegib for Gorlin Syndrome. In addition, we and LEO Pharma have formed a joint development committee to oversee the development of, and to make decisions regarding the commercialization of, patidegib.

BBP-589: Asset Purchase Agreement with Shire Human Genetic Therapies, Inc. and Lotus Tissue Repair

In July 2017, through our subsidiary, Phoenix Tissue Repair, Inc. or Phoenix, we entered into an asset purchase agreement with Shire Human Genetic Therapies, Inc., or Shire, and Lotus Tissue Repair, Inc. or Lotus, pursuant to which we acquired from Shire and Lotus the right, title and interest in certain assets relating to recombinant human collagen type VII, including patents and other intellectual property rights, as well as data and regulatory filings, relating to the treatment of DEB, and assumed certain liabilities with respect thereto. In connection with the acquisition of such assets, (1) Shire and Lotus granted to us a non-exclusive, worldwide, irrevocable, perpetual, royalty-free, sublicensable license under certain intellectual property related to the acquired assets but retained by Shire and Lotus, for the exploitation of certain recombinant human collagen type VII products in all fields, and (2) we granted to Shire and Lotus a non-exclusive, worldwide, irrevocable, perpetual, royalty-free, sublicensable license under certain of the acquired intellectual property assets to exploit products other than recombinant human collagen type VII products and other than for the treatment of DEB in humans.

As partial consideration for our acquisition of the assets, we agreed to pay a purchase price of $1.5 million and issued shares of common stock in Phoenix at a nominal value to Lotus. We are obligated to make contingent milestone payments totaling $27.0 million upon achievement of certain regulatory milestones. In addition, we are obligated to make contingent milestone payments totaling $60.0 million upon achievement of certain sales milestones. We also agreed to pay to Shire and Lotus tiered single-digit royalties on annual net sales for products containing the recombinant human collagen type VII.

We are obligated to use commercially reasonable efforts to develop, obtain FDA approval for and commercialize at least one product for the treatment of DEB in humans.

BBP-454: License Agreement with Regents of The University of California

In September 2016, through our subsidiary TheRas, Inc., or TheRas, we entered into a license agreement with the Regents of the University of California, or UCSF, which was amended in January 2017, August 2017, September 2018 and December 2019, relating to certain patent rights related to KRAS inhibitors and modulators, which we refer to collectively as the UCSF License.

Under the UCSF License, we acquired an exclusive, royalty-bearing, sublicensable, worldwide license to make, have made, use, sell, offer for sale and import products, services, and methods covered by the licensed patent rights, and to perform licensed processes, in each case, in prophylactic and therapeutic uses in humans. In addition, we received an option for certain inventions conceived and reduced to practice during a specified term. Under the UCSF License, UCSF retains, on behalf of itself and a third party, the right to make, use and practice certain of the licensed intellectual property rights for research and educational purposes, and the right to license to other academic and nonprofit organizations to practice the patent rights for research and educational purposes, including with respect to sponsored research performed on behalf of commercial entities. The rights and interests of any such commercial entity shall be subject to the licenses granted to us pursuant to the UCSF License. The UCSF License is also subject to pre- existing rights of the U.S. Government and the NIH.

In connection with the UCSF License and subsequent amendments, we paid issue fees totaling $300,000. In addition, under the terms of the UCSF License, we are required to pay to UCSF certain annual license maintenance fees unless we are selling or otherwise exploiting licensed products or services paying royalties to UCSF on net sales for such licensed products or services. With respect to such royalty obligations, we agreed to pay UCSF low single-digit tiered royalties on annual net sales of licensed products and services, with a minimum royalty requirement of $100,000. Our obligation to pay royalties continues on a country-by-country basis until the expiration of all licensed patent rights covering licensed products in such country. In addition, we are obligated to make contingent milestone payments totaling up to $22.4 million upon the achievement of certain clinical or regulatory milestones. In the event that we sublicense the patent rights, UCSF is also entitled to receive a percentage of the sublicensing income received by us.

We are also required to make a one-time “Index Milestone Payment” to UCSF in the event of (i) an initial public offering, or (ii) a change of control transaction, in each case with respect to TheRas. Such Index Milestone Payment is calculated by multiplying (a) a number of shares equal to a specified percentage of the then-outstanding fully-diluted shares of common stock of TheRas by (b)(1) in the case of an initial public offering by TheRas, the offering price per share of the securities sold to the underwriters in the offering, or (2) in the case of a change of control transaction with respect to TheRas, the per share consideration that would be received by TheRas’ shareholders in such transaction, in each case subject to certain adjustments. To the extent that an Index Milestone Payment becomes due prior to a bona fide financing transaction of at least $45 million, such Index Milestone Payment is equal to the greater of the amount calculated as described above, or $1.8 million.

Under the UCSF License, we also assumed certain obligations with respect to fund-raising, and must report on our progress in achieving the milestones set forth in the UCSF License on a periodic basis. The UCSF License also includes certain participation rights pursuant to which UCSF has the right to purchase specified amounts of securities offered by TheRas in financing transactions.

Under the UCSF License, we are obligated to diligently proceed with the development, manufacture and sale of at least one licensed product and/or service, and to earnestly and diligently market such licensed product and/or service after receipt of any requisite regulatory approvals and in quantities sufficient to meet market demand. We are also required to use good faith and diligent efforts to meet the milestones set forth in the UCSF License, subject to any revisions that may be permitted under certain circumstances. UCSF has the right to either terminate the UCSF License or reduce the license to a nonexclusive license if we are unable to perform our diligence obligations.

The agreement will continue until the last to expire or abandonment of the patent rights on a licensed product-by-licensed product and country-by-country basis. We may terminate the agreement by providing prior written notice to UCSF or we may terminate the rights under patent rights on a country-by-country basis by giving notice in writing to UCSF. UCSF has the right to terminate the agreement if we fail to make any payments, challenge any UCSF patent rights or otherwise materially breach the agreement and fail to cure such breach within a specified grace period.

BBP-398: Collaboration and License Agreement with the Board of Regents of The University of Texas System and The University of Texas M.D. Anderson Cancer Center

In March 2017, through our subsidiary Navire Pharma, Inc. (formerly known as PTP Pharmaceuticals, Inc.), or Navire, we entered into a collaboration and license agreement with The Board of Regents of the University of Texas System, or the Board of Regents, and The University of Texas M.D. Anderson Cancer Center, or MD Anderson. Under the agreement, we acquired an exclusive, royalty-bearing, sublicensable, worldwide license to develop, make, use and sell SHP2 and PTPN11 inhibitors covered by the licensed technology in all fields. The Board of Regents and MD Anderson each retain the right to practice the licensed patent rights for non-commercial, research and academic purposes, and also to grant non-exclusive licenses to other academic and nonprofit organizations to practice the patent rights for non-commercial, research and educational purposes (but excluding any research sponsored by a for-profit entity). Our license is also subject to a non-exclusive license granted to the U.S. government. To further the goals of the collaboration agreement, we granted a non-exclusive license to our technology to MD Anderson for the purpose of carrying out the development plan.

In partial consideration for the exclusive license grant, we issued the Board of Regents shares of common stock of Navire valued at approximately $280,000 pursuant to a stock purchase agreement entered into simultaneously. If commercial sales of a licensed product commence, we will pay MD Anderson royalties at percentage rates ranging in the low single digits on net sales of licensed products. We may offset payments made to third parties to obtain rights needed for the commercialization of a licensed product against royalties payable to MD Anderson provided that such expenses in a given year may not be credited against more than a specified percentage of the royalties in such year and subject to a minimum floor in the low single digits. Our obligation to pay various royalties continues on a country by country basis with respect to any licensed product depends on regulatory status, patent coverage, and financing status. For licensed products that satisfy certain regulatory conditions, the related royalty extends for three years after the first sale. Additionally, if certain financing conditions are achieved, then (i) for licensed products covered by licensed patents, the royalty obligation continues until the expiration of all licensed patent rights covering such licensed product in such country, and (ii) for licensed products without coverage by licensed patents, the royalty obligation extends for 10 years after first sale.

Under the collaboration and license agreement, we are obligated to use commercially reasonable efforts to conduct all development activities under the agreement and to commercialize the licensed products following regulatory approval.

The agreement will continue for thirty years unless earlier terminated. We may terminate the agreement for convenience, provided that MD Anderson shall not be required to forego payments made or equity issued to MD Anderson under the collaboration and license agreement or the stock purchase agreement. MD Anderson has the right to terminate the agreement if we fail to pay royalties or otherwise materially breach the agreement or the stock purchase agreement and fail to cure such breach within a specified cure period, or if BridgeBio Pharma LLC commits a material breach of its obligations under any agreement with Navire, or if Navire breaches obligations under a Series A Preferred Stock Purchase Agreement between Navire and BridgeBio Pharma LLC.

Government Regulation

Government authorities in the United States at the federal, state and local level and in other countries regulate, among other things, the research, development, manufacture, testing, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of drug and biological products, including gene therapies, as well as diagnostics, and any future product candidates. Generally, before a new drug, biologic or diagnostic can be marketed, considerable data demonstrating its quality, safety and efficacy must be obtained, organized into a format specific for each regulatory authority, submitted for review and approved, authorized, or cleared by the applicable regulatory authority.

U.S. Government Regulation of Drug and Biological Products

In the United States, the FDA regulates drugs under the FDCA, and its implementing regulations and biologics under the FDCA and the Public Health Service Act, or PHSA, and their implementing regulations. Both drugs and biologics also are subject to other federal, state and local statutes and regulations, such as those related to competition. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, and local statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or following approval may subject an applicant to administrative actions or judicial sanctions. These actions and sanctions could include, among other actions, the FDA's refusal to approve pending applications, withdrawal of an approval, license revocation, a clinical hold, untitled or warning letters, voluntary or mandatory product recalls or market withdrawals, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement and civil or criminal fines or penalties. Any agency or judicial enforcement action could have a material adverse effect on our business, the market acceptance of our products and our reputation.

Our product candidates must be approved by the FDA through either an NDA, or a BLA, process before they may be legally marketed in the United States. The process generally involves the following:

- completion of extensive preclinical studies in accordance with applicable regulations, including studies conducted in accordance with GLP, requirements;
- submission to the FDA of an IND application, which must become effective before human clinical trials may begin;
- approval by an IRB, or independent ethics committee at each clinical trial site before each human trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with applicable IND regulations, GCP, requirements and other clinical trial-related regulations to establish the safety and efficacy of the investigational product for each proposed indication;
- submission to the FDA of an NDA or BLA;
- a determination by the FDA within 60 days of its receipt of an NDA or BLA to accept the filing for review;
- satisfactory completion of one or more FDA pre-approval inspections of the manufacturing facility or facilities where the drug or biologic will be produced to assess compliance with Current Good Manufacturing Practices, or cGMP, requirements to assure that the facilities, methods and controls are adequate to preserve the drug or biologic's identity, strength, quality and purity;
- potential FDA audit of the clinical trial sites that generated the data in support of the NDA or BLA;
- payment of user fees for FDA review of the NDA or BLA; and
- FDA review and approval of the NDA or BLA, including consideration of the views of any FDA advisory committee, prior to any commercial marketing or sale of the drug or biologic in the United States.

The preclinical and clinical testing and approval process requires substantial time, effort and financial resources, and the regulatory scheme for drugs and biologics is evolving and subject to change at any time. We cannot be certain that any approvals for our product candidates will be granted on a timely basis, or at all.

Preclinical Studies

Before testing any drug, biological or gene therapy candidate in humans, the product candidate must undergo rigorous preclinical testing. Preclinical studies include laboratory evaluation of product chemistry and formulation, as well as in vitro and animal studies to assess safety and in some cases to establish a rationale for therapeutic use. The conduct of preclinical studies is subject to federal and state regulations and requirements, including GLP regulations for safety/toxicology studies.

An IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical trials, among other things, to the FDA as part of an IND. An IND is a request for authorization from the FDA to administer an investigational product to humans, and must become effective before human clinical trials may begin. Some long-term preclinical testing, such as animal tests of reproductive AEs and carcinogenicity, may continue after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time, the FDA raises concerns or questions related to one or more proposed clinical trials and places the trial on clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence. Additionally, the review of information in an IND submission may prompt FDA to, among other things, scrutinize existing INDs or marketed products and could generate requests for information or clinical holds on other product candidates or programs.

Clinical Trials

The clinical stage of development involves the administration of the investigational product to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control, in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria and the parameters to be used to monitor subject safety and assess efficacy. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Furthermore, each clinical trial must be reviewed and approved by an IRB for each institution at which the clinical trial will be conducted to ensure that the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative, and must monitor the clinical trial until completed. There also are requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries. Information about certain clinical trials, including clinical trial results, must be submitted within specific timeframes for publication on the www.clinicaltrials.gov website.

In addition to the submission of an IND to the FDA before initiation of a clinical trial in the United States, certain human clinical trials involving recombinant or synthetic nucleic acid molecules had historically been subject to review by the RAC, of the NIH Office of Biotechnology Activities, or the OBA, pursuant to the NIH Guideline. On August 17, 2018, the NIH issued a notice in the Federal Register and issued a public statement proposing changes to the oversight framework for gene therapy trials, including changes to the applicable NIH Guidelines to modify the roles and responsibilities of the RAC with respect to human clinical trials of gene therapy products, and requesting public comment on its proposed modifications. During the public comment period, which closed October 16, 2018, the NIH announced that it will no longer accept new human gene transfer protocols for review as a part of the protocol registration process or convene the RAC to review individual clinical protocols. In April 2019, NIH announced the updated guidelines, which reflect these proposed changes, and clarify that these trials will remain subject to the FDA's oversight and other clinical trial regulations, and oversight at the local level will continue as set forth in the NIH Guidelines. Specifically, under the NIH Guidelines, supervision of human gene transfer trials includes evaluation and assessment by an IBC, a local institutional committee that reviews and oversees research utilizing recombinant or synthetic nucleic acid molecules at that institution. The IBC assesses the safety of the research and identifies any potential risk to public health or the environment, and such review may result in some delay before initiation of a clinical trial. While the NIH Guidelines are not mandatory unless the research in question being conducted at or sponsored by institutions receiving NIH funding of recombinant or synthetic nucleic acid molecule research, many companies and other institutions not otherwise subject to the NIH Guidelines voluntarily follow them.

A sponsor who wishes to conduct a clinical trial outside of the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. If a foreign clinical trial is not conducted under an IND, the sponsor may submit data from the clinical trial to the FDA in support of an NDA or BLA. The FDA will accept a well-designed and well-conducted foreign clinical study not conducted under an IND if the study was conducted in accordance with GCP requirements, and the FDA is able to validate the data through an onsite inspection if deemed necessary.

Clinical trials generally are conducted in three sequential phases, known as Phase 1, Phase 2 and Phase 3, and may overlap.

- Phase 1 clinical trials generally involve a small number of healthy volunteers or disease-affected patients who are initially exposed to a single dose and then multiple doses of the product candidate. The primary purpose of these clinical trials is to assess the metabolism, pharmacologic action, side effect tolerability and safety of the product candidate.
- Phase 2 clinical trials involve studies in disease-affected patients to evaluate proof of concept and/or determine the dose required to produce the desired benefits. At the same time, safety and further PK and PD information is collected, possible adverse effects and safety risks are identified and a preliminary evaluation of efficacy is conducted.
- Phase 3 clinical trials generally involve a large number of patients at multiple sites and are designed to provide the data necessary to demonstrate the effectiveness of the product for its intended use, its safety in use and to establish the overall benefit/risk relationship of the product and provide an adequate basis for product labeling.

In August 2018, the FDA released a draft guidance entitled “Expansion Cohorts: Use in First-In-Human Clinical Trials to Expedite Development of Oncology Drugs and Biologics,” which outlines how drug developers can utilize an adaptive trial design commonly referred to as a seamless trial design in early stages of oncology drug development, i.e., the first-in-human clinical trial, to compress the traditional three phases of trials into one continuous trial called an expansion cohort trial. Information to support the design of individual expansion cohorts are included in IND applications and assessed by FDA. Expansion cohort trials can potentially bring efficiency to drug development and reduce developmental costs and time.

Post-approval trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication and are commonly intended to generate additional safety data regarding use of the product in a clinical setting. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA or BLA.

Progress reports detailing the results of the clinical trials, among other information, must be submitted at least annually to the FDA and written IND safety reports must be submitted to the FDA and the investigators 15 days after the trial sponsor determines the information qualifies for reporting for serious and unexpected suspected AEs, findings from other studies or animal or in vitro testing that suggest a significant risk for human subjects and any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must also notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction as soon as possible but in no case later than seven calendar days after the sponsor’s initial receipt of the information.

Phase 1, Phase 2, Phase 3 and other types of clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB’s requirements or if the drug or biologic has been associated with unexpected serious harm to patients. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether a trial may move forward at designated check points based on access to certain data from the trial. Concurrent with clinical trials, companies usually complete additional animal studies and also must develop additional information about the chemistry and physical characteristics of the drug or biologic as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product and, among other things, companies must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidates do not undergo unacceptable deterioration over their shelf life.

FDA Review Process

Following completion of the clinical trials, data are analyzed to assess whether the investigational product is safe and effective for the proposed indicated use or uses. The results of preclinical studies and clinical trials are then submitted to the FDA as part of an NDA or BLA, along with proposed labeling, chemistry and manufacturing information to ensure product quality and other relevant data. The NDA or BLA is a request for approval to market the drug or biologic for one or more specified indications and must contain proof of safety and efficacy for a drug or safety, purity and potency for a biologic. The application may include both negative and ambiguous results of preclinical studies and clinical trials, as well as positive findings. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a product's use or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the investigational product to the satisfaction of FDA. FDA approval of an NDA or BLA must be obtained before a drug or biologic may be marketed in the United States.

Under the Prescription Drug User Fee Act, or PDUFA, as amended, each NDA or BLA must be accompanied by a user fee. FDA adjusts the PDUFA user fees on an annual basis. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on NDAs or BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

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

Before approving an NDA or BLA, the FDA will conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether they comply with cGMP requirements. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. The FDA also may audit data from clinical trials to ensure compliance with GCP requirements. Additionally, the FDA may refer applications for novel products or products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions, if any. The FDA is not bound by recommendations of an advisory committee, but it considers such recommendations when making decisions on approval. The FDA likely will reanalyze the clinical trial data, which could result in extensive discussions between the FDA and the applicant during the review process. After the FDA evaluates an NDA or BLA, it will issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug or biologic with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application will not be approved in its present form. A Complete Response Letter usually describes all of the specific deficiencies in the NDA or BLA identified by the FDA. The Complete Response Letter may require the applicant to obtain additional clinical data, including the potential requirement to conduct additional pivotal Phase 3 clinical trial(s) and/or to complete other significant and time-consuming requirements related to clinical trials, or to conduct additional preclinical studies or manufacturing activities. If a Complete Response Letter is issued, the applicant may either resubmit the NDA or BLA, addressing all of the deficiencies identified in the letter, or withdraw the application or request an opportunity for a hearing. Even if such data and information are submitted, the FDA may decide that the NDA or BLA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data.

Orphan Drug Designation and Exclusivity

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making the product available in the United States for this type of disease or condition will be recovered from sales of the product.

Orphan drug designation must be requested before submitting an NDA or BLA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication for seven years from the date of such approval, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity by means of greater effectiveness, greater safety or providing a major contribution to patient care or in instances of drug supply issues. Competitors, however, may receive approval of either a different product for the same indication or the same product for a different indication but that could be used off-label in the orphan indication. Orphan drug exclusivity also could block the approval of one of our products for seven years if a competitor obtains approval before we do for the same product, as defined by the FDA, for the same indication we are seeking approval, or if our product is determined to be contained within the scope of the competitor's product for the same indication or disease. If we pursue marketing approval for an indication broader than the orphan drug designation we have received, we may not be entitled to orphan drug exclusivity. Orphan drug status in the European Union has similar, but not identical, requirements and benefits.

Rare Pediatric Disease Designation and Priority Review Vouchers

Under the FDCA, as amended, the FDA incentivizes the development of drugs and biologics that meet the definition of a "rare pediatric disease," defined to mean a serious or life-threatening disease in which the serious of life-threatening manifestations primarily affect individuals aged from birth to 18 years and the disease affects fewer than 200,000 individuals in the United States or affects more than 200,000 in the United States and for which there is no reasonable expectation that the cost of developing and making in the United States a drug for such disease or condition will be received from sales in the United States of such drug. The sponsor of a product candidate for a rare pediatric disease may be eligible for a voucher that can be used to obtain a priority review for a subsequent human drug or biologic application after the date of approval of the rare pediatric disease drug product, referred to as a priority review voucher, or PRV. A sponsor may request rare pediatric disease designation from the FDA prior to the submission of its NDA or BLA. A rare pediatric disease designation does not guarantee that a sponsor will receive a PRV upon approval of its NDA or BLA. Moreover, a sponsor who chooses not to submit a rare pediatric disease designation request may nonetheless receive a PRV upon approval of their marketing application if they request such a voucher in their original marketing application and meet all of the eligibility criteria. If a PRV is received, it may be sold or transferred an unlimited number of times. Congress has extended the PRV program until September 30, 2020, with the potential for PRVs to be granted until 2022.

Expedited Development and Review Programs

A sponsor may seek to develop and obtain approval of its product candidates under programs designed to accelerate the development, FDA review and approval of new drugs and biologics that meet certain criteria. For example, the FDA has a fast track program that is intended to expedite or facilitate the process for reviewing new drugs and biologics that are intended to treat a serious or life threatening disease or condition and demonstrate the potential to address unmet medical needs for the condition. Fast track designation applies to both the product and the specific indication for which it is being studied. For a fast track-designated product, the FDA may consider sections of the NDA or BLA for review 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. The sponsor can request the FDA to designate the product for fast track status any time before receiving NDA or BLA approval, but ideally no later than the pre-NDA or pre-BLA meeting.

A product submitted to the FDA for marketing, including under a fast track program, may be eligible for other types of FDA programs intended to expedite development or review, such as priority review and accelerated approval. Priority review means that, for a new molecular entity or original BLA, the FDA sets a target date for FDA action on the marketing application at six months after accepting the application for filing as opposed to ten months. A product is eligible for priority review if it is designed to treat a serious or life-threatening disease condition and, if approved, would provide a significant improvement in safety and effectiveness compared to available therapies. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug or biologic designated for priority review in an effort to facilitate the review. If criteria are not met for priority review, the application for a new molecular entity or original BLA is subject to the standard FDA review period of ten months after FDA accepts the application for filing. Priority review designation does not change the scientific/medical standard for approval or the quality of evidence necessary to support approval.

A product may also be eligible for accelerated approval if it is designed to treat a serious or life-threatening disease or condition and demonstrates an effect on either a surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, or IMM, that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity, or prevalence of the disease or condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require that a sponsor of a drug or biologic receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. FDA may withdraw approval of a drug or indication approved under accelerated approval if, for example, the confirmatory trial fails to verify the predicted clinical benefit of the product.

Additionally, a drug or biologic may be eligible for designation as a breakthrough therapy if the product is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. If the FDA designates a breakthrough therapy, it may take actions appropriate to expedite the development and review of the application, which may include holding meetings with the sponsor and the review team throughout the development of the therapy; providing timely advice to, and interactive communication with, the sponsor regarding the development of the drug to ensure that the development program to gather the nonclinical and clinical data necessary for approval is as efficient as practicable; involving senior managers and experienced review staff, as appropriate, in a collaborative, cross-disciplinary review; assigning a cross-disciplinary project lead for the FDA review team to facilitate an efficient review of the development program and to serve as a scientific liaison between the review team and the sponsor; and considering alternative clinical trial designs when scientifically appropriate, which may result in smaller trials or more efficient trials that require less time to complete and may minimize the number of patients exposed to a potentially less efficacious treatment. Breakthrough therapy designation comes with all of the benefits of fast track designation, which means that the sponsor may file sections of the BLA for review on a rolling basis if certain conditions are satisfied, including an agreement with the FDA on the proposed schedule for submission of portions of the application and the payment of applicable user fees before the FDA may initiate a review.

As part of the 21st Century Cures Act, Congress amended the FDCA to facilitate an efficient development program for, and expedite review of regenerative medicine advanced therapies, or RMATs, which include cell and gene therapies, therapeutic tissue engineering products, human cell and tissue products, and combination products using any such therapies or products. RMATs do not include those human cells, tissues, and cellular and tissue based products regulated solely under section 361 of the PHSA and 21 CFR Part 1271. This program is intended to facilitate efficient development and expedite review of regenerative medicine therapies, which are intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition and qualify for RMAT designation. A drug sponsor may request that FDA designate a drug as a RMAT concurrently with or at any time after submission of an IND. FDA has 60 calendar days to determine whether the drug meets the criteria, including whether there is preliminary clinical evidence indicating that the drug has the potential to address unmet medical needs for a serious or life-threatening disease or condition. A BLA for a regenerative medicine therapy that has received RMAT designation may be eligible for priority review or accelerated approval through use of surrogate or intermediate endpoints reasonably likely to predict long-term clinical benefit, or reliance upon data obtained from a meaningful number of sites. Benefits of RMAT designation also include early interactions with FDA to discuss any potential surrogate or intermediate endpoint to be used to support accelerated approval. A regenerative medicine therapy with RMAT designation that is granted accelerated approval and is subject to post-approval requirements may fulfill such requirements through the submission of clinical evidence from clinical studies, patient registries, or other sources of real world evidence, such as electronic health records; the collection of larger confirmatory data sets; or post-approval monitoring of all patients treated with such therapy prior to its approval.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or the time period for FDA review or approval may not be shortened. Furthermore, fast track designation, priority review, accelerated approval, breakthrough therapy and RMAT designation do not change the standards for approval.

Pediatric Information and Pediatric Exclusivity

Under the Pediatric Research Equity Act, or PREA, certain NDAs and BLAs and certain supplements to an NDA or BLA must contain data to assess the safety and efficacy of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of pediatric data or full or partial waivers. The Food and Drug Administration Safety and Innovation Act, or FDASIA, amended the FDCA to require that a sponsor who is planning to submit a marketing application for a drug that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial Pediatric Study Plan, or PSP, within 60 days of an end-of-Phase 2 meeting or, if there is no such meeting, as early as practicable before the initiation of the Phase 3 or Phase 2/3 study. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA and the sponsor must reach an agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from preclinical studies, early phase clinical trials and/or other clinical development programs.

A drug or biologic product can also obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued “Written Request” for such a study.

Post-Marketing Requirements

Following approval of a new product, the manufacturer and the approved product are subject to continuing regulation by the FDA, including, among other things, monitoring and record-keeping activities, reporting of adverse experiences, complying with promotion and advertising requirements, which include restrictions on promoting products for unapproved uses or patient populations (known as “off-label use”) and limitations on industry-sponsored scientific and educational activities. Although physicians may prescribe legally available

products for off-label uses, manufacturers may not market or promote such uses. 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 uses may be subject to significant liability, including investigation by federal and state authorities. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use or first publication. Further, if there are any modifications to the drug or biologic, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new NDA/BLA or NDA/BLA supplement, which may require the development of additional data or preclinical studies and clinical trials.

The FDA may also place other conditions on approvals including the requirement for a REMS, to assure the safe use of the product. If the FDA concludes a REMS is needed, the sponsor of the NDA or BLA must submit a proposed REMS. The FDA will not approve the NDA or BLA without an approved REMS, if required. A REMS could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing.

FDA regulations require that products be manufactured in specific approved facilities and in accordance with cGMP regulations. We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products in accordance with cGMP regulations. These manufacturers must comply with cGMP regulations that require, among other things, quality control and quality assurance, the maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Manufacturers and other entities involved in the manufacture and distribution of approved drugs or biologics are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP requirements and other laws. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. The discovery of violative conditions, including failure to conform to cGMP regulations, could result in enforcement actions, and the discovery of problems with a product after approval may result in restrictions on a product, manufacturer or holder of an approved NDA or BLA, including recall.

Once an approval is granted, the FDA may issue enforcement letters or withdraw the approval of the product if compliance with regulatory requirements and standards is not maintained or if problems occur after the drug or biologic reaches the market. Corrective action could delay drug or biologic distribution and require significant time and financial expenditures. Later discovery of previously unknown problems with a drug or biologic, including AEs of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the drug or biologic, suspension of the approval, complete withdrawal of the drug from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve applications or supplements to approved applications, or suspension or revocation of drug or biologic approvals;
- drug or biologic seizure or detention, or refusal to permit the import or export of drugs; or
- injunctions or the imposition of civil or criminal penalties.

Regulation of Companion Diagnostics

We believe that the success of certain of our product candidates may depend, in part, on the development and commercialization of a companion diagnostic. Companion diagnostics identify patients who are most likely to benefit from a particular therapeutic product; identify patients likely to be at increased risk for serious side effects as a result of treatment with a particular therapeutic product; or monitor response to treatment with a particular

therapeutic product for the purpose of adjusting treatment to achieve improved safety or effectiveness. Companion diagnostics are regulated as medical devices by the FDA. In the United States, the FDCA and its implementing regulations, and other federal and state statutes and regulations govern, among other things, medical device design and development, preclinical and clinical testing, premarket clearance or approval, registration and listing, manufacturing, labeling, storage, advertising and promotion, sales and distribution, export and import, and post-market surveillance. Unless an exemption or FDA exercise of enforcement discretion applies, diagnostic tests generally require marketing clearance or approval from the FDA prior to commercialization. The two primary types of FDA marketing authorization applicable to a medical device are premarket notification, also called 510(k) clearance, and approval of a premarket, or PMA approval.

To obtain 510(k) clearance for a medical device, or for certain modifications to devices that have received 510(k) clearance, a manufacturer must submit a premarket notification demonstrating that the proposed device is substantially equivalent to a previously cleared 510(k) device or to a preamendment device that was in commercial distribution before May 28, 1976, or a predicate device, for which the FDA has not yet called for the submission of a PMA. In making a determination that the device is substantially equivalent to a predicate device, the FDA compares the proposed device to the predicate device or predicate devices and assesses whether the subject device is comparable to the predicate device or predicate devices with respect to intended use, technology, design and other features which could affect safety and effectiveness. If the FDA determines that the subject device is substantially equivalent to the predicate device or predicate devices, the subject device may be cleared for marketing. The 510(k) premarket notification pathway generally takes from three to twelve months from the date the application is completed, but can take significantly longer.

PMA applications must be supported by valid scientific evidence, which typically requires extensive data, including technical, preclinical, clinical and manufacturing data, to demonstrate to the FDA's satisfaction the safety and effectiveness of the device. For diagnostic tests, a PMA application typically includes data regarding analytical and clinical validation studies. As part of its review of the PMA, the FDA will conduct a pre-approval inspection of the manufacturing facility or facilities to ensure compliance with the Quality System Regulation, or QSR, which requires manufacturers to follow design, testing, control, documentation and other quality assurance procedures. The FDA's review of an initial PMA application is required by statute to take between six to ten months, although the process typically takes longer, and may require several years to complete. If the FDA evaluations of both the PMA application and the manufacturing facilities are favorable, the FDA will either issue an approval letter or an approvable letter, which usually contains a number of conditions that must be met in order to secure the final approval of the PMA. If the FDA's evaluation of the PMA or manufacturing facilities is not favorable, the FDA will deny the approval of the PMA or issue a not approvable letter. A not approvable letter will outline the deficiencies in the application and, where practical, will identify what is necessary to make the PMA approvable. Once granted, PMA approval may be withdrawn by the FDA if compliance with post-approval requirements, conditions of approval or other regulatory standards is not maintained or problems are identified following initial marketing.

On July 31, 2014, the FDA issued a final guidance document addressing the development and approval process for "In Vitro Companion Diagnostic Devices." According to the guidance document, for novel therapeutic products that depend on the use of a diagnostic test and where the diagnostic device could be essential for the safe and effective use of the corresponding therapeutic product, the premarket application for the companion diagnostic device should be developed and approved or cleared contemporaneously with the therapeutic, although the FDA recognizes that there may be cases when contemporaneous development may not be possible. However, in cases where a drug cannot be used safely or effectively without the companion diagnostic, the FDA's guidance indicates it will generally not approve the drug without the approval or clearance of the diagnostic device. The FDA also issued a draft guidance in July 2016 setting forth the principles for co-development of an in vitro companion diagnostic device with a therapeutic product. The draft guidance describes principles to guide the development and contemporaneous marketing authorization for the therapeutic product and its corresponding in vitro companion diagnostic.

Once cleared or approved, the companion diagnostic device must adhere to post-marketing requirements including the requirements of FDA's quality system regulation, adverse event reporting, recalls and corrections along with product marketing requirements and limitations. Like drug and biologic makers, companion diagnostic makers are subject to unannounced FDA inspections at any time during which the FDA will conduct an audit of the product(s) and the company's facilities for compliance with its authorities.

Biosimilars and Exclusivity

Certain of our product candidates are regulated as biologics. An abbreviated approval pathway for biological products shown to be similar to, or interchangeable with, an FDA-licensed reference biological product was created by the Biologics Price Competition and Innovation Act of 2009, or BPCI Act, as part of the ACA. This amendment to the PHSA, in part, attempts to minimize duplicative testing. Biosimilarity, which requires that the biological product be highly similar to the reference product notwithstanding minor differences in clinically inactive components and that there be no clinically meaningful differences between the product and the reference product in terms of safety, purity and potency, can be shown through analytical studies, animal studies and a clinical trial or trials. Interchangeability requires that a biological product be biosimilar to the reference product and that the product can be expected to produce the same clinical results as the reference product in any given patient and, for products administered multiple times to an individual, that the product and the reference product may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biological product without such alternation or switch. Complexities associated with the larger, and often more complex, structure of biological products as compared to small molecule drugs, as well as the processes by which such products are manufactured, pose significant hurdles to implementation that are still being worked out by the FDA.

A reference biological product is granted four and twelve year exclusivity periods from the time of first licensure of the product. FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product, and FDA will not approve an application for a biosimilar or interchangeable product based on the reference biological product until twelve years after the date of first licensure of the reference product. “First licensure” typically means the initial date the particular product at issue was licensed in the United States. Date of first licensure does not include the date of licensure of (and a new period of exclusivity is not available for) a biological product if the licensure is for a supplement for the biological product or for a subsequent application by the same sponsor or manufacturer of the biological product (or licensor, predecessor in interest, or other related entity) for a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device or strength, or for a modification to the structure of the biological product that does not result in a change in safety, purity, or potency. Therefore, one must determine whether a new product includes a modification to the structure of a previously licensed product that results in a change in safety, purity, or potency to assess whether the licensure of the new product is a first licensure that triggers its own period of exclusivity. Whether a subsequent application, if approved, warrants exclusivity as the “first licensure” of a biological product is determined on a case-by-case basis with data submitted by the sponsor.

Other Regulatory Matters

Manufacturing, sales, promotion and other activities following product approval are also subject to regulation by numerous regulatory authorities in the United States in addition to the FDA, including the CMS, including the Office of Inspector General and Office for Civil Rights, other divisions of the Department of HHS, the Department of Justice, the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency and state and local governments.

Healthcare providers, physicians, and third party payors will play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. Our current and future arrangements with healthcare providers and physicians and any future arrangements with third party payers, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any drugs for which we obtain marketing approval. In the United States, these laws include: the federal Anti-Kickback Statute, the False Claims Act, and HIPAA.

The Anti-Kickback Statute makes it illegal for any person, including a prescription drug manufacturer (or a party acting on its behalf), to knowingly and willfully solicit, receive, offer or pay any remuneration, directly or indirectly, in cash or in kind, that is intended to induce or reward referrals, including the purchase, recommendation, order or prescription of a particular drug, for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. Violations of this law are punishable by imprisonment, criminal fines, administrative civil money penalties and exclusion from participation in federal healthcare programs. In addition, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it. Moreover, the ACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.

Although we would not submit claims directly to payors, drug manufacturers can be held liable under the federal civil False Claims Act, which imposes civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities (including manufacturers) for, among other things, knowingly presenting, or causing to be presented to federal programs (including Medicare and Medicaid) claims for items or services, including drugs, that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. Penalties for a False Claims Act violation include three times the actual damages sustained by the government, plus mandatory civil penalties for each separate false claim, the potential for exclusion from participation in federal healthcare programs and, although the federal False Claims Act is a civil statute, conduct that results in a False Claims Act violation may also implicate various federal criminal statutes. The government may deem manufacturers to have "caused" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. Claims which include items or services resulting from a violation of the federal Anti-Kickback Statute are false or fraudulent claims for purposes of the False Claims Act. Our future marketing and activities relating to the reporting of wholesaler or estimated retail prices for our products, if approved, the reporting of prices used to calculate Medicaid rebate information and other information affecting federal, state and third-party reimbursement for our products, and the sale and marketing of our product candidates, are subject to scrutiny under this law.

HIPAA created new federal criminal statutes that prohibit among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, 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. Like the federal Anti-Kickback Statute a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

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.

We may be subject to data privacy and security regulations by both the federal government and the states in which we conduct our business. HIPAA, as amended by HITECH, and their implementing regulations, mandates, among other things, the adoption of uniform standards for the electronic exchange of information in common healthcare transactions, as well as standards relating to the privacy and security of individually identifiable health information, which require the adoption of administrative, physical and technical safeguards to protect such information. Among other things, HITECH makes HIPAA's security standards directly applicable to business associates, defined as independent contractors or agents of covered entities, which include certain health care providers, health plans, and healthcare clearinghouses, that create, receive or obtain protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities and business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, certain state laws govern the privacy and security of health information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and criminal penalties.

Additionally, the federal Physician Payments Sunshine Act, or the Sunshine Act, within the ACA, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) report annually to CMS information related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, physicians, certain other healthcare professionals, and teaching hospitals and to report annually certain ownership and investment interests held by physicians, certain other healthcare professionals, and their immediate family members. Effective January 1, 2022, these reporting obligations will extend to include transfers of value made to certain non-physician providers such as physician assistants and nurse practitioners. In addition, many states also govern the reporting of payments or other transfers of value, many of which differ from each other in significant ways, are often not pre-empted, and may have a more prohibitive effect than the Sunshine Act, thus further complicating compliance efforts.

Similar federal, state and foreign fraud and abuse laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services. Such laws are generally broad and are enforced by various state agencies and private actions. 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. Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant federal government compliance guidance, and require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures.

In order to distribute products commercially, we must comply with state laws that require the registration of manufacturers and wholesale distributors of drug and biological products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Several states have enacted legislation requiring pharmaceutical and biotechnology companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, and/or register their sales representatives, as well as to prohibit pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical and biotechnology companies for use in sales and marketing, and to prohibit certain other sales and marketing practices. All of our activities are potentially subject to federal and state consumer protection and unfair competition laws.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, individual imprisonment, exclusion of drugs from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company's attention from the business.

Current and Future Legislation

In the United States and some foreign jurisdictions, there have been, and likely will continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system directed at broadening the availability of healthcare, improving the quality of healthcare, and containing or lowering the cost of healthcare.

For example, in March 2010, the ACA was enacted in the United States. The ACA includes measures that have significantly changed, and are expected to continue to significantly change, the way healthcare is financed by both governmental and private insurers. Among the provisions of the ACA of greatest importance to the pharmaceutical industry are that the ACA:

- made several changes to the Medicaid Drug Rebate Program, including increasing pharmaceutical manufacturers' rebate liability by raising the minimum basic Medicaid rebate on most branded prescription drugs to 23.1% of average manufacturer price, or AMP, and adding a new rebate calculation for "line extensions" (i.e., new formulations, such as extended release formulations) of solid oral dosage forms of branded products, as well as potentially impacting their rebate liability by modifying the statutory definition of AMP.
- imposed a requirement on manufacturers of branded drugs to provide a 70% (increased pursuant to the Bipartisan Budget Act of 2018, effective as of 2019) point-of-sale discount off the negotiated price of branded drugs dispensed to Medicare Part D beneficiaries in the coverage gap (i.e., "donut hole") as a condition for a manufacturer's outpatient drugs being covered under Medicare Part D.
- extended a manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations.
- expanded the entities eligible for discounts under the 340B Drug Discount Program.
- established a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected.
- imposed an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs, apportioned among these entities according to their market share in certain government healthcare programs.
- established a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research. The research conducted by the Patient-Centered Outcomes Research Institute may affect the market for certain pharmaceutical products. The ACA established the Center for Medicare and Medicaid Innovation within CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending. Funding has been allocated to support the mission of the Center for Medicare and Medicaid Innovation through 2020.

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. Various portions of the ACA are currently undergoing legal and constitutional challenges in the Fifth Circuit Court and the United States Supreme Court; the Trump Administration has issued various Executive Orders which eliminated cost sharing subsidies and various provisions that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices; and Congress has introduced several pieces of legislation aimed at significantly revising or repealing the ACA. It is unclear whether the ACA will be overturned, repealed, replaced, or further amended. We cannot predict what affect further changes to the ACA would have on our business.

Moreover, in May 2018, the Trump administration released its "Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs," or the Blueprint. The Blueprint contains several potential regulatory actions and legislative recommendations aimed at lowering prescription drug prices, including measures to promote innovation and competition for biologics, changes to Medicare Part D to give plan sponsors more leverage when negotiating prices with manufacturers, and updating the Medicare drug-pricing dashboard to make price increases and generic competition more transparent. In addition, the Department of HHS released a Request for Information, or RFI, soliciting public input on ways to lower drug pricing. Together, the recommendations in the Blueprint and RFI, if enacted by Congress and HHS, could lead to changes to Medicare Parts B and D, including the transition of certain drugs covered under Part B to Part D or the offering of alternative purchasing options under the Competitive Acquisition Program that currently applies to selected drugs and biologics covered under Part B. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy, a type of prior authorization, for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. While most of the proposed measures will require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative, administrative and/or additional measures to control drug costs.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year, which went into effect in April 2013, following passage of the Bipartisan Budget Act of 2013, and will remain in effect through 2029 unless additional congressional action is taken. Further, in January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability. Additionally, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices.

Specifically, there have been several recent U.S. 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.

Further, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017, or the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to request access to certain investigational new drug products that have completed a Phase I clinical trial and that are undergoing investigation for FDA approval. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

We cannot predict what healthcare reform initiatives may be adopted in the future. Further federal, state and foreign legislative and regulatory developments are likely, and we expect ongoing initiatives to increase pressure on drug pricing. Such reforms could have an adverse effect on anticipated revenues from product candidates and may affect our overall financial condition and ability to develop product candidates.

Packaging and Distribution in the United States

If our products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, sales, promotion and other activities also are potentially subject to federal and state consumer protection and unfair competition laws.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

The failure to comply with any of these laws or regulatory requirements subjects firms to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in criminal prosecution, fines or other penalties, injunctions, exclusion from federal healthcare programs, requests for recall, seizure of products, total or partial suspension of production, denial or withdrawal of product approvals, or refusal to allow a firm to enter into supply contracts, including government contracts. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Prohibitions or restrictions on sales or withdrawal of future products marketed by us could materially affect our business in an adverse way.

Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

Other U.S. Environmental, Health and Safety Laws and Regulations

We may be subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. From time to time and in the future, our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials, and may also produce hazardous waste products. Even if we contract with third parties for the disposal of these materials and waste products, we cannot completely eliminate the risk of contamination or injury resulting from these materials. In the event of contamination or injury resulting from the use or disposal of our hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

We maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees, but this insurance may not provide adequate coverage against potential liabilities. However, we do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. Current or future environmental laws and regulations may impair our research, development or production efforts. In addition, failure to comply with these laws and regulations may result in substantial fines, penalties or other sanctions.

U.S. Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of FDA approval of our future product candidates, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit restoration of the patent term of up to five years as compensation for patent term lost during the FDA regulatory review process. Patent-term restoration, however, cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. The patent-term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA or BLA plus the time between the submission date of an NDA or BLA and the approval of that application, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may apply for restoration of patent term for our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant NDA or BLA.

Marketing exclusivity provisions under the FDCA also can delay the submission or the approval of certain applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an ANDA, or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions of use associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

European Union Drug Development

In the European Union, our future products also may be subject to extensive regulatory requirements. As in the United States, medicinal products can be marketed only if a marketing authorization from the competent regulatory agencies has been obtained.

Similar to the United States, the various phases of preclinical and clinical research in the European Union are subject to significant regulatory controls. Although the EU Clinical Trials Directive 2001/20/EC has sought to harmonize the EU clinical trials regulatory framework, setting out common rules for the control and authorization of clinical trials in the European Union, the EU Member States have transposed and applied the provisions of the Directive differently into their national laws. This has led to significant variations in the member state regimes. Under the current regime, before a clinical trial can be initiated it must be approved in each of the EU countries where the trial is to be conducted by two distinct bodies: the National Competent Authority, or NCA, and one or more Ethics Committees, or ECs. Under the current regime all suspected unexpected serious adverse reactions to the investigated drug that occur during the clinical trial have to be reported to the NCA and ECs of the Member State where they occurred.

The EU clinical trials legislation currently is undergoing a transition process mainly aimed at harmonizing and streamlining clinical-trial authorization, simplifying adverse-event reporting procedures, improving the supervision of clinical trials and increasing their transparency. In April 2014, the EU adopted a new Clinical Trials Regulation (EU) No 536/2014, which is set to replace the current Clinical Trials Directive 2001/20/EC. It will overhaul the current system of approvals for clinical trials in the EU. Specifically, the new regulation, which will be directly applicable in all member states, aims at simplifying and streamlining the approval of clinical trials in the EU. For instance, the new Clinical Trials Regulation provides for a streamlined application procedure via a single entry point and strictly defined deadlines for the assessment of clinical trial applications. It is expected that the new Clinical Trials Regulation (EU) No 536/2014 will apply following confirmation of full functionality of the Clinical Trials Information System, the centralized EU portal and database for clinical trials foreseen by the regulation, through an independent audit.

European Union Drug Marketing

Much like the Anti-Kickback Statue prohibition in the United States, the provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the European Union. The provision of benefits or advantages to physicians is governed by the national anti-bribery laws of European Union Member States, such as the UK Bribery Act 2010. Infringement of these laws could result in substantial fines and imprisonment.

Payments made to physicians in certain European Union Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization and/or the regulatory authorities of the individual EU Member States. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the EU Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

European Union Drug Review and Approval

In the European Economic Area, or EEA, which is comprised of the 27 Member States of the European Union (including Norway and excluding Croatia), Iceland and Liechtenstein, medicinal products can only be commercialized after obtaining a marketing authorization, or MA. There are two types of marketing authorizations.

- The Community MA is issued by the European Commission through the Centralized Procedure, based on the opinion of the Committee for Medicinal Products for Human Use, or CHMP, of the EMA, and is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, advanced-therapy medicines such as gene-therapy, somatic cell-therapy or tissue-engineered medicines and medicinal products containing a new active substance indicated for the treatment of HIV, AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and other immune dysfunctions and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the European Union.
- National MAs, which are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, are available for products not falling within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in a Member State of the EEA, this National MA can be recognized in another Member States through the Mutual Recognition Procedure. If the product has not received a National MA in any Member State at the time of application, it can be approved simultaneously in various Member States through the Decentralized Procedure. Under the Decentralized Procedure an identical dossier is submitted to the competent authorities of each of the Member States in which the MA is sought, one of which is selected by the applicant as the Reference Member State, or RMS. The competent authority of the RMS prepares a draft assessment report, a draft summary of the product characteristics, or SPC, and a draft of the labeling and package leaflet, which are sent to the other Member States (referred to as the Member States Concerned) for their approval. If the Member States Concerned raise no objections, based on a potential serious risk to public health, to the assessment, SPC, labeling, or packaging proposed by the RMS, the product is subsequently granted a national MA in all the Member States (i.e., in the RMS and the Member States Concerned).

Under the above described procedures, before granting the MA, the EMA or the competent authorities of the Member States of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

European Union New Chemical Entity Exclusivity

In the European Union, new chemical entities, sometimes referred to as new active substances, qualify for eight years of data exclusivity upon marketing authorization and an additional two years of market exclusivity. The data exclusivity, if granted, prevents regulatory authorities in the European Union from referencing the innovator's data to assess a generic application for eight years, after which generic marketing authorization can be submitted, and the innovator's data may be referenced, but not approved for two years. The overall ten-year period will be extended to a maximum of 11 years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are determined to bring a significant clinical benefit in comparison with currently approved therapies.

European Union Orphan Designation and Exclusivity

In the European Union, the EMA's Committee for Orphan Medicinal Products grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting not more than five in 10,000 persons in the European Union community (or where it is unlikely that the development of the medicine would generate sufficient return to justify the investment) and for which no satisfactory method of diagnosis, prevention or treatment has been authorized (or, if a method exists, the product would be a significant benefit to those affected).

In the European Union, orphan drug designation entitles a party to financial incentives such as reduction of fees or fee waivers and ten years of market exclusivity is granted following medicinal 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. Orphan drug designation must be requested before submitting an application for marketing approval. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

European Pediatric Investigation Plan

In the EEA, MAAs for new medicinal products not authorized have to include the results of studies conducted in the pediatric population, in compliance with a pediatric investigation plan, or PIP, agreed with the EMA's Pediatric Committee, or PDCO. The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the drug for which marketing authorization is being sought. The PDCO can grant a deferral of the obligation to implement some or all of the measures of the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults. Further, the obligation to provide pediatric clinical trial data can be waived by the PDCO when this data is not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. Once the marketing authorization is obtained in all Member States of the European Union and trial results are included in the product information, even when negative, the product is eligible for six months' supplementary protection certificate extension.

European Data Collection

The collection and use of personal health data in the European Economic Area, or the EEA, is governed by the GDPR, which became effective May 25, 2018. The GDPR applies to any company established in the EEA and to companies established outside the EEA that process personal data in connection with the offering of goods or services to data subjects in the EU or the monitoring of the behavior of data subjects in the European Union. The GDPR enhances data protection obligations for data controllers of personal data, including stringent requirements relating to the consent of data subjects, expanded disclosures about how personal data is used, requirements to conduct privacy impact assessments for "high risk" processing, limitations on retention of personal data, mandatory data breach notification and "privacy by design" requirements, and creates direct obligations on service providers acting as data processors. The GDPR also imposes strict rules on the transfer of personal data outside of the EEA to countries that do not ensure an adequate level of protection, like the U.S. Failure to comply with the requirements of the GDPR and the related national data protection laws of the EEA Member States may result in fines up to 20 million Euros or 4% of a company's global annual revenues for the preceding financial year, whichever is higher. Moreover, the GDPR grants data subjects the right to claim material and non material damages resulting from infringement of the GDPR. Given the breadth and depth of changes in data protection obligations, maintaining compliance with the GDPR, will require significant time, resources and expense, and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules. This may be onerous and adversely affect our business, financial condition, results of operations and prospects. Further, the United Kingdom's decision to leave the EU, often referred to as Brexit, has created uncertainty with regard to data protection regulation in the United Kingdom. In particular, it is unclear how data transfers to and from the United Kingdom will be regulated now that the United Kingdom has left the EU.

Rest of the World Regulation

For other countries outside of the European Union and the United States, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. Additionally, the clinical trials must be conducted in accordance with GCP requirements and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

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

Additional Laws and Regulations Governing International Operations

If we further expand our operations outside of the United States, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we expand our presence outside of the United States, it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our development costs.

The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

Coverage and Reimbursement

Successful commercialization of new drug products depends in part on the extent to which reimbursement for those drug products will be available from government health administration authorities, private health insurers, and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drug products they will pay for and establish reimbursement levels. The availability and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford a drug product. Sales of drug products depend substantially, both domestically and abroad, on the extent to which the costs of drugs products are paid for by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular drug products. In many countries, the prices of drug products are subject to varying price control mechanisms as part of national health systems. In general, the prices of drug products under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for drug products, but monitor and control company profits. Accordingly, in markets outside the United States, the reimbursement for drug products may be reduced compared with the United States.

In the United States, the principal decisions about reimbursement for new drug products are typically made by CMS, an agency within the HHS. CMS decides whether and to what extent a new drug product will be covered and reimbursed under Medicare, and private payors tend to follow CMS to a substantial degree. However, no uniform policy of coverage and reimbursement for drug products exists among third-party payors and coverage and reimbursement levels for drug products can differ significantly from payor to payor.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the MMA, established the Medicare Part D program to provide a voluntary prescription drug benefit to Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities that provide coverage of outpatient prescription drugs. Unlike Medicare Parts A and B, Part D coverage is not standardized. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. While all Medicare drug plans must give at least a standard level of coverage set by Medicare, Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government payment for some of the costs of prescription drugs may increase demand for drugs for which we obtain marketing approval. Any negotiated prices for any of our products covered by a Part D prescription drug plan will likely be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-governmental payors.

For a drug product to receive federal reimbursement under the Medicaid or Medicare Part B programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the 340B drug pricing program. The required 340B discount on a given product is calculated based on the average manufacturer price, or AMP, and Medicaid rebate amounts reported by the manufacturer. As of 2010, the ACA expanded the types of entities eligible to receive discounted 340B pricing, although under the current state of the law these newly eligible entities (with the exception of children’s hospitals) will not be eligible to receive discounted 340B pricing on orphan drugs. As 340B drug pricing is determined based on AMP and Medicaid rebate data, the revisions to the Medicaid rebate formula and AMP definition described above could cause the required 340B discount to increase. The American Recovery and Reinvestment Act of 2009 provides funding for the federal government to compare the effectiveness of different treatments for the same illness. The plan for the research was published in 2012 by the Department of HHS, the Agency for Healthcare Research and Quality and the National Institutes for Health, and periodic reports on the status of the research and related expenditures are made to Congress. Although the results of the comparative effectiveness studies are not intended to mandate coverage policies for public or private payors, it is not clear what effect, if any, the research will have on the sales of our drug candidates, if any such drug or the condition that they are intended to treat are the subject of a trial. It is also possible that comparative effectiveness research demonstrating benefits in a competitor’s drug could adversely affect the sales of our drug candidate. If third-party payors do not consider our drugs to be cost-effective compared to other available therapies, they may not cover our drugs after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our drugs on a profitable basis.

These laws, and future state and federal healthcare reform measures may be adopted in the future, any of which may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

Outside of the United States, the pricing of pharmaceutical products and medical devices is subject to governmental control in many countries. For example, in the European Union, pricing and reimbursement schemes vary widely from country to country. Some countries provide that products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost effectiveness of a particular therapy to currently available therapies or so-called health technology assessments, in order to obtain reimbursement or pricing approval. Other countries may allow companies to fix their own prices for products, but monitor and control product volumes and issue guidance to physicians to limit prescriptions. Efforts to control prices and utilization of pharmaceutical products and medical devices will likely continue as countries attempt to manage healthcare expenditures.

Employees

As of December 31, 2019, we had 248 full-time employees, including 44 Eidos employees. We have never had a work stoppage, and none of our employees is represented by a labor organization or under any collective-bargaining arrangements. We consider our employee relations to be good.

Corporate and Other Information

We were incorporated as a Delaware corporation in 2019, under the name BridgeBio Pharma, Inc. Our principal executive offices are located at 421 Kipling Street, Palo Alto, CA 94301. Our telephone number is (650) 391-9740.

Our web page address is *https://bridgebio.com*. Our investor relations website is located at *https://investor.bridgebio.com*. We make available free of charge on our investor relations website under "SEC Filings" our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, our directors' and officers' Section 16 Reports and any amendments to those reports after filing or furnishing such materials to the SEC. References to our website address do not constitute incorporation by reference of the information contained on the website, and the information contained on the website is not part of this document or any other document that we file with or furnish to the SEC.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012. As such, we are eligible for exemptions from various reporting requirements applicable to other public companies that are not emerging growth companies, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002 and reduced disclosure obligations regarding executive compensation. We will remain an emerging growth company until the earliest of (i) December 31, 2024, (ii) the last day of the first fiscal year in which our annual gross revenues are $1.07 billion or more, (iii) the date on which we have, during the previous rolling three-year period, issued more than $1.0 billion in non-convertible debt securities, and (iv) the date on which we are deemed to be a "large accelerated filer" as defined in the Securities Exchange Act of 1934, as amended.

ITEM 1A. RISK FACTORS

Our business involves significant risks, some of which are described below. You should carefully consider the risks and uncertainties described below, together with all of the other information contained in this Annual Report on Form 10-K, including "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the consolidated financial statements and the related notes. If any of the following risks actually occur, it could harm our business, prospects, operating results and financial condition and future prospects. In such event, the market price of our common stock could decline and you could lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations. This Annual Report on Form 10-K also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of factors that are described below and elsewhere in this Annual Report.

Risk Related to our Financial Position, Need for Additional Capital and Growth Strategy

Drug development is a highly uncertain undertaking and involves a substantial degree of risk. We have incurred significant losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future. We have not generated any revenue since inception, which, together with our limited operating history, may make it difficult for you to assess our future viability.

Pharmaceutical and biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We are a clinical-stage biopharmaceutical company with a limited operating history upon which you can evaluate our business and prospects. Our subsidiaries, on whose success we largely rely, are also early-stage biopharmaceutical companies. To date, we have focused principally on identifying, acquiring or in-licensing and developing our product candidates at the subsidiary level, all of which are in discovery, lead optimization, preclinical or clinical development. Our product candidates will require substantial additional development time, including extensive clinical research, and resources before we would be able to apply for or receive regulatory approvals and begin generating revenue from product sales.

We are not profitable and have incurred losses in each year since our inception in April 2015. Our net losses for the years ended December 31, 2019, 2018 and 2017 were $288.6 million, $169.5 million and $43.8 million, respectively. As of December 31, 2019, we had an accumulated deficit of $440.0 million. We have no products approved for commercial sale and have not generated any revenues from product sales, and have financed operations solely through the sale of equity securities and debt financings. We continue to incur significant research and development, or R&D, and other expenses related to ongoing operations and expect to incur losses for the foreseeable future. We anticipate these losses will increase substantially in future periods and we will not generate any revenue from product sales until after we have successfully completed clinical development and received regulatory approval for the commercial sale of one or more product candidates.

Because of the numerous risks and uncertainties associated with drug development, we are unable to predict the timing or amount of our expenses, or when we will be able to generate any meaningful revenue or achieve or maintain profitability, if ever. In addition, our expenses could increase beyond our current expectations if we are required by the U.S. Food and Drug Administration, or FDA, or comparable foreign regulatory authorities, to perform nonclinical or preclinical studies or clinical trials in addition to those that we currently anticipate, or if there are any delays in any of our or our future collaborators' clinical trials or the development of our product candidates that we may identify. Even if our future product candidates that we may identify are approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate and ongoing compliance efforts.

We may never be able to develop or commercialize a marketable drug or achieve profitability. Revenue from the sale of any product candidate for which regulatory approval is obtained will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the accepted price for the product, the ability to obtain reimbursement at any price and whether we own the commercial rights for that territory. Our growth strategy depends on our ability to generate revenue. In addition, if the number of addressable patients is not as anticipated, the indication approved by regulatory authorities is narrower than expected, or the reasonably accepted population for treatment is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved. Even if we are able to generate revenue from the sale of any approved products, we may not become profitable and may need to obtain additional funding to continue operations. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our failure to achieve sustained profitability would depress the value of our company and could impair our ability to raise capital, expand our business, diversify our research and development pipeline, market our product candidates, if approved, that we may identify and pursue or continue our operations. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity and working capital.

We will require substantial additional funding to achieve our business goals. If we are unable to obtain this funding when needed and on acceptable terms, we could be forced to delay, limit or terminate our product development efforts.

Developing biopharmaceutical products is expensive and time-consuming, and we expect to require substantial additional capital to conduct research, preclinical testing and human studies, may establish pilot scale and commercial scale manufacturing processes and facilities, and establish and develop quality control, regulatory, marketing, sales and administrative capabilities to support our existing programs and pursue potential additional programs. We are also responsible for the payments to third parties of expenses that may include milestone payments, license maintenance fees and royalties, including in the case of certain of our agreements with academic institutions or other companies from whom intellectual property rights underlying their respective programs have been in-licensed or acquired. Because the outcome of any preclinical or clinical development and regulatory approval process is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development, regulatory approval process and commercialization of any future product candidates we may identify.

As of December 31, 2019, we had working capital of $508.2 million and cash, cash equivalents and marketable securities of $577.1 million. We expect that our cash and cash equivalents will be sufficient to fund our operations through at least the next 12 months from the date of this report. However, our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings or other sources, such as strategic collaborations or license and development agreements. Any additional fundraising efforts for us may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize product candidates that we may identify and pursue. Moreover, such financing may result in dilution to stockholders, imposition of debt covenants and repayment obligations, or other restrictions that may affect our business. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

Our future funding requirements will depend on many factors, including, but not limited to:

- the time and cost necessary to complete ongoing and planned clinical trials, including Eidos' ongoing and planned Phase 3 clinical trials of BBP-265; our Phase 2 clinical trial of infigratinib in CCA as a second-line therapy, Phase 3 clinical trial of infigratinib in CCA as a first-line therapy and Phase 3 clinical trial of infigratinib in adjuvant UC; and our Phase 1/2 clinical trial of BBP-589 in dystrophic epidermolysis bullosa;
- the time and cost necessary to pursue regulatory approvals for our product candidates, and the costs of post-marketing studies that could be required by regulatory authorities;
- the progress, timing, scope and costs of our nonclinical studies, preclinical studies, clinical trials and other related activities, including the ability to enroll patients in a timely manner, for the ongoing and planned clinical trials set forth above, and potential future clinical trials;
- the costs of obtaining adequate clinical and commercial supplies of raw materials and drug products for our product candidates, including protein or gene therapies such as BBP-589, BBP-631, and BBP-812 and any other product candidates we may identify and develop;
- our ability to successfully identify and negotiate acceptable terms for third-party supply and contract manufacturing agreements with contract manufacturing organizations, or CMOs;
- our ability to successfully commercialize product candidates;
- the manufacturing, selling and marketing costs associated with our product candidates, including the cost and timing of expanding our internal sales and marketing capabilities or entering into strategic collaborations with third parties to leverage or access these capabilities;
- the amount and timing of sales and other revenues from our product candidates, if any are approved, including the sales price and the availability of adequate third-party reimbursement;
- the cash requirements of any future acquisitions or discovery of product candidates;
- the time and cost necessary to respond to technological and market developments;
- the costs of acquiring, licensing or investing in intellectual property rights, products, product candidates and businesses;
- our ability to continue to discover and develop additional product candidates, and the time and costs associated with identifying additional product candidates;
- our ability to attract, hire and retain qualified personnel; and
- the costs of maintaining, expanding and protecting our intellectual property portfolio.

Additional funds may not be available when we need them, on terms that are acceptable, or at all. If adequate funds are not available to us on a timely basis, we may be required to delay, limit or terminate one or more research or development programs or the commercialization of any product candidates or be unable to expand operations or otherwise capitalize on business opportunities, as desired, which could materially affect our business, prospects, financial condition and results of operations.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to current product candidates or to any future product candidates on unfavorable terms.

We may seek additional capital through any number of available sources, including but not limited to public and private equity offerings, debt financings, strategic partnerships and alliances and licensing arrangements. We, and indirectly, our stockholders, will bear the cost of issuing and servicing any such securities and of entering into and maintaining any such strategic partnerships or other arrangements. Because any decision by us to issue debt or equity securities in the future will depend on market conditions and other factors beyond our control, we cannot predict or estimate the amount, timing or nature of any future financing transactions. To the extent that we raise additional capital through the sale of equity or debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. The incurrence of additional indebtedness would result in increased fixed payment obligations and could involve additional restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Additionally, any future collaborations we enter into with third parties may provide capital in the near term, but limit our potential cash flow and revenue in the future. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses or other rights on unfavorable terms.

In addition, if one of our subsidiaries raises funds through the issuance of equity securities, and our stockholders' equity interest in such subsidiary could be substantially diminished. If one of our subsidiaries raises additional funds through collaboration and licensing arrangements, it may be necessary to relinquish some rights to our technologies or our product candidates or grant licenses on terms that are not favorable to us.

If we engage in other acquisitions or strategic partnerships, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

We may engage in various acquisitions and strategic partnerships in the future, including licensing or acquiring complementary products, intellectual property rights, technologies, or businesses. Any acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of indebtedness or contingent liabilities;
- the issuance of our equity securities which would result in dilution to our stockholders;
- assimilation of operations, intellectual property, products and product candidates of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing product programs and initiatives in pursuing such an acquisition or strategic partnership;
- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and regulatory approvals; and
- our inability to generate revenue from acquired intellectual property, technology and/or products sufficient to meet our objectives or even to offset the associated transaction and maintenance costs.

In addition, if we undertake such a transaction, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense.

If we obtain a controlling interest in additional companies in the future, it could adversely affect our operating results and the value of our common stock, thereby disrupting our business.

As part of our strategy, we expect to form and invest in additional wholly-owned subsidiaries and variable interest entities, or VIEs. Investments in our existing and any future subsidiaries involve numerous risks, including, but not necessarily limited to:

- risk of conducting research and development activities in new therapeutic areas or treatment modalities in which we have little to no experience;
- diversion of financial and managerial resources from existing operations;
- our ability to negotiate a proposed acquisition, in-license or investment in a timely manner or at a price or on terms and conditions favorable to us;
- our ability to combine and integrate a potential acquisition into our existing business to fully realize the benefits of such acquisition;
- the impact of regulatory reviews on a proposed acquisition, in-license or investment; and
- the outcome of any legal proceedings that may be instituted with respect to the proposed acquisition, in-license or investment.

If we fail to properly evaluate potential acquisitions, in-licenses, investments or other transactions associated with the creation of new research and development programs or the maintenance of existing ones, we might not achieve the anticipated benefits of any such transaction, we might incur costs in excess of what we anticipate, and management resources and attention might be diverted from other necessary or valuable activities. For instance, in August 2019, we announced a non-binding proposal to acquire all of the outstanding shares of common stock of Eidos that were not then owned by us or our subsidiaries (or the "Eidos Buyout Offer"). Although discussions between a special committee comprised of Eidos' disinterested and independent directors and us with respect to the proposed transaction have terminated, the attention of certain members of each company's management and each company's resources were diverted from day-to-day business operations during our exploration of the Eidos Buyout Offer, and we may engage in similar discussions in the future with respect to other potential transactions that may divert our time and resources from our ongoing operations.

Risks Related to our Business and the Clinical Development, Regulatory Review and Approval of our Product Candidates

Our product candidates are in preclinical or clinical development, which is a lengthy and expensive process with uncertain outcomes and the potential for substantial delays. We cannot give any assurance that any of our product candidates will receive regulatory approval, which is necessary before they can be commercialized.

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidates in humans. To date, we have focused substantially all of our efforts and financial resources on identifying, acquiring, and developing our product candidates, including conducting lead optimization, nonclinical studies, preclinical studies and clinical trials, and providing general and administrative support for these operations. We cannot be certain that any clinical trials will be conducted as planned or completed on schedule, if at all. Our inability to successfully complete preclinical and clinical development could result in additional costs to us and negatively impact our ability to generate revenue. Our future success is dependent on our ability to successfully develop, obtain regulatory approval for, and then successfully commercialize product candidates. We currently have no products approved for sale and have not generated any revenue from sales of drugs, and we may never be able to develop or successfully commercialize a marketable drug.

All of our product candidates require additional development; management of preclinical, clinical, and manufacturing activities; and regulatory approval. In addition, we will need to obtain adequate manufacturing supply; build a commercial organization; commence marketing efforts; and obtain reimbursement before we generate any significant revenue from commercial product sales, if ever. Many of our product candidates are in early-stage research or translational phases of development, and the risk of failure for these programs is high. We cannot be certain that any of our product candidates will be successful in clinical trials or receive regulatory approval. Further, our product candidates may not receive regulatory approval even if they are successful in clinical trials. If we do not receive regulatory approvals for our product candidates, we and our subsidiaries may not be able to continue operations, which may result in us dissolving the subsidiary, selling or out-licensing the technology or pursuing an alternative strategy.

If we are unable to obtain regulatory approval in one or more jurisdictions for any product candidates that we may identify and develop, our business will be substantially harmed.

We cannot commercialize a product until the appropriate regulatory authorities have reviewed and approved the product candidate. Approval by the FDA and comparable foreign regulatory authorities is lengthy and unpredictable, and depends upon numerous factors, including substantial discretion of the regulatory authorities. Approval policies, regulations, or the type and amount of nonclinical or clinical data necessary to gain approval may change during the course of a product candidate's 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 candidates, and it is possible that our current product candidates and any other product candidates which we may seek to develop in the future will not ever obtain regulatory approval. We cannot be certain that any of our product candidates will receive regulatory approval or be successfully commercialized even if we receive regulatory approval.

Obtaining marketing approval is an extensive, lengthy, expensive and inherently uncertain process, and regulatory authorities may delay, limit or deny approval of our product candidates for many reasons, including but not limited to:

- the inability to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that the applicable product candidate is safe and effective as a treatment for our targeted indications;
- the FDA or comparable foreign regulatory authorities may disagree with the design, endpoints or implementation of our clinical trials;
- the population studied in the clinical program may not be sufficiently broad or representative to assure safety or efficacy in the full population for which we seek approval;
- the FDA or comparable foreign regulatory authorities may require additional preclinical studies or clinical trials beyond those that we currently anticipate;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from nonclinical studies or clinical trials;
- the data collected from clinical trials of product candidates that we may identify and pursue may not be sufficient to support the submission of an NDA, biologics license application, or BLA, or other submission for regulatory approval in the United States or elsewhere;
- we may be unable to demonstrate to the FDA or comparable foreign regulatory authorities that a product candidate's risk-benefit ratio for its proposed indication is acceptable;
- the FDA or comparable foreign regulatory authorities may identify deficiencies in the manufacturing processes, test procedures and specifications, or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may change in a manner that renders the clinical trial design or data insufficient for approval.

The lengthy approval process, as well as the unpredictability of the results of clinical trials and evolving regulatory requirements, may result in our failure to obtain regulatory approval to market product candidates that we may pursue in the United States or elsewhere, which would significantly harm our business, prospects, financial condition and results of operations.

We may encounter substantial delays in clinical trials, or may not be able to conduct or complete clinical trials on the expected timelines, if at all.

Clinical testing is expensive, time consuming, and subject to uncertainty. We cannot guarantee that any of our ongoing and planned clinical trials will be conducted as planned or completed on schedule, if at all. Moreover, even if these trials are initiated or conducted on a timely basis, issues may arise that could result in the suspension or termination of such clinical trials. A failure of one or more clinical trials can occur at any stage of testing, and our ongoing and future clinical trials may not be successful. Events that may prevent successful or timely initiation or completion of clinical trials include:

- inability to generate sufficient preclinical, toxicology, or other *in vivo* or *in vitro* data to support the initiation or continuation of clinical trials;
- delays in confirming target engagement, patient selection or other relevant biomarkers to be utilized in preclinical and clinical product candidate development;
- delays in reaching a consensus with regulatory agencies as to the design or implementation of our clinical studies;
- delays in reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- delays in identifying, recruiting and training suitable clinical investigators;
- delays in obtaining required Institutional Review Board, or IRB, approval at each clinical trial site;
- imposition of a temporary or permanent clinical hold by regulatory agencies for a number of reasons, including after review of an IND or amendment, clinical trial application, or CTA, or amendment, or equivalent application or amendment; as a result of a new safety finding that presents unreasonable risk to clinical trial participants; a negative finding from an inspection of our clinical trial operations or study sites;
- developments in trials for other product candidates with the same targets or related modalities as our product candidates conducted by competitors that raise regulatory or safety concerns about risk to patients of the treatment; or if the FDA finds that the investigational protocol or plan is clearly deficient to meet its stated objectives;
- difficulties in securing access to materials for the comparator arm of certain of our clinical trials;
- delays in identifying, recruiting and enrolling suitable patients to participate in clinical trials, and delays caused by patients withdrawing from clinical trials or failing to return for post-treatment follow-up;
- difficulty collaborating with patient groups and investigators;
- failure by CROs, other third parties, or us to adhere to clinical trial requirements;
- failure to perform in accordance with the FDA’s or any other regulatory authority’s current good clinical practices, or GCP, requirements, or regulatory guidelines in other countries;
- occurrence of adverse events, or AEs, associated with the product candidate that are viewed to outweigh its potential benefits;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- changes in the standard of care on which a clinical development plan was based, which may require new or additional trials;
- the cost of clinical trials of any product candidates that we may identify and pursue being greater than we anticipate;

- clinical trials of any product candidates that we may identify and pursue producing negative or inconclusive results, which may result in our deciding, or regulators requiring us, to conduct additional clinical trials or abandon product development programs;
- transfer of manufacturing processes to larger-scale facilities operated by a CMO, or by us, and delays or failure by our CMOs or us to make any necessary changes to such manufacturing process; and
- delays in manufacturing, testing, releasing, validating, or importing/exporting sufficient stable quantities of product candidates that we may identify for use in clinical trials or the inability to do any of the foregoing.

Any inability to successfully initiate or complete clinical trials could result in additional costs to us or impair our ability to generate revenue. In addition, if we make manufacturing or formulation changes to our product candidates, we may be required to or we may elect to conduct additional nonclinical studies or clinical trials to bridge data obtained from our modified product candidates to data obtained from nonclinical and clinical research conducted using earlier versions. Clinical trial delays could also shorten any periods during which our products have patent protection and may allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize product candidates and may harm our business and results of operations.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the data safety monitoring board, or DSMB, including for our ongoing and planned Phase 3 clinical trials of BBP-265, our ongoing and planned Phase 3 clinical trials of BBP-831 and our ongoing Phase 3 and Phase 2b clinical trials of BBP-009, or by the FDA or other regulatory authority, or if the IRBs of the institutions in which such trials are being conducted suspend or terminate the participation of their clinical investigators and sites subject to their review. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. For example, on October 30, 2018, the FDA notified our subsidiary Phoenix Tissue Report Inc. of a partial clinical hold, but allowed it to proceed with the planned Phase 1/2 study using only the existing drug substance of BBP-589 that was identified by the FDA. The FDA requested additional development of the analytical test method to quantitate relative potency of any new batch of product we intend to use for future clinical studies. We provided a complete response in January 2020, and the FDA removed the partial clinical hold in February 2020. Although the partial clinical hold on BBP-589 was removed, we may be required or may voluntarily determine to place BBP-589 or other product candidates on clinical hold in the future for various reasons.

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA or comparable foreign regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or comparable foreign regulatory authority, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our product candidates.

Delays in the initiation, conduct or completion of any clinical trial of our product candidates will increase our costs, slow down the product candidate development and approval process and delay or potentially jeopardize our ability to commence product sales and generate revenue. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. In the event we identify any additional product candidates to pursue, we cannot be sure that submission of an IND or a CTA will result in the FDA or comparable foreign regulatory authority allowing clinical trials to begin in a timely manner, if at all. Any of these events could have a material adverse effect on our business, prospects, financial condition and results of operations.

Our clinical trials may fail to demonstrate substantial evidence of the safety and effectiveness of product candidates that we may identify and pursue for their intended uses, which would prevent, delay or limit the scope of regulatory approval and commercialization.

Before obtaining regulatory approvals for the commercial sale of any of our product candidates, we must demonstrate through lengthy, complex and expensive nonclinical studies, preclinical studies and clinical trials that the applicable product candidate is both safe and effective for use in each target indication, and in the case of our product candidates regulated as biological products, that the product candidate is safe, pure, and potent for use in its targeted indication. Each product candidate must demonstrate an adequate risk versus benefit profile in its intended patient population and for its intended use.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical development process. Most product candidates that begin clinical trials are never approved by regulatory authorities for commercialization. We have limited experience in designing clinical trials and may be unable to design and execute a clinical trial to support marketing approval.

We cannot be certain that our current clinical trials or any other future clinical trials will be successful. Additionally, any safety concerns observed in any one of our clinical trials in our targeted indications could limit the prospects for regulatory approval of our product candidates in those and other indications, which could have a material adverse effect on our business, financial condition and results of operations. In addition, even if such clinical trials are successfully completed, we cannot guarantee that the FDA or comparable foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit our product candidates for approval. This is particularly true for clinical trials in very rare diseases, such as with BBP-870 for MoCD Type A, where the very small patient population makes it difficult or impossible to conduct two traditional, adequate and well-controlled studies, and therefore the FDA or comparable foreign regulatory authorities are often required to exercise flexibility in approving therapies for such diseases. Moreover, results acceptable to support approval in one jurisdiction may be deemed inadequate by another regulatory authority to support regulatory approval in that other jurisdiction. To the extent that the results of the trials are not satisfactory to the FDA or comparable foreign regulatory authorities for support of a marketing application, we may be required to expend significant resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates. For example, we intend to file an NDA for BBP-831 in second line and later advanced CCA with FGFR2 fusions or translocations in 2020. However, the FDA could disagree that data from our Phase 2 trial are sufficient to file an NDA or to approve BBP-831 for such an indication. Even if regulatory approval is secured for a product candidate, the terms of such approval may limit the scope and use of the specific product candidate, which may also limit its commercial potential.

Results of earlier studies or clinical trials may not be predictive of future clinical trial results, and initial studies or clinical trials may not establish an adequate safety or efficacy profile for our product candidates to justify proceeding to advanced clinical trials or an application for regulatory approval.

The results of nonclinical and preclinical studies and clinical trials may not be predictive of the results of later-stage clinical trials, and interim results of a clinical trial do not necessarily predict final results. In addition, for certain of our product candidates that we acquired, we did not undertake the preclinical studies and clinical trials ourselves. The results of preclinical studies and clinical trials in one set of patients or disease indications, or from preclinical studies or clinical trials that we did not lead, may not be predictive of those obtained in another. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the dosing regimen and other clinical trial protocols and the rate of dropout among clinical trial participants. In addition, preclinical and clinical data are often susceptible to various interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through nonclinical studies and initial clinical trials. A number of companies in the pharmaceutical and biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier studies, and we cannot be certain that we will not face similar setbacks. Even if early-stage clinical trials are successful, we

may need to conduct additional clinical trials of our product candidates in additional patient populations or under different treatment conditions before we are able to seek approvals from the FDA and regulatory authorities outside the United States to market and sell these product candidates. Our failure to obtain marketing approval for our product candidates would substantially harm our business, prospects, financial condition and results of operations. For example, if BBP-265 is first approved for ATTR-CM on the basis of efficacy endpoints other than for reduction in mortality or hospitalization, BBP-265 might be limited to a second-line claim until such data were available. Any of these events could limit the commercial potential of BBP-265 and have a material adverse effect on our business, prospects, financial condition and results of operations.

Additionally, some of the clinical trials performed to date were generated from open-label studies and were conducted at a limited number of clinical sites on a limited number of patients. An "open-label" clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved drug or placebo. Most typically, open-label clinical trials test only the investigational product candidate and sometimes may do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label clinical trials are aware when they are receiving treatment. Open-label clinical trials may be subject to a "patient bias" where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. Moreover, patients selected for early clinical studies often include the most severe sufferers and their symptoms may have been bound to improve notwithstanding the new treatment. In addition, open-label clinical trials may be subject to an "investigator bias" where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. Given that our Phase 2 clinical trial of BBP-265 includes an open-label clinical trial extension, the results from this clinical trial may not be predictive of future clinical trial results with this or other product candidates for which we include an open-label clinical trial when studied in a controlled environment with a placebo or active control.

We may encounter difficulties enrolling patients in clinical trials, and clinical development activities could thereby be delayed or otherwise adversely affected.

The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. The indications for which we plan to evaluate our current product candidates represent a rare disease or condition with limited patient populations from which to draw participants in clinical trials. Due to our focus on the development of product candidates for the treatment of Mendelian diseases and genetically driven cancers, many of which are rare conditions, we may not be able to identify and enroll a sufficient number of patients, or those with required or desired characteristics and criteria, in a timely manner.

We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons, including:

- the size and nature of a patient population;
- the patient eligibility criteria defined in the applicable clinical trial protocols, which may limit the patient populations eligible for clinical trials to a greater extent than competing clinical trials for the same indication;
- the size of the study population required for analysis of the trial's primary endpoints;
- the severity of the disease under investigation;
- the proximity of patients to a trial site;
- the design of the trial;
- the ability to recruit clinical trial investigators with the appropriate competencies and experience;
- the approval or concurrent enrollment of clinical trials involving competing product candidates currently under development for Mendelian diseases or genetically driven cancers or competing clinical trials for similar therapies or targeting patient populations meeting our patient eligibility criteria;

- clinicians' and patients' perceptions as to the potential advantages and side effects of the product candidate being studied in relation to other available therapies and product candidates;
- the ability to obtain and maintain patient consents; and
- the risk that patients enrolled in clinical trials will not complete such trials, for any reason.

If we have difficulty enrolling sufficient numbers of patients to conduct clinical trials as planned, we may need to delay or terminate ongoing or planned clinical trials, either of which would have an adverse effect on our business.

Use of our product candidates could be associated with side effects, adverse events or other properties or safety risks, which could delay or halt their clinical development, prevent their regulatory approval, cause us to suspend or discontinue clinical trials, abandon a product candidate, limit their commercial potential, if approved, or result in other significant negative consequences that could severely harm our business, prospects, operating results and financial condition.

As is the case with pharmaceuticals generally, it is likely that there may be side effects and AEs associated with our product candidates' use. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

Moreover, if our product candidates are associated with undesirable side effects in preclinical studies or clinical trials or have characteristics that are unexpected, we may elect to abandon their development or limit their development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective, which may limit the commercial expectations for the product candidate if approved. We may also be required to modify or terminate our study plans based on findings in our preclinical studies or clinical trials. For instance, in our Phase 2 clinical trial of BPP-831 for the treatment of FGFR-driven cancers, the most commonly reported treatment emergent adverse event of any grade was hyperphosphatemia, which is an electrolyte disorder in which there is an elevated level of phosphate in the blood. These and other AEs that we may observe in our ongoing and future clinical trials of our product candidates could require us to delay, modify or abandon our development plans for the affected product candidate or other product candidates that share properties of the affected product candidate. Many product candidates that initially show promise in early-stage testing may later be found to cause side effects that prevent further development. As we work to advance existing product candidates and to identify new product candidates, we cannot be certain that later testing or trials of product candidates that initially showed promise in early testing will not be found to cause similar or different unacceptable side effects that prevent their further development.

It is possible that as we test our product candidates in larger, longer and more extensive clinical trials, or as the use of these product candidates becomes more widespread if they receive regulatory approval, illnesses, injuries, discomforts and other AEs that were observed in earlier trials, as well as conditions that did not occur or went undetected in previous trials, will be reported by subjects. If such side effects become known later in development or upon approval, if any, such findings may harm our business, financial condition and prospects significantly.

Additionally, adverse developments in clinical trials of pharmaceutical and biopharmaceutical products conducted by others may cause the FDA or other regulatory oversight bodies to suspend or terminate our clinical trials or to change the requirements for approval of any of our product candidates.

In addition to side effects caused by the product candidate, the administration process or related procedures also can cause adverse side effects. If any such AEs occur, our clinical trials could be suspended or terminated. If we are unable to demonstrate that any AEs were caused by the administration process or related procedures, the FDA, the European Commission, the European Medicines Agency, or the EMA, or other regulatory authorities could order us to cease further development of, or deny approval of, a product candidate for any or all targeted indications. Even if can demonstrate that all future serious adverse events, or SAEs, are not product-related, such occurrences could affect patient recruitment or the ability of enrolled patients to complete the trial. Moreover, if we elect, or are required, to not initiate, delay, suspend or terminate any future clinical trial of any of our product candidates, the commercial prospects of such product candidates may be harmed and our ability to generate product revenues from any of these product candidates may be delayed or eliminated. Any of these occurrences may harm our ability to develop other product candidates, and may harm our business, financial condition and prospects significantly.

Additionally, if any of our product candidates receives marketing approval, the FDA could impose a boxed warning in the labeling of our product and could require us to adopt a risk evaluation and mitigation strategy, or REMS, and could apply elements to assure safe use to ensure that the benefits of the product outweigh its risks, which may include, among other things, a Medication Guide outlining the risks of the product for distribution to patients and a communication plan to health care practitioners. Furthermore, if we or others later identify undesirable side effects caused by our product candidates once approved, several potentially significant negative consequences could result, including:

- regulatory authorities may suspend or withdraw approvals of such product candidate;
- regulatory authorities may require additional warnings on the label;
- we may be required by the FDA to implement a REMS;
- we may be required to change the way a product candidate is administered or conduct additional clinical trials;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these occurrences could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and may harm our business, financial condition and prospects significantly.

Certain of our product candidates under development for the treatment of patient populations with significant comorbidities that may result in deaths or serious adverse or unacceptable side effects and require us to abandon or limit our clinical development activities.

Patients in certain of our ongoing and planned clinical trials of product candidates in genetically driven cancers, including clinical trials of BBP-831 of FGFR-driven cancers, as well as patients who may undergo treatment with other product candidates that we may develop, may also receive chemotherapy, radiation, and/or other high dose or myeloablative treatments in the course of treatment of their disease, and may therefore experience side effects or AEs, including death, that are unrelated to our product candidates. While these side effects or AEs may be unrelated to our product candidates, they may still affect the success of our clinical trials. The inclusion of critically ill patients in our clinical trials may also result in deaths or other adverse medical events due to underlying disease or to other therapies or medications that such patients may receive. Any of these events could prevent us from advancing our product candidates through clinical development, and from obtaining regulatory approval, and would impair our ability to commercialize our product candidates. Any inability to advance our product candidates through clinical development may harm our business, financial condition, results of operations and prospects.

We may in the future conduct clinical trials for product candidates outside the United States, and the FDA and comparable foreign regulatory authorities may not accept data from such trials.

We may in the future choose to conduct one or more clinical trials outside the United States, including in Europe. For instance, our clinical trials of BBP-831 and BBP-870 each included patients outside of the United States and our Phase 3 clinical trials of BBP-265 will include patients outside of the United States. The acceptance by the FDA or comparable foreign regulatory authority of study data from clinical trials conducted outside the United States or another jurisdiction may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; and (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction, including from our ongoing and planned Phase 3 clinical trials of BBP-265, for which we plan to enroll cohorts outside the United States. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan, and which may result in product candidates that we may develop not receiving approval or clearance for commercialization in the applicable jurisdiction.

Even if we obtain FDA approval for product candidates that we may identify and pursue in the United States, we may never obtain approval to commercialize any product candidates outside of the United States, which would limit our ability to realize their full market potential.

In order to market any products outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and effectiveness. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval processes vary among countries and can involve additional product testing and validation and additional or different administrative review periods from those in the United States, including additional preclinical studies or clinical trials, as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

Seeking foreign regulatory approval could result in difficulties and costs and require additional nonclinical studies or clinical trials which could be costly and time-consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our product candidates in those countries. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approval in international markets is delayed, our target market will be reduced and our ability to realize the full market potential of our products will be harmed.

Interim, "top-line," and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available or as additional analyses are conducted, and as the data are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim, "top-line," or preliminary data from our clinical studies. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or "top-line" data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Material adverse changes between preliminary, "top-line," or interim data and final data could significantly harm our business prospects.

Even though we may apply for orphan drug designation for our product candidates, we may not be able to obtain orphan drug marketing exclusivity.

Our business strategy focuses on the development of product candidates for the treatment of genetic diseases, which may be eligible for FDA or EMA orphan drug designation. Regulatory authorities in some jurisdictions, including the United States and European Union, may designate drugs or biologics for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually 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 order to obtain orphan drug designation, the request must be made before submitting an NDA or BLA. 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. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval of that particular product for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including an NDA or BLA, to market the same drug or biologic for the same indication for seven years, except in limited circumstances such as a showing of clinical superiority to the product with orphan drug exclusivity or if FDA finds that the holder of the orphan drug 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. As a result, even if one of our product candidates receives orphan exclusivity, the FDA can still approve other drugs or biologics for use in treating the same indication or disease or the same biologic for a different indication or disease during the exclusivity period. Furthermore, the FDA can waive orphan exclusivity if we are unable to manufacture sufficient supply of our product or if a subsequent applicant demonstrates clinical superiority over our product.

In the European Union, the Committee for Orphan Medicinal Products of the EMA grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the European Union (or where it is unlikely that the development of the medicine would generate sufficient return to justify the investment) and for which no satisfactory method of diagnosis, prevention, or treatment is authorized or, if a method exists, the product would be of significant benefit to those affected by the condition.

We have obtained from the FDA orphan drug designations for: BBP-009 for the treatment of nevoid basal cell carcinoma syndrome, or Gorlin syndrome; BBP-265 for the treatment of transthyretin amyloidosis; BBP-589 for the treatment of dystrophic epidermolysis bullosa; BBP-631 for the treatment of CAH 21OHD; BBP-870 for the treatment of molybdenum cofactor deficiency type A; BBP-551 for the treatment of Leber congenital amaurosis (LCA) due to inherited mutations in RPE65 or LRAT genes and for the treatment of retinitis pigmentosa; and infigratinib for the treatment of cholangiocarcinoma. We have obtained from the EMA orphan drug designation for: BBP-009 for the treatment of nevoid basal cell carcinoma syndrome (Gorlin syndrome); BBP-265 for the treatment of ATTR amyloidosis; BBP-589 for the treatment of epidermolysis bullosa; BBP-870 for the treatment of molybdenum cofactor deficiency type A; and BBP-551 for the treatment of of retinitis pigmentosa and for the treatment of Leber’s congenital amaurosis; and BBP-631 for the treatment of congenital adrenal hyperplasia. We may seek orphan drug designation for certain other of our product candidates. Even if we obtain orphan drug designation, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan designated indication and may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition, or if a subsequent applicant demonstrates clinical superiority over our products, if approved. In addition, although we may seek orphan drug designation for other product candidates, we may never receive such designations.

Certain of our product candidates, including our protein therapeutic and gene therapy product candidates, are novel, complex and difficult to manufacture. We could experience manufacturing problems that result in delays in our development or commercialization programs or otherwise harm our business.

The manufacturing processes our CMOs use to produce our product candidates, including our protein therapeutic and gene therapy product candidates, are complex, novel and have not been validated for commercial use. Several factors could cause production interruptions, including equipment malfunctions, facility contamination, raw material shortages or contamination, natural disasters, disruption in utility services, human error or disruptions in the operations of our suppliers.

Several of our small molecule product candidates are particularly complex and difficult to manufacture, in some cases due to the number of steps required, the process complexity and the toxicity of end or intermediate-stage products. Our protein therapeutic and gene therapy product candidates require processing steps that are more complex than those required for most small molecule drugs. Moreover, unlike small molecules, the physical and chemical properties of biologics such as ours generally cannot be fully characterized. As a result, assays of the finished product may not be sufficient to ensure that the product is consistent from lot-to-lot or will perform in the intended manner. Accordingly, our CMOs must employ multiple steps to control the manufacturing process to assure that the process is reproducible and the product candidate is made strictly and consistently in compliance with the process. Problems with the manufacturing process, even minor deviations from the normal process, could result in product defects or manufacturing failures that result in lot failures, product recalls, product liability claims or insufficient inventory to conduct clinical trials or supply commercial markets. We may encounter problems achieving adequate quantities and quality of clinical-grade materials that meet the FDA, the EMA or other applicable standards or specifications with consistent and acceptable production yields and costs.

In addition, the FDA, the EMA and other foreign regulatory authorities may require us to submit samples of any lot of any approved product together with the protocols showing the results of applicable tests at any time. Under some circumstances, the FDA, the EMA or other foreign regulatory authorities may require that we not distribute a lot until the agency authorizes its release. Slight deviations in the manufacturing process, including those affecting quality attributes and stability, may result in unacceptable changes in the product that could result in lot failures or product recalls. Lot failures or product recalls could cause us to delay product launches or clinical trials, which could be costly to us and otherwise harm our business, financial condition, results of operations and prospects.

Our CMOs also may encounter problems hiring and retaining the experienced scientific, quality assurance, quality-control and manufacturing personnel needed to operate our manufacturing processes, which could result in delays in production or difficulties in maintaining compliance with applicable regulatory requirements.

Any problems in our CMOs' manufacturing process or facilities could result in delays in planned clinical trials and increased costs, and could make us a less attractive collaborator for potential partners, including larger biotechnology companies and academic research institutions, which could limit access to additional attractive development programs. Problems in our manufacturing process could restrict our ability to meet potential future market demand for products.

Certain of our product candidates are based on a novel AAV, gene therapy technology with which there is limited clinical or regulatory experience to date, which makes it difficult to predict the time and cost of product candidate development and subsequently obtaining regulatory approval.

Certain of our product candidates are based on gene therapy technology and our future success depends on the successful development of this novel therapeutic approach. We cannot assure you that any development problems we or other gene therapy companies experience in the future related to gene therapy technology will not cause significant delays or unanticipated costs in the development of our product candidates, or that such development problems can be solved. In addition, the clinical study requirements of the FDA, EMA and other regulatory agencies and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of the potential products. The regulatory approval process for novel product candidates such as ours can be more expensive and take longer than for other, better known or extensively studied therapeutic modalities. Further, as we are developing novel treatments for diseases in which there is limited clinical experience with new endpoints and methodologies, there is heightened risk that the FDA, EMA or comparable foreign regulatory bodies may not consider the clinical trial endpoints to provide

clinically meaningful results, and the resulting clinical data and results may be more difficult to analyze. To date, few gene therapy products have been approved by the FDA or comparable foreign regulatory authorities, which makes it difficult to determine how long it will take or how much it will cost to obtain regulatory approvals for our product candidates in the United States, the European Union or other jurisdictions. Further, approvals by one regulatory agency may not be indicative of what other regulatory agencies may require for approval.

Regulatory requirements governing gene therapy products have evolved and may continue to change in the future. For example, the FDA established the Office of Tissues and Advanced Therapies within its Center for Biologics Evaluation and Research, or CBER, to consolidate the review of gene therapy and related products, and the Cellular, Tissue and Gene Therapies Advisory Committee to advise CBER on its review. These and other regulatory review agencies, committees and advisory groups and the requirements and guidelines they promulgate may lengthen the regulatory review process, require us to perform additional preclinical studies or clinical trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of these treatment candidates or lead to significant post-approval limitations or restrictions.

The FDA, National Institutes of Health, or NIH, other regulatory agencies at both the federal and state level in the United States, U.S. congressional committees, and the EMA and other foreign governments, have expressed interest in further regulating the biotechnology industry, including gene therapy and genetic testing. For example, the EMA advocates a risk-based approach to the development of a gene therapy product. Any such further regulation may delay or prevent commercialization of some or all of our product candidates. For example, in 1999, a patient died during a gene therapy clinical trial that utilized an adenovirus vector and it was later discovered that adenoviruses could generate an extreme immune system reaction that can be life-threatening. In January 2000, the FDA halted that trial and began investigating 69 other gene therapy trials underway in the United States, 13 of which required remedial action. In 2003, the FDA suspended 27 additional gene therapy trials involving several hundred patients after learning that some patients treated in a clinical trial in France had subsequently developed leukemia. While the new AAV vectors that we use across our portfolio of gene therapy product candidates have been designed and developed to help reduce these side effects, gene therapy is still a relatively new approach to disease treatment and past as well as different adverse side effects could develop.

Regulatory requirements in the United States and abroad governing gene therapy products have changed frequently and may continue to change in the future. For example, in addition to the submission of an IND, to the FDA, before initiation of a clinical trial in the United States, certain human clinical trials for cell therapy products and gene therapy had historically been subject to review by the NIH Office of Biotechnology Activities' Recombinant DNA Advisory Committee, or the RAC, pursuant to the NIH Guidelines for Research Involving Recombinant DNA Molecules, or NIH Guidelines. Following an initial review, RAC members would make a recommendation as to whether the protocol raises important scientific, safety, medical, ethical or social issues that warrant in-depth discussion at the RAC's quarterly meetings. Although the FDA decides whether individual gene therapy protocols may proceed under an IND, the RAC's recommendations were shared with the FDA and, the RAC public review process, if undertaken, could have impeded or delayed the initiation of a clinical trial, even if the FDA has reviewed the trial and approved its initiation or has notified the sponsor that the study may begin. Conversely, the FDA can put an IND on clinical hold even if the RAC provided a favorable review or has recommended against an in-depth, public review.

On August 17, 2018, the NIH issued a notice in the Federal Register and issued a public statement proposing changes to the oversight framework for gene therapy trials, including changes to the applicable NIH Guidelines to modify the roles and responsibilities of the RAC with respect to human clinical trials of gene therapy products, and requesting public comment on its proposed modifications. During the public comment period, which closed on October 16, 2018, the NIH had announced that it would no longer accept new human gene transfer protocols for review as part of the protocol registration process under the existing NIH Guidelines or convene the RAC to review individual clinical protocols. In April 2019, NIH announced the updated guidelines, which reflect these proposed changes, and clarify that these trials will remain subject to the FDA's oversight and other clinical trial regulations, and oversight at the local level will continue as otherwise set forth in the NIH Guidelines. Specifically, under the NIH Guidelines, supervision of human gene transfer trials includes evaluation and assessment by an IBC, a local institutional committee that reviews and oversees research utilizing recombinant or synthetic nucleic acid molecules at that institution. The IBC assesses the safety of the research and identifies any potential risk to the public health or

the environment, and such review may result in some delay before initiation of a clinical trial. While the NIH Guidelines are not mandatory unless the research in question is being conducted at or sponsored by institutions receiving NIH funding of recombinant or synthetic nucleic acid molecule research, many companies and other institutions not otherwise subject to the NIH Guidelines voluntarily follow them. Even though we may not be required to submit a protocol for our gene therapy product candidates through the NIH for RAC review, we will still be subject to significant regulatory oversight by the FDA, and in addition to the government regulators, the applicable IBC and IRB, of each institution at which we or our collaborators conduct clinical trials of our product candidates, or a central IRB if appropriate, would need to review and approve the proposed clinical trial.

Similarly, the EMA governs the development of gene therapies in the European Union and may issue new guidelines concerning the development and marketing authorization for gene therapy products and require that we comply with these new guidelines.

These regulatory review committees and advisory groups and the new guidelines they promulgate may lengthen the regulatory review process, require us to perform additional studies or trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post-approval limitations or restrictions. As we advance our product candidates, we will be required to consult with these regulatory and advisory groups and comply with applicable guidelines. If we fail to do so, we may be required to delay or discontinue development of such product candidates. These additional processes may result in a review and approval process that is longer than we otherwise would have expected. Delays as a result of an increased or lengthier regulatory approval process or further restrictions on the development of our product candidates can be costly and could negatively impact our ability to complete clinical trials and commercialize our current and future product candidates in a timely manner, if at all.

Our product candidates based on gene therapy technology may cause undesirable and unforeseen side effects or be perceived by the public as unsafe, which could delay or prevent their advancement into clinical trials or regulatory approval, limit the commercial potential or result in significant negative consequences.

Public attitudes may be influenced by claims that gene therapy technology is unsafe, unethical, or immoral, and, consequently, our product candidates may not gain the acceptance of the public or the medical community. Adverse public attitudes may adversely impact our ability to enroll clinical trials. Moreover, our success will depend upon physicians prescribing, and their patients being willing to receive, treatments that involve the use of product candidates we may develop in lieu of, or in addition to, existing treatments with which they are already familiar and for which greater clinical data may be available. For example, there have been several significant adverse side effects in prior clinical trials of gene therapy product candidates, including reported cases of leukemia and death seen in other trials using other vectors. While new AAV vectors have been developed to reduce these side effects, gene therapy is still a relatively new approach to disease treatment and additional adverse side effects could develop. There also is the potential risk of delayed AEs following exposure to gene therapy products due to persistent biologic activity of the genetic material or other components of products used to carry the genetic material.

Possible adverse side effects that could occur with treatment with gene therapy products include an immunologic reaction early after administration which could be detrimental to the patient’s health or substantially limit the effectiveness and durability of the treatment. For example, an increasingly anticipated side effect of AAV gene therapy is the development of a T-cell immunological response, most often seen affecting the liver.

The FDA has granted rare pediatric disease designation to BBP-870 for the treatment of molybdenum cofactor deficiency type A. However, a marketing application for BBP-870, if approved, may not meet the eligibility criteria for a priority review voucher.

The FDA has granted rare pediatric disease designation to BBP-870 for the treatment of molybdenum cofactor deficiency type A, or MoCD Type A. Designation of a drug as a drug for a rare pediatric disease does not guarantee that an NDA for such drug will meet the eligibility criteria for a rare pediatric disease priority review voucher at the time the application is approved. Under the Federal Food, Drugs, and Cosmetic Act, or FDCA, we will need to request a rare pediatric disease priority review voucher in our original NDA for BBP-870. The FDA may determine that an NDA for BBP-870, if approved, does not meet the eligibility criteria for a priority review voucher, including for the following reasons:

- MoCD Type A no longer meets the definition of a rare pediatric disease;
- the NDA contains an active ingredient (including any ester or salt of the active ingredient) that has been previously approved in an NDA;
- the NDA is not deemed eligible for priority review;
- the NDA does not rely on clinical data derived from studies examining a pediatric population and dosages of the drug intended for that population (that is, if the NDA does not contain sufficient clinical data to allow for adequate labeling for use by the full range of affected pediatric patients); or
- the NDA is approved for a different adult indication than the rare pediatric disease for which BBP-870 is designated (for example, if BBP-870 is approved for an indication based on specific genetic alterations that would be inclusive of, but not limited to, BBP-870).

The authority for the FDA to award rare pediatric disease priority review vouchers for drugs that have received rare pediatric disease designation prior to September 30, 2020 currently expires on September 30, 2022. If the NDA for BBP-870 is not approved prior to September 30, 2022 for any reason, regardless of whether it meets the criteria for a rare pediatric disease priority review voucher, it will not be eligible for a priority review voucher. However, it is also possible the authority for FDA to award rare pediatric disease priority review vouchers will be further extended through Federal lawmaking.

We may not elect or be able to take advantage of any expedited development or regulatory review and approval processes available to product candidates granted breakthrough therapy, fast track or regenerative medicine advanced therapy designation by the FDA.

We intend to evaluate and continue ongoing discussions with the FDA on regulatory strategies that could enable us to take advantage of expedited development pathways for certain of our product candidates, although we cannot be certain that our product candidates will qualify for any expedited development pathways or that regulatory authorities will grant, or allow us to maintain, the relevant qualifying designations. Potential expedited development pathways that we could pursue include breakthrough therapy, fast track designation and or regenerative medicine advanced therapy, or RMAT.

Breakthrough therapy designation is intended to expedite the development and review of product candidates that are designed to treat serious or life-threatening diseases when “preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development.” The designation of a product candidate as a breakthrough therapy provides potential benefits that include more frequent meetings with FDA to discuss the development plan for the product candidate and ensure collection of appropriate data needed to support approval; more frequent written correspondence from FDA about such things as the design of the proposed clinical trials and use of biomarkers; intensive guidance on an efficient drug development program, beginning as early as Phase 1; organizational commitment involving senior managers; and eligibility for rolling review and priority review.

Fast track designation is designed for product candidates intended for the treatment of a serious or life-threatening disease or condition, where nonclinical or clinical data demonstrate the potential to address an unmet medical need for this disease or condition.

We may seek RMAT designation for one or more of our product candidates. In 2017, the FDA established the RMAT designation as part of its implementation of the 21st Century Cures Act to expedite review of any drug that meets the following criteria: it qualifies as a RMAT, which is defined as a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or any combination product using such therapies or products, with limited exceptions; it is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such a disease or condition. Like breakthrough therapy designation, RMAT designation provides potential benefits that include more frequent meetings with FDA to discuss the development plan for the product candidate, and eligibility for rolling review and priority review. Products granted RMAT designation may also be eligible for accelerated approval on the basis of a surrogate or intermediate endpoint reasonably likely to predict long-term clinical benefit, or reliance upon data obtained from a meaningful number of sites, including through expansion to additional sites. RMAT-designated products that receive accelerated approval may, as appropriate, fulfill their post-approval requirements through the submission of clinical evidence, clinical trials, patient registries, or other sources of real world evidence, such as electronic health records; through the collection of larger confirmatory data sets; or via post-approval monitoring of all patients treated with such therapy prior to approval of the therapy.

Although BBP-589 has received fast track designation for the treatment of dystrophic epidermolysis bullosa, or DEB, BBP-870 has received breakthrough therapy designation for MoCD, BBP-009 has received breakthrough therapy designation for the reduction of life-long, serious clinical morbidity and disease burden of persistently developing BCCs in patients with basal cell nevus syndrome, or BCNS, which is also known as Gorlin Syndrome, infigratinib has received fast track designation for the first-line treatment of adult patients with unresectable locally advanced or metastatic cholangiocarcinoma with FGFR2 gene fusions or translocations, and BBP-551 has received fast track designation for the treatment of LCA due to inherited mutations in LRAT and RPE65 genes and for the treatment of autosomal recessive RP due to inherited mutations in LRAT and RPE genes, we may elect not to pursue any of breakthrough therapy, fast track or RMAT designations for our other product candidates, and the FDA has broad discretion whether or not to grant these designations.

Accordingly, even if we believe a particular product candidate is eligible for breakthrough therapy, fast track designation or RMAT, we cannot assure you that the FDA would decide to grant it. Breakthrough therapy designation, fast track and RMAT designation do not change the standards for product approval, and there is no assurance that such designation or eligibility will result in expedited review or approval or that the approved indication will not be narrower than the indication covered by the breakthrough therapy, fast track or RMAT designation. Thus, even if we do receive breakthrough therapy, fast track or RMAT designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw breakthrough therapy, fast track or RMAT designation if it believes that the product no longer meets the qualifying criteria. Our business may be harmed if we are unable to avail ourselves of these or any other expedited development and regulatory pathways.

If we are unable to successfully validate, develop and obtain regulatory approval for companion diagnostic tests for our drug candidates that require or would commercially benefit from such tests, or experience significant delays in doing so, we may not realize the full commercial potential of these drug candidates.

In connection with the clinical development of our drug candidates for certain indications, we may work with collaborators to develop or obtain access to *in vitro* companion diagnostic tests to identify patient subsets within a disease category who may derive selective and meaningful benefit from our drug candidates. For example, we are currently developing a companion diagnostic for BBP-831 in patients with CCA in collaboration with Foundation Medicine, or FMI. Such companion diagnostics would be used during our clinical trials as well as in connection with the commercialization of our product candidates. To be successful, we or our collaborators will need to address a number of scientific, technical, regulatory and logistical challenges. The FDA and comparable foreign regulatory authorities regulate *in vitro* companion diagnostics as medical devices and, under that regulatory framework, will likely require the conduct of clinical trials to demonstrate the safety and effectiveness of any diagnostics we may develop, which we expect will require separate regulatory clearance or approval prior to commercialization.

We may rely on third parties for the design, development and manufacture of companion diagnostic tests for our therapeutic drug candidates that may require such tests. If we enter into such collaborative agreements, we will be dependent on the sustained cooperation and effort of our future collaborators in developing and obtaining approval for these companion diagnostics. It may be necessary to resolve issues such as selectivity/specificity, analytical validation, reproducibility, or clinical validation of companion diagnostics during the development and regulatory approval processes. Moreover, even if data from preclinical studies and early clinical trials appear to support development of a companion diagnostic for a product candidate, data generated in later clinical trials may fail to support the analytical and clinical validation of the companion diagnostic. We and our future collaborators may encounter difficulties in developing, obtaining regulatory approval for, manufacturing and commercializing companion diagnostics similar to those we face with respect to our therapeutic candidates themselves, including issues with achieving regulatory clearance or approval, production of sufficient quantities at commercial scale and with appropriate quality standards, and in gaining market acceptance. If we are unable to successfully develop companion diagnostics for these therapeutic drug candidates, or experience delays in doing so, the development of these therapeutic drug candidates may be adversely affected, these therapeutic drug candidates may not obtain marketing approval, and we may not realize the full commercial potential of any of these therapeutics that obtain marketing approval. As a result, our business, results of operations and financial condition could be materially harmed. In addition, a diagnostic company with whom we contract may decide to discontinue selling or manufacturing the companion diagnostic test that we anticipate using in connection with development and commercialization of our product candidates or our relationship with such diagnostic company may otherwise terminate. We may not be able to enter into arrangements with another diagnostic company to obtain supplies of an alternative diagnostic test for use in connection with the development and commercialization of our product candidates or do so on commercially reasonable terms, which could adversely affect and/or delay the development or commercialization of our therapeutic candidates.

If approved, our investigational products regulated as biologics may face competition from biosimilars approved through an abbreviated regulatory pathway.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity, and potency of the other company's product. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty.

We believe that any of our product candidates approved as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our investigational medicines to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, once licensed, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

If competitors are able to obtain marketing approval for biosimilars referencing our products, our products may become subject to competition from such biosimilars, with the attendant competitive pressure and consequences.

Even if we obtain regulatory approval for a product candidate, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

If any of our product candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies, and submission of safety, efficacy, and other post-market 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 comply with extensive requirements imposed by the FDA and comparable foreign regulatory authorities, including ensuring that quality control and manufacturing procedures conform to current good manufacturing practices, or cGMP, regulations. As such, we and our CMOs will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any NDA, BLA or marketing authorization application, or MAA. Accordingly, we and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

Any regulatory approvals that we may receive for our product candidates will be subject to limitations on the approved indicated uses for which the product may be marketed and promoted 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.

The FDA and other agencies, including the Department of Justice, closely regulate and monitor the post-approval marketing, labeling, advertising and promotion of products to ensure that they are manufactured, marketed and distributed only for the approved indications and in accordance with the provisions of the approved label. We will have to comply with requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label. As such, we may not promote our products for indications or uses for which they do not have approval.

The holder of an approved NDA, BLA or MAA must submit new or supplemental applications and obtain approval for certain changes to the approved product, product labeling, or manufacturing process. We could also be asked to conduct post-marketing clinical trials to verify the safety and efficacy of our products in general or in specific patient subsets. If original marketing approval was obtained via the accelerated approval pathway, we could be required to conduct a successful post-marketing clinical trial to confirm 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 AEs 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, such 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 that would result in adverse publicity;
- impose civil or criminal penalties;
- suspend or withdraw regulatory approvals;
- suspend any of our ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications submitted by us;
- impose restrictions on our operations, including closing our CMOs' facilities;
- seize or detain products; or
- require a product recall.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response, and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected. The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. For example, certain policies of the Trump administration may impact our business and industry. Namely, the Trump administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. If these executive actions impose constraints on FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.

If any of our product candidates are approved and we are found to have improperly promoted off-label uses of those products, we may become subject to significant liability. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, if approved. In particular, while FDA permits the dissemination of truthful and non-misleading information about an approved product, a manufacturer may not promote a product for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. If we are found to have promoted such off-label uses, we may become subject to significant liability. The federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees, corporate integrity agreements or permanent injunctions under which specified promotional conduct must be changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

Risks Related to Reliance on Third Parties

We expect to rely on third parties to conduct our clinical trials and some aspects of our research and preclinical testing, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research, or testing.

We currently rely and expect to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions, and clinical investigators, to conduct some aspects of research and preclinical testing and clinical trials. Any of these third parties may terminate their engagements with us or be unable to fulfill their contractual obligations. If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative third parties on commercially reasonable terms, or at all. If we need to enter into alternative arrangements, it would delay product development activities.

Our reliance on these third parties for research and development activities reduces control over these activities but does not relieve us of our responsibilities. For example, we remain responsible for ensuring that each of our respective clinical trials is conducted in accordance with the general investigational plan and protocols for the trial and applicable legal, regulatory, and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. In addition, the FDA and comparable foreign regulatory authorities require compliance with GCPs for conducting, recording, and reporting the results of clinical trials to assure that data and reported results are credible, reproducible and accurate and that the rights, integrity, and confidentiality of trial participants are protected. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators, and trial sites. If we or any of these third parties fail to comply with applicable GCP regulations, some or all of the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional nonclinical or clinical trials or to enroll additional patients before approving our marketing applications. We cannot be certain that, upon inspection, such regulatory authorities will determine that any of our clinical trials complies with the GCP regulations. For any violations of laws and regulations during the conduct of clinical trials, we could be subject to untitled and warning letters or enforcement action that may include civil penalties up to and including criminal prosecution. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database within certain timeframes. Failure to do so can result in fines, adverse publicity, and civil and criminal sanctions.

If these third parties do not successfully carry out their contractual duties, meet expected deadlines, or conduct clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for any product candidates we may develop and will not be able to, or may be delayed in our efforts to, successfully commercialize our medicines. Our failure or the failure of these third parties to comply applicable regulatory requirements or our stated protocols could also subject us to enforcement action.

We also expect to rely on other third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of any product candidates we may develop or commercialization of our medicines, producing additional losses and depriving us of potential product revenue.

We rely entirely on third parties for the manufacturing of our product candidates or other product candidates that we may develop for preclinical studies and clinical trials and expect to continue to do so for commercialization. Our business could be harmed if those third parties fail to provide us with sufficient quantities of drug product, or fail to do so at acceptable quality levels or prices.

We do not currently have, nor do we plan to acquire, the infrastructure or capability internally to manufacture drug supplies for our ongoing clinical trials or any future clinical trials that we may conduct, and we lack the resources to manufacture any product candidates on a commercial scale. We rely, and expect to continue to rely, on third-party manufacturers to produce our current product candidates or other product candidates that we may identify for clinical trials, as well as for commercial manufacture if any product candidates that receive marketing approval. Although we generally do not begin a clinical trial unless we believe we have a sufficient supply of a product candidate to complete the trial, any significant delay or discontinuity in the supply of a product candidate, or the raw material components thereof, for an ongoing clinical trial due to the need to replace a third-party manufacturer could considerably delay the clinical development and potential regulatory approval of our product candidates, which could harm our business and results of operations. We also expect to rely primarily on third parties for the manufacturing of commercial supply of our product candidates, if approved.

We may be unable to identify and appropriately qualify third-party manufacturers or establish agreements with third-party manufacturers or do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- reliance on the third party for sourcing of raw materials, components, and such other goods as may be required for execution of its manufacturing processes and the oversight by the third party of its suppliers;
- reliance on the third party for regulatory compliance and quality assurance for the manufacturing activities each performs;
- the possible breach of the manufacturing agreement by the third party;
- the possible misappropriation of proprietary information, including trade secrets and know-how; and
- the possible termination or non-renewal of the agreement by the third party at a time that is costly or inconvenient for us.

Furthermore, all of our CMOs are engaged with other companies to supply and/or manufacture materials or products for such companies, which exposes our manufacturers to regulatory risks for the production of such materials and products. The facilities used by our contract manufacturers to manufacture our product candidates are subject to review by the FDA pursuant to inspections that will be conducted after we submit an NDA or BLA to the FDA. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with the regulatory requirements, known as current good manufacturing practice, or cGMP, requirements for manufacture of drug and biologic products. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, we will not be able to secure or maintain regulatory approval for our product candidates manufactured at these manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory agency does not approve these facilities for the manufacture of our product candidates or if any agency withdraws its approval in the future, we may need to find alternative manufacturing facilities, which would negatively impact the ability to develop, obtain regulatory approval for or market our product candidates, if approved.

Our product candidates may compete with other product candidates and marketed drugs for access to manufacturing facilities. Any performance failure on the part of our existing or future manufacturers could delay clinical development, marketing approval or commercialization. Our current and anticipated future dependence upon others for the manufacturing of our product candidates may adversely affect our future profit margins and our ability to commercialize any product candidates that receive marketing approval on a timely and competitive basis.

The drug substance and drug product for certain of our product candidates are currently acquired from single-source suppliers. The loss of these suppliers, or their failure to supply us with the drug substance or drug product, could materially and adversely affect our business.

The drug substance and drug product for certain of our product candidates, including Veratrum californicum, or corn lily, from which we obtain cyclopamine for BBP-009, are grown or manufactured by single-source suppliers or CMOs under development and manufacturing contracts and services and quality agreements and purchase orders. We do not currently have any other suppliers for the drug substance or drug product of these product candidates and, although we believe that there are alternate sources of supply that could satisfy our clinical and commercial requirements, we cannot assure you that identifying alternate sources and establishing relationships with such sources would not result in significant delay in the development of our product candidates.

Our dependence on single-source suppliers exposes us to certain risks, including the following:

- our suppliers may cease or reduce production or deliveries, raise prices or renegotiate terms;
- delays caused by supply issues may harm our reputation; and
- our ability to progress our business could be materially and adversely impacted if our single-source suppliers upon which we rely were to experience a significant business challenges, disruption or failures due to issues such as financial difficulties or bankruptcy, issues relating regulatory or quality compliance issues, or other legal or reputational issues.

Additionally, we may not be able to enter into supply arrangements with alternative suppliers on commercially reasonable terms, or at all. A delay in the development of our product candidates or having to enter into a new agreement with a different third party on less favorable terms than we have with our current suppliers could have a material adverse impact upon on our business.

If the contract manufacturing facilities on which we rely do not continue to meet regulatory requirements or are unable to meet our supply demands, our business will be harmed.

All entities involved in the preparation of product candidates for clinical trials or commercial sale, including our existing CMOs for all of our product candidates, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical trials must be manufactured in accordance with cGMP, or similar regulatory requirements outside the United States. These regulations govern manufacturing processes and procedures, including recordkeeping, and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of contaminants or to inadvertent changes in the properties or stability of our product candidates. Our failure, or the failure of third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, suspension of production, seizures or recalls of product candidates or marketed drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect clinical or commercial supplies of our product candidates.

We or our CMOs must supply all necessary documentation in support of an NDA, BLA or MAA on a timely basis and must adhere to regulations enforced by the FDA and other regulatory agencies through their facilities inspection program. Some of our CMOs have never produced a commercially approved pharmaceutical product and therefore have not obtained the requisite regulatory authority approvals to do so. The facilities and quality systems of some or all of our third-party contractors must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our product candidates or any of our other potential products. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our product candidates or our other potential products or the associated quality systems for compliance with the regulations applicable to the activities being conducted. Although we oversee the CMOs, we cannot control the manufacturing process of, and are completely dependent on, our CMO partners for compliance with the regulatory requirements. If these facilities do not pass a pre-approval plant inspection, regulatory approval of the products may not be granted or may be substantially delayed until any violations are corrected to the satisfaction of the regulatory authority, if ever.

The regulatory authorities also may, at any time following approval of a product for sale, audit the manufacturing facilities of our third-party contractors. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and/or time consuming for us or a third party to implement, and that may include the temporary or permanent suspension of a clinical study or commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business.

Additionally, if supply from one approved manufacturer is interrupted, an alternative manufacturer would need to be qualified through an NDA, BLA supplement or MAA variation, or equivalent foreign regulatory filing, which could result in further delay. The regulatory agencies may also require additional studies if a new manufacturer is relied upon for commercial production. Switching manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines.

These factors could cause us to incur higher costs and could cause the delay or termination of clinical trials, regulatory submissions, required approvals, or commercialization of our product candidates. Furthermore, if our suppliers fail to meet contractual requirements and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical trials may be delayed or we could lose potential revenue.

Collaborative relationships with third parties could cause us to expend significant resources and incur substantial business risk with no assurance of financial return.

We anticipate relying upon strategic collaborations for marketing and commercializing our existing product candidates, and we may rely even more on strategic collaborations for R&D of other product candidates. We may sell product offerings through strategic partnerships with pharmaceutical and biotechnology companies.

If we enter into R&D collaborations during the early phases of product development, success will in part depend on the performance of research collaborators. We will not directly control the amount or timing of resources devoted by research collaborators to activities related to product candidates. Research collaborators may not commit sufficient resources to our R&D programs. If any research collaborator fails to commit sufficient resources, the preclinical or clinical development programs related to the collaboration could be delayed or terminated. Also, collaborators may pursue existing or other development-stage products or alternative technologies in preference to those being developed in collaboration with us. Finally, if we fail to make required milestone or royalty payments to collaborators or to observe other obligations in agreements with them, the collaborators may have the right to terminate or stop performance of those agreements.

Establishing strategic collaborations is difficult and time-consuming. Our discussions with potential collaborators may not lead to the establishment of collaborations on favorable terms, if at all. Potential collaborators may reject collaborations based upon their assessment of our financial, regulatory or intellectual property position. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. Even if we successfully establish new collaborations, these relationships may never result in the successful development or commercialization of product candidates or the generation of sales revenue. To the extent that we enter into collaborative arrangements, the related product revenues are likely to be lower than if we directly marketed and sold products. Such collaborators may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for any future product candidate.

Management of our relationships with collaborators will require:

- significant time and effort from our management team;
- coordination of our marketing and R&D programs with the marketing and R&D priorities of our collaborators; and
- effective allocation of our resources to multiple projects.

If we are unable to establish or maintain such strategic collaborations on terms favorable to us in the future, our R&D efforts and potential to generate revenue may be limited.

We are parties to and may seek to enter into additional collaborations, licenses and other similar arrangements and may not be successful in maintaining existing arrangements or entering into new ones, and even if we are, we may not realize the benefits of such relationships.

The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborations are subject to numerous risks, which may include risks that:

- collaborators may have significant discretion in determining the efforts and resources that they will apply to collaborations;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in their strategic focus due to their acquisition of competitive products or their internal development of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;

- collaborators may delay clinical trials, provide insufficient funding for a development program, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates;
- a collaborator with marketing, manufacturing and distribution rights to one or more products may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our current or future product candidates or that results in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated, which may result in a need for additional capital to pursue further development or commercialization of the applicable current or future product candidates;
- collaborators may own or co-own intellectual property covering products that result from our collaboration with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property;
- disputes may arise with respect to the ownership of any intellectual property developed pursuant to our collaborations; and
- a collaborator's sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings.

Additionally, we may seek to enter into additional collaborations, joint ventures, licenses and other similar arrangements for the development or commercialization of our product candidates, due to capital costs required to develop or commercialize the product candidate or manufacturing constraints. We may not be successful in our efforts to establish such collaborations for our product candidates because our research and development pipeline may be insufficient, our product candidates may be deemed to be at too early of a stage of development for collaborative effort or third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy or significant commercial opportunity. In addition, we face significant competition in seeking appropriate strategic partners, and the negotiation process can be time consuming and complex. Further, any future collaboration agreements may restrict us from entering into additional agreements with potential collaborators. We cannot be certain that, following a strategic transaction or license, we will achieve an economic benefit that justifies such transaction.

Even if we are successful in our efforts to establish such collaborations, the terms that we agree upon may not be favorable to us, and we may not be able to maintain such collaborations if, for example, development or approval of a product candidate is delayed, the safety of a product candidate is questioned or sales of an approved product candidate are unsatisfactory.

In addition, any potential future collaborations may be terminable by our strategic partners, and we may not be able to adequately protect our rights under these agreements. Furthermore, strategic partners may negotiate for certain rights to control decisions regarding the development and commercialization of our product candidates, if approved, and may not conduct those activities in the same manner as we do. Any termination of collaborations we enter into in the future, or any delay in entering into collaborations related to our product candidates, could delay the development and commercialization of our product candidates and reduce their competitiveness if they reach the market, which could have a material adverse effect on our business, financial condition and results of operations.

Risks Related to our Intellectual Property

If we are unable to obtain and maintain sufficient intellectual property protection for BBP-265, BBP-831, BBP-454, BBP-631 or other product candidates that we may identify, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize product candidates similar or identical to ours, and our ability to successfully commercialize BBP-265, BBP-831, BBP-454, BBP-631 and other product candidates that we may pursue may be impaired.

As is the case with other pharmaceutical and biopharmaceutical companies, our success depends in large part on our ability to obtain and maintain protection of the intellectual property we may own solely and jointly with others, particularly patents, in the United States and other countries with respect to our product candidates and technology. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to BBP-265, BBP-831, BBP-454, BBP-631 or other product candidates that we may identify.

Obtaining and enforcing pharmaceutical and biopharmaceutical patents is costly, time consuming and complex, and we may not be able to file and prosecute all necessary or desirable patent applications, or maintain, enforce and license any patents that may issue from such 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. We may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the rights to patents licensed to third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal, technological and factual questions and has in recent years been the subject of much litigation. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States, or vice versa. Further, we may not be aware of all third-party intellectual property rights potentially relating to our product candidates. 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. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. Furthermore, the scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history and can involve other factors such as expert opinion. Our analysis of these issues, including interpreting the relevance or the scope of claims in a patent or a pending application, determining applicability of such claims to our proprietary technologies or product candidates, predicting whether a third party's pending patent application will issue with claims of relevant scope, and determining the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our product candidates. We do not always conduct independent reviews of pending patent applications of and patents issued to third parties. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued that protect our product candidates, in whole or in part, or which effectively prevent others from commercializing competitive product candidates. Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our patents by developing similar or alternative product candidates in a non-infringing manner.

Our ability to enforce patent rights also depends on our ability to detect infringement. It may be difficult to detect infringers who do not advertise the components or methods that are used in connection with their products and services. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor's or potential competitor's product or service. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded if we were to prevail may not be commercially meaningful. If we initiate lawsuits to protect or enforce our patents, or litigate against third-party claims, such proceedings would be expensive and would divert the attention of our management and technical personnel. Such proceedings could also provoke third parties to assert claims against us, including that some or all of the claims in one or more of our patents are invalid or otherwise unenforceable.

Moreover, we may be subject to a third-party preissuance submission of prior art to the United States Patent and Trademark Office, or the USPTO, or become involved in opposition, derivation, reexamination, inter partes review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize drugs without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

In addition, the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical product candidates to ours, or limit the duration of the patent protection of our product candidates. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing drugs similar or identical to ours.

Furthermore, our intellectual property rights may be subject to a reservation of rights by one or more third parties. For example, the research resulting in certain of our patent rights and technology was funded in part by the U.S. government. As a result, the government has certain rights, including march-in rights, to such patent rights and technology. When new technologies are developed with government funding, the government generally obtains certain rights in any resulting patents, including a non-exclusive license authorizing the government to use the invention or to have others use the invention on its behalf. These rights may permit the government to disclose our information to third parties and to exercise march-in rights to use or allow third parties to use our technology. The government can exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to U.S. industry. In addition, our rights in such inventions may be subject to certain requirements to manufacture products embodying such inventions in the United States. Any exercise by the government of such rights or by any third party of its reserved rights could harm our competitive position, business, financial condition, results of operations, and prospects.

Our rights to develop and commercialize our product candidates are subject in part to the terms and conditions of licenses granted to us by others, and the patent protection, prosecution and enforcement for some of our product candidates may be dependent on our licensors.

We currently are reliant upon licenses of certain intellectual property rights and proprietary technology from third parties that are important or necessary to the development of our proprietary technology, including technology related to our product candidates. These licenses, and other licenses we may enter into in the future, may not provide adequate rights to use such intellectual property rights and proprietary technology in all relevant fields of use or in all territories in which we may wish to develop or commercialize technology and product candidates in the future. Licenses to additional third-party proprietary technology or intellectual property rights that may be required for our development programs may not be available in the future or may not be available on commercially reasonable terms. In that event, we may be required to expend significant time and resources to redesign our proprietary technology or product candidates or to develop or license replacement technology, which may not be feasible on a technical or commercial basis. If we are unable to do so, we may not be able to develop and commercialize technology and product candidates in fields of use and territories for which we are not granted rights pursuant to such licenses, which could harm our competitive position, business, financial condition, results of operations and prospects significantly.

In some circumstances, we may not have the right to control the preparation, filing, prosecution and enforcement of patent applications, or to maintain the patents, covering technology that we license from third parties. In addition, some of our agreements with our licensors require us to obtain consent from the licensor before we can enforce patent rights, and our licensor may withhold such consent or may not provide it on a timely basis. Therefore, we cannot be certain that our licensors or collaborators will prosecute, maintain, enforce and defend such intellectual property rights in a manner consistent with the best interests of our business, including by taking reasonable measures to protect the confidentiality of know-how and trade secrets, or by paying all applicable

prosecution and maintenance fees related to intellectual property registrations for any of our product candidates. We also cannot be certain that our licensors have drafted or prosecuted the patents and patent applications licensed to us in compliance with applicable laws and regulations, which may affect the validity and enforceability of such patents or any patents that may issue from such applications. This could cause us to lose rights in any applicable intellectual property that we in-license, and as a result our ability to develop and commercialize product candidates may be adversely affected and we may be unable to prevent competitors from making, using and selling competing products.

In addition, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing or otherwise violating the licensor's rights. In addition, while we cannot currently determine the amount of the royalty obligations we would be required to pay on sales of future products, if any, the amounts may be significant. The amount of our future royalty obligations will depend on the technology and intellectual property we use in product candidates that we successfully develop and commercialize, if any. Therefore, even if we successfully develop and commercialize product candidates, we may be unable to achieve or maintain profitability. In addition, we may seek to obtain additional licenses from our licensors and, in connection with obtaining such licenses, we may agree to amend our existing licenses in a manner that may be more favorable to the licensors, including by agreeing to terms that could enable third parties (potentially including our competitors) to receive licenses to a portion of the intellectual property rights that are subject to our existing licenses. Any of these events could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

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

We are party to various agreements that we depend on to operate our business, and our rights to use currently licensed intellectual property, or intellectual property to be licensed in the future, are or will be subject to the continuation of and our compliance with the terms of these agreements. For example, we are a party to an exclusive license agreement with the Board of Trustees of the Leland Stanford Junior University, or Stanford, and may need to obtain additional licenses from others to advance our research and development activities to allow the commercialization of BBP-265 or any other product candidates we may identify and pursue. Our license agreement with Stanford imposes, and we expect that future license agreements will impose, various development, diligence, commercialization, and other obligations on us. For example, under our license agreement with Stanford, we are required to use commercially reasonable efforts to engage in various development and commercialization activities with respect to licensed products, and must satisfy specified milestone and royalty payment obligations. We are also a party to a license agreement with Novartis International Pharmaceutical Ltd. for BBP-831 under which we are required to use commercially reasonable efforts to develop BBP-831, and to obtain regulatory approval for and commercialize at least one therapeutic product incorporating BBP-831 in the United States and the European Union.

In spite of our efforts, our licensors might conclude that we have materially breached our obligations under such license agreements and might therefore terminate the license agreements, thereby removing or limiting our ability to develop and commercialize products and technology covered by these license agreements. For example, if our license agreement with Stanford is terminated, competitors or other third parties would have the freedom to seek regulatory approval of, and to market, products identical to BBP-265 and we may be required to cease our development and commercialization of BBP-265. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

Moreover, disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our product candidates, technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;

- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, certain provisions in our license agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

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. However, our research, development and commercialization activities may be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions and inter partes 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 pursuing development candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that BBP-265, BBP-831, BBP-454, BBP-631 or other product candidates that we may identify may be subject to claims of infringement of the patent rights of third parties.

Other third parties may assert that we are employing their proprietary technology without authorization. There may be other 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 BBP-265, BBP-831, BBP-454, BBP-631 or other product candidates that we may identify. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that BBP-265, BBP-831, BBP-454, BBP-631 or other product candidates that we may identify may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of BBP-265, BBP-831, BBP-454, BBP-631 or other product candidates that we may identify, 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.

Similarly, if any third-party patents, including any patents that may issue from the ‘257 application, were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy, the holders of any such patents may be able to block our ability to develop and commercialize the applicable product candidate unless we obtained a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all, or it may be non-exclusive, which could result in our competitors gaining access to the same intellectual property.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize BBP-265, BBP-831, BBP-454, BBP-631 or other product candidates that we may identify. 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.

Parties making claims against us may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have material adverse effect on ability to raise additional funds or otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

Patent terms may be inadequate to protect our competitive position on product candidates for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional or international patent application filing date. Various extensions may be available, but 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, we may be open to competition from competitive products, including generics or biosimilars. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

If we are not able to obtain patent term extension or non-patent exclusivity in the United States under the Hatch-Waxman Act and in foreign countries under similar legislation, thereby potentially extending the marketing exclusivity term of our product candidates, our business may be materially harmed.

Depending upon the timing, duration and specifics of FDA marketing approval of our product candidates, one of the U.S. patents covering each of such product candidates or the use thereof may be eligible for up to five years of patent term extension under the Hatch-Waxman Act. The Hatch-Waxman Act allows a maximum of one patent to be extended per FDA approved product as compensation for the patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. Patent term extension also may be available in certain foreign countries upon regulatory approval of our product candidates. Nevertheless, we may not be granted patent term extension either in the United States or in any foreign country because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the term of extension, as well as the scope of patent protection during any such extension, afforded by the governmental authority could be less than we request.

If we are unable to obtain patent term extension or restoration, or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our product may be shortened and our competitors may obtain approval of competing products following our patent expiration sooner, and our revenue could be reduced, possibly materially.

It is possible that we will not obtain patent term extension under the Hatch-Waxman Act for a U.S. patent covering a product candidate even where that patent is eligible for patent term extension, or if we obtain such an extension, it may be for a shorter period than we had sought. Further, for certain of our licensed patents, we do not have the right to control prosecution, including filing with the USPTO, a petition for patent term extension under the Hatch-Waxman Act. Thus, if one of our licensed patents is eligible for patent term extension under the Hatch-Waxman Act, we may not be able to control whether a petition to obtain a patent term extension is filed, or obtained, from the USPTO.

Also, there are detailed rules and requirements regarding the patents that may be submitted to the FDA for listing in the Approved Drug Products with Therapeutic Equivalence Evaluations, or the Orange Book. We may be unable to obtain patents covering our product candidates that contain one or more claims that satisfy the requirements for listing in the Orange Book. Even if we submit a patent for listing in the Orange Book, the FDA may decline to list the patent, or a manufacturer of generic drugs may challenge the listing. If one of product candidates is approved and a patent covering that product candidate is not listed in the Orange Book, a manufacturer of generic drugs would not have to provide advance notice to us of any abbreviated new drug application, or ANDA, filed with the FDA to obtain permission to sell a generic version of such product candidate.

If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be materially adversely affected and our business would be harmed.

We seek to protect our confidential proprietary information, in part, by confidentiality agreements and invention assignment agreements with our employees, consultants, scientific advisors, contractors and collaborators. These agreements are designed to protect our proprietary information. However, we cannot be certain that such agreements have been entered into with all relevant parties, and we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. For example, any of these parties may breach the agreements and disclose proprietary information, including trade secrets, and we may not be able to obtain adequate remedies for such breaches. We also seek to preserve the integrity and confidentiality of our confidential proprietary information by maintaining physical security of our premises and physical and electronic security of our information technology systems, but it is possible that these security measures could be breached. If any of our confidential proprietary information were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position.

Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our products that we consider proprietary. We may not be able to obtain adequate remedies in the event of such unauthorized use. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Trade secrets will also over time be disseminated within the industry through independent development, the publication of journal articles and the movement of personnel skilled in the art from company to company or academic to industry scientific positions. Though our agreements with third parties typically restrict the ability of our advisors, employees, collaborators, licensors, suppliers, third-party contractors and consultants to publish data potentially relating to our trade secrets, our agreements may contain certain limited publication rights. In addition, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position. Despite employing the contractual and other security precautions described above, the need to share trade secrets increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. If any of these events occurs or if we otherwise lose protection for our trade secrets, the value of this information may be greatly reduced and our competitive position, business, financial condition, results of operations, and prospects would be harmed.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential collaborators or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. We may license our trademarks and trade names to third

parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names. Our efforts to enforce or protect our proprietary rights related to trademarks, trade names, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our competitive position, business, financial condition, results of operations and prospects.

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

Competitors may infringe our patents or other intellectual property. If we were to initiate legal proceedings against a third party to enforce a patent covering one or more 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 novelty, nonobviousness, written description or 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 or derivation 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. 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 or at all, or if a non-exclusive license is offered and our competitors gain access to the same technology. Our defense of litigation or interference or derivation 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 clinical trials, continue research programs, license necessary technology from third parties, or enter into development partnerships that would help us bring 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 challenging the inventorship of our patents and other intellectual property.

Our agreements with employees and our personnel policies provide that any inventions conceived by an individual in the course of rendering services to us shall be our exclusive property. Although our policy is to have all such individuals complete these agreements, we may not obtain these agreements in all circumstances, and individuals with whom we have these agreements may not comply with their terms. The assignment of intellectual property may not be automatic upon the creation of an invention and despite such agreement, such inventions may become assigned to third parties. In the event of unauthorized use or disclosure of our trade secrets or proprietary information, these agreements, even if obtained, may not provide meaningful protection, particularly for our trade secrets or other confidential information.

We or our licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in-licensed patents, trade secrets, or other intellectual property as an inventor or co-inventor. For example, we or our licensors may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or our or our licensors' ownership of our owned or in-licensed patents, trade secrets or other intellectual property. If we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our product candidates. 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.

Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

Issued patents covering our product candidates could be found invalid or unenforceable if challenged in court.

If we or one of our licensing partners initiated legal proceedings against a third party to enforce a patent covering one or more of our product candidates, the defendant could counterclaim that the patent covering the relevant 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 novelty, nonobviousness, written description or 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. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Such a loss of patent protection would have a material adverse impact on our business.

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

As is common in the biotechnology and pharmaceutical industry, we employ individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and independent contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of any of our employee's former employer or other third parties. 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.

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

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and/or applications. We have systems in place to remind us to pay these fees, and we employ an outside firm and rely on outside counsel to pay these fees due to non-U.S. patent agencies. However, we cannot guarantee that our licensors have similar systems and procedures in place to pay such fees. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market and this circumstance would have a material adverse effect on our business.

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

Filing, prosecuting and defending patents on our 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. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. 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 and pharmaceutical 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.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to a patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith America Invents Act, or the America Invents Act, enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013, but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our licensors were the first to either (i) file any patent application related to our product candidates or (ii) invent any of the inventions claimed in our or our licensor’s patents or patent applications.

The America Invents Act also includes a number of significant changes that affect the way patent applications are prosecuted and also may affect patent litigation. These include allowing third party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, inter partes review, and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Therefore, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our owned or in-licensed patent applications and the enforcement or defense of our owned or in-licensed issued patents, all of which could have a material adverse effect on our competitive position, business, financial condition, results of operations, and prospects.

In addition, the patent positions of companies in the development and commercialization of pharmaceuticals are particularly uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on future actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future.

Risks Related to Commercialization

Even if any product candidates we develop receive marketing approval, they may fail to achieve the degree of market acceptance by physicians, patients, healthcare payors, and others in the medical community necessary for commercial success.

The commercial success of our product candidates will depend upon their degree of market acceptance by physicians, patients, third-party payors, and others in the medical community. Even if any product candidates we may develop receive marketing approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, healthcare payors, and others in the medical community. The degree of market acceptance of any product candidates we may develop, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and safety of such product candidates as demonstrated in pivotal clinical trials and published in peer-reviewed journals;
- the potential and perceived advantages compared to alternative treatments, including any similar generic treatments;
- the ability to offer these products for sale at competitive prices;
- the ability to offer appropriate patient access programs, such as co-pay assistance;
- convenience and ease of dosing and administration compared to alternative treatments;
- the clinical indications for which the product candidate is approved by FDA or comparable regulatory agencies;
- product labeling or product insert requirements of the FDA or other comparable foreign regulatory authorities, including any limitations, contraindications or warnings contained in a product's approved labeling;
- restrictions on how the product is distributed;
- the timing of market introduction of competitive products;
- publicity concerning these products or competing products and treatments;
- the strength of marketing and distribution support;
- favorable third-party coverage and sufficient reimbursement; and
- the prevalence and severity of any side effects or AEs.

Sales of medical products also depend on the willingness of physicians to prescribe the treatment, which is likely to be based on a determination by these physicians that the products are safe, therapeutically effective and cost effective. In addition, the inclusion or exclusion of products from treatment guidelines established by various physician groups and the viewpoints of influential physicians can affect the willingness of other physicians to prescribe the treatment. We cannot predict whether physicians, physicians' organizations, hospitals, other healthcare providers, government agencies or private insurers will determine that our product is safe, therapeutically effective and cost effective as compared with competing treatments. If any product candidates we develop do not achieve an adequate level of acceptance, we may not generate significant product revenue, and we may not become profitable.

If, in the future, we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market any product candidates we may develop, we may not be successful in commercializing those product candidates if and when they are approved.

We do not have a sales or marketing infrastructure and have little experience in the sale, marketing, or distribution of pharmaceutical products. To achieve commercial success for any approved product for which we retain sales and marketing responsibilities, we must either develop a sales and marketing organization or outsource these functions to third parties. In the future, we may choose to build a focused sales, marketing, and commercial support infrastructure to market and sell our product candidates, if and when they are approved. We may also elect to enter into collaborations or strategic partnerships with third parties to engage in commercialization activities with respect to selected product candidates, indications or geographic territories, including territories outside the United States, although there is no guarantee we will be able to enter into these arrangements even if the intent is to do so.

There are risks involved with both establishing our own commercial capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force or reimbursement specialists is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing and other commercialization capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition commercialization personnel.

Factors that may inhibit our efforts to commercialize any approved product on our own include:

- the inability to recruit and retain adequate numbers of effective sales, marketing, reimbursement, customer service, medical affairs, and other support personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future approved products;
- the inability of reimbursement professionals to negotiate arrangements for formulary access, reimbursement, and other acceptance by payors;
- the inability to price products at a sufficient price point to ensure an adequate and attractive level of profitability;
- restricted or closed distribution channels that make it difficult to distribute our products to segments of the patient population;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent commercialization organization.

If we enter into arrangements with third parties to perform sales, marketing, commercial support, and distribution services, our product revenue or the profitability of product revenue may be lower than if we were to market and sell any products we may develop internally. In addition, we may not be successful in entering into arrangements with third parties to commercialize our product candidates or may be unable to do so on terms that are favorable to us or them. We may have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively or may expose us to legal and regulatory risk by not adhering to regulatory requirements and restrictions governing the sale and promotion of prescription drug products, including those restricting off-label promotion. If we do not establish commercialization capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates, if approved.

The insurance coverage and reimbursement status of newly-approved products is uncertain. Our product candidates may become subject to unfavorable pricing regulations, third-party coverage and reimbursement practices, or healthcare reform initiatives, which would harm our business. Failure to obtain or maintain adequate coverage and reimbursement for new or current products could limit our ability to market those products and decrease our ability to generate revenue.

The regulations that govern marketing approvals, pricing, coverage, and reimbursement for new drugs vary widely from country to country. In the United States, recently enacted legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenue we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if any product candidates we may develop obtain marketing approval.

Our ability to successfully commercialize our product candidates also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers, and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. The availability of coverage and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford treatments such as gene therapy products. Sales of these or other product candidates that we may identify will depend substantially, both domestically and abroad, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. If coverage and adequate reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. In general, the prices of medicines under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for medicines, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenues and profits.

There is also significant uncertainty related to the insurance coverage and reimbursement of newly approved products and coverage may be more limited than the purposes for which the medicine is approved by the FDA or comparable foreign regulatory authorities. In the United States, the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. No uniform policy of coverage and reimbursement for products exists among third-party payors and coverage and reimbursement levels for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time consuming and costly process that may require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. It is difficult to predict what CMS will decide with respect to reimbursement for fundamentally novel products such as ours, as there is no body of established practices and precedents for these new products. Reimbursement agencies in Europe may be more conservative than CMS. For example, a number of cancer drugs have been approved for reimbursement in the United States and have not been approved for reimbursement in certain European countries. Moreover, eligibility for

reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale, and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved products we may develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize product candidates, and our overall financial condition.

Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Our inability to promptly obtain coverage and profitable reimbursement rates third-party payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, the level of reimbursement. Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. In order to obtain reimbursement, physicians may need to show that patients have superior treatment outcomes with our products compared to standard of care drugs, including lower-priced generic versions of standard of care drugs. We expect to experience pricing pressures in connection with the sale of any of our product candidates, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

Additionally, we may develop companion diagnostic tests for use with our product candidates. For instance, we are partnered with FMI to develop a companion diagnostic for use in our planned NDA submission for BBP-831 for second-line CCA. We, or our collaborators, may be required to obtain coverage and reimbursement for these tests separate and apart from the coverage and reimbursement we seek for our product candidates, once approved. Even if we obtain regulatory approval or clearance for such companion diagnostics, there is significant uncertainty regarding our ability to obtain coverage and adequate reimbursement for the same reasons applicable to our product candidates. Medicare reimbursement methodologies, whether under Part A, Part B, or clinical laboratory fee schedule may be amended from time to time, and we cannot predict what effect any change to these methodologies would have on any product candidate or companion diagnostic for which we receive approval. Our inability to promptly obtain coverage and adequate reimbursement from both third-party payors for the companion diagnostic tests that we develop and for which we obtain regulatory approval could have a material and adverse effect on our business, financial condition, results of operations and prospects.

If we fail to comply with healthcare laws, we could face substantial penalties and our business, operations and financial conditions could be adversely affected.

Healthcare providers, physicians and third-party payors in the United States and elsewhere play a primary role in the recommendation and prescription of pharmaceutical products. Arrangements with third-party payors and customers can expose pharmaceutical manufacturers to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act, which may constrain the business or financial arrangements and relationships through which such companies sell, market and distribute pharmaceutical products. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of ownership, pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. The applicable federal and state healthcare laws and regulations laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Violations are subject to civil and criminal fines and penalties, plus up to three times the remuneration involved, imprisonment of up to ten years, and exclusion from government healthcare programs. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution;
- federal civil and criminal false claims laws and civil monetary penalty laws, including the False Claims Act, which impose criminal and civil penalties, including through civil “qui tam” or “whistleblower” actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid, or other federal health care programs that are false or fraudulent; knowingly making or causing a false statement material to a false or fraudulent claim or an obligation to pay money to the federal government; or knowingly concealing or knowingly and improperly avoiding or decreasing such an obligation. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to “cause” the submission of false or fraudulent claims. The FCA also permits a private individual acting as a “whistleblower” to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery. When an entity is determined to have violated the federal civil False Claims Act, the government may impose civil fines and penalties for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating HIPAA without actual knowledge of the statute or specific intent to violate it;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;
- the federal Physician Payments Sunshine Act, created under the ACA, and its implementing regulations, which require manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually to the U.S. Department of Health and Human Services under the Open Payments Program, information related to payments or other transfers of value made to physicians, certain other healthcare professionals, and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Effective January 1, 2022, these reporting obligations will extend to include transfers of value made to certain non-physician providers such as physician assistants and nurse practitioners;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
- analogous state and foreign laws and regulations, such as state and foreign anti-kickback, false claims, consumer protection and unfair competition laws which may apply to pharmaceutical business practices, including but not limited to, research, distribution, sales and marketing arrangements as well as submitting claims involving healthcare items or services reimbursed by any third-party payer, 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 that otherwise restricts payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to file reports with states regarding pricing and marketing information, such as the tracking and reporting of gifts, compensations and other remuneration and items of value provided to healthcare professionals and entities; state and local laws requiring the registration of pharmaceutical sales representatives; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that some of our business activities, including compensation of physicians with stock or stock options, could, despite efforts to comply, be subject to challenge under one or more of such laws. Additionally, FDA or foreign regulators may not agree that we have mitigated any risk of bias in our clinical trials due to payments or equity interests provided to investigators or institutions which could limit a regulator's acceptance of those clinical trial data in support of a marketing application. Moreover, efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and 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 civil, criminal and administrative penalties, damages, disgorgement, monetary fines, exclusion from participation in Medicare, Medicaid and other federal healthcare programs, integrity and oversight agreements to resolve allegations of non-compliance, contractual damages, reputational harm, diminished profits and future earnings, and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. In addition, the approval and commercialization of any of our product candidates outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

Failure to comply with health and data protection laws and regulations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business.

We and any potential collaborators may be subject to federal, state, and foreign data protection laws and regulations (i.e., laws and regulations that address privacy and data security). In the United States, numerous federal and state laws and regulations, including federal health information privacy laws, 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 collaborators. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA, as amended by HITECH. Depending on the facts and circumstances, we could be subject to civil, criminal, and administrative penalties if we knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

California recently enacted the California Consumer Privacy Act, or CCPA, which creates new individual privacy rights for California consumers (as defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA will require covered companies to provide certain disclosures to consumers about its data collection, use and sharing practices, and to provide affected California residents with ways to opt-out of certain sales or transfers of personal information. The CCPA went into effect on January 1, 2020, and the California Attorney General will commence enforcement actions against violators beginning July 1, 2020. While there is currently an exception for protected health information that is subject to HIPAA and clinical trial regulations, as currently written, the CCPA may impact certain of our business activities. The California Attorney General has proposed draft regulations, which have not been finalized to date, that may further impact our business activities if they are adopted. The uncertainty surrounding the implementation of CCPA exemplifies the vulnerability of our business to the evolving regulatory environment related to personal data and protected health information.

Compliance with U.S. and international data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Failure to comply with these laws and regulations could result in government enforcement actions (which could include civil, criminal and administrative penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects, employees and other individuals about whom we or our potential collaborators obtain personal information, as well as the providers who share this information with us, may limit our ability to collect, 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, 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.

European data collection is governed by restrictive regulations governing the use, processing and cross-border transfer of personal information.

In the event we decide to conduct clinical trials or continue to enroll subjects in our ongoing or future clinical trials in the European Union, we may be subject to additional privacy restrictions. The collection and use of personal health data in the European Union is governed by the provisions of the General Data Protection Regulation 2016/679, or GDPR. This directive imposes several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, notification of data processing obligations to the competent national data protection authorities and the security and confidentiality of the personal data. The GDPR also imposes strict rules on the transfer of personal data out of the European Union to the United States. Failure to comply with the requirements of the Data Protection Directive, which governs the collection and use of personal health data in the European Union, the GDPR, and the related national data protection laws of the European Union Member States may result in fines and other administrative penalties. The GDPR introduced new data protection requirements in the European Union and substantial fines for breaches of the data protection rules. The GDPR regulations may impose additional responsibility and liability in relation to personal data that we process and we may be required to put in place additional mechanisms ensuring compliance with these and/or new data protection rules. This may be onerous and adversely affect our business, financial condition, prospects and results of operations. Further, the United Kingdom's decision to leave the EU, often referred to as Brexit, has created uncertainty with regard to data protection regulation in the United Kingdom. In particular, it is unclear how data transfers to and from the United Kingdom will be regulated now that the United Kingdom has left the EU.

Healthcare legislative measures aimed at reducing healthcare costs may have a material adverse effect on our business and results of operations.

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of our product candidates or any future product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product for which we obtain marketing approval. Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

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 ACA was passed, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the U.S. pharmaceutical industry. The ACA, among other things, subjects biological products to potential competition by lower-cost biosimilars, addresses a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations, establishes annual fees and taxes on manufacturers of certain branded prescription drugs, and creates a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% (as of 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

There have been a number of significant changes to the ACA and its implementation. The Tax Cuts and Jobs Act of 2017, or Tax Act, includes a provision that repealed effective January 1, 2019 the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, or the Texas District Court Judge, ruled that the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the ACA are invalid as well. On December 18, 2019, the Fifth Circuit U.S. Court of Appeals held that the individual mandate is unconstitutional, and remanded the case to the lower court to reconsider its earlier invalidation of the full ACA. It is unclear how this decision, subsequent appeals and other efforts to repeal and replace the ACA will impact the ACA and our business.

On January 20, 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. On October 13, 2017, President Trump signed an Executive Order terminating the cost-sharing subsidies that reimburse insurers under the ACA. Several state Attorneys General filed suit to stop the administration from terminating the subsidies, but their request for a restraining order was denied by a federal judge in California on October 25, 2017. On June 14, 2018, U.S. Court of Appeals for the Federal Circuit ruled that the federal government was not required to pay more than $12 billion in ACA risk corridor payments to third-party payors who argued were owed to them. On December 10, 2019, the U.S. Supreme Court heard arguments in *Moda Health Plan, Inc. v. United States*, which will determine whether the government must make risk corridor payments. The U.S. Supreme Court's decision will be released in the coming months, but we cannot predict how the U.S. Supreme Court will rule. The effects of this gap in reimbursement on third-party payors, the viability of the ACA marketplace, providers, and potentially our business, are not yet known.

Moreover, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. On December 20, 2019, President Trump signed into law the Further Consolidated Appropriations Act (H.R. 1865), which repeals the Cadillac tax, the health insurance provider tax, and the medical device excise tax. The Bipartisan Budget Act of

2018, also amended the ACA, effective January 1, 2019, by increasing the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and closing the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." In July 2018, CMS published a final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. In addition, CMS published a final rule that gives states greater flexibility, starting in 2020, in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect in 2013, and, due to subsequent legislative amendments, will remain in effect through 2029 unless additional Congressional action is taken. The American Taxpayer Relief Act of 2012 further reduced Medicare payments to several providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the federal level, the Trump administration's budget for fiscal year 2020 contains further drug price control measures that could be enacted during the 2020 legislative session, or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Additionally, the Trump administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase 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. The U.S. Department of HHS, has already started the process of soliciting feedback on some of these measures and, at the same time, is immediately implementing others under its existing authority. In May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy, a type of prior authorization, for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. 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.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at containing or lowering the cost of healthcare. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product. Such reforms could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our product candidates, if approved;
- our ability to receive or set a price that we believe is fair for our products;
- our ability to generate revenue and achieve or maintain profitability;

- the amount of taxes that we are required to pay; and
- the availability of capital.

We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, lower reimbursement, and new payment methodologies. This could lower the price that we receive for any approved product. Any denial in coverage or reduction in reimbursement from Medicare or other government-funded programs may result in a similar denial or reduction in payments from private payors, which may prevent us from being able to generate sufficient revenue, attain profitability or commercialize our product candidates, if approved.

Recent federal legislation and actions by state and local governments may permit reimportation of drugs from foreign countries into the United States, including foreign countries where the drugs are sold at lower prices than in the United States, which could materially adversely affect our operating results.

We may face competition in the United States for our product candidates, if approved, from therapies sourced from foreign countries that have placed price controls on pharmaceutical products. In the United States, the Medicare Modernization Act contains provisions that may change U.S. importation laws and expand pharmacists' and wholesalers' ability to import cheaper versions of an approved drug and competing products from Canada, where there are government price controls. These changes to U.S. importation laws will not take effect unless and until the Secretary of the HHS certifies that the changes will pose no additional risk to the public's health and safety and will result in a significant reduction in the cost of products to consumers. On December 18, 2019, FDA issued a notice of proposed rulemaking that, if finalized, would allow for the importation of certain prescription drugs from Canada. The Secretary of HHS would make the above certification to Congress upon issuance of a final rule based on this proposal. FDA also issued a draft guidance document outlining a potential pathway for manufacturers to obtain an additional National Drug Code, or NDC, for an FDA-approved drug that was originally intended to be marketed in a foreign country and that was authorized for sale in that foreign country. The regulatory and market implications of the notice of proposed rulemaking and draft guidance are unknown at this time. Proponents of drug reimportation may attempt to pass legislation that would directly allow reimportation under certain circumstances. Legislation or regulations allowing the reimportation of drugs, if enacted, could decrease the price we receive for any products that we may develop and adversely affect our future revenues and prospects for profitability.

We face significant competition in an environment of rapid technological and scientific change, and there is a possibility that our competitors may achieve regulatory approval before us or develop therapies that are safer, more advanced or more effective than ours, which may negatively impact our ability to successfully market or commercialize any product candidates we may develop and ultimately harm our financial condition.

The development and commercialization of new drug products is highly competitive. We may face competition with respect to any product candidates that we seek to develop or commercialize in the future from major pharmaceutical companies, specialty pharmaceutical companies, and biotechnology companies worldwide. Potential competitors also include academic institutions, government agencies, and other public and private research organizations that conduct research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing, and commercialization.

There are a number of large pharmaceutical and biotechnology companies that are currently pursuing the development and commercialization of products for the treatment of the indications that our four key value drivers are pursuing, including but not limited to: tafamidis, a TTR tetramer stabilizer (presently marketed by Pfizer Inc. as Vyndamax and Vyndaqel), a competitor to BBP-265; pemigatinib, a small molecule FGFR inhibitor, a competitor to BBP-831; NBI-74788, a corticotropin releasing factor receptor antagonist, a competitor to BBP-631; and MRTX849, a KRAS G12C inhibitor, a competitor to BBP-454. If any of these or other competitors, including competitors for our other product candidates, receive FDA approval before we do, our product candidates would not be the first treatment on the market, and our market share may be limited. In addition to competition from other companies targeting our target indications, any products we may develop may also face competition from other types of therapies.

Many of our current or potential competitors, either alone or with their strategic partners, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products than we do.

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive than any products that we may develop. Furthermore, currently approved products could be discovered to have application for treatment of our targeted disease indications or similar indications, which could give such products significant regulatory and market timing advantages over our product candidates. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours and may obtain orphan product exclusivity from the FDA for indications that we are targeting, which could result in our competitors establishing a strong market position before we are able to enter the market. Additionally, products or technologies developed by our competitors may render our potential product candidates uneconomical or obsolete and we may not be successful in marketing any product candidates we may develop against competitors.

In addition, we could face litigation or other proceedings with respect to the scope, ownership, validity and/or enforceability of our patents relating to our competitors' products and our competitors may allege that our products infringe, misappropriate or otherwise violate their intellectual property. The availability of our competitors' products could limit the demand, and the price we are able to charge, for any products that we may develop and commercialize. See "Risks related to our intellectual property."

If the market opportunities for our product candidates are smaller than we believe they are, our revenue may be adversely affected, and our business may suffer. Our ability to successfully identify patients and acquire a significant market share will be necessary for us to achieve profitability and growth.

We focus research and product development on treatments for Mendelian diseases and genetically driven cancers, many of which are rare or orphan indications. Our projections of both the number of individuals who are affected by our target disease indications and 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, 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. The effort to identify patients with diseases we seek to treat is in early stages, and we cannot accurately predict the number of patients for whom treatment might be possible. Additionally, the potentially addressable patient population for BBP-265, BBP-831, BBP-454, BBP-631 or other product candidates that we may identify may be limited or may not be amenable to treatment with BBP-265, BBP-831, BBP-454, BBP-631 or other product candidates that we may identify, and new patients may become increasingly difficult to identify or gain access to, which would adversely affect our results of operations and our business. Further, even if we obtain significant market share for BBP-265, BBP-831, BBP-454, BBP-631 or other product candidates that we may identify, because the potential target populations are small, we may never achieve profitability despite obtaining such significant market share. In addition, market share could be limited by the availability of other treatments including Vyndamax (tafamidis) and Vyndaqel (tafamidis meglumine), for which Pfizer Inc. has been approved for the treatment of ATTR-CM the United States and Japan (Vyndaqel only). As a result, BBP-265 is not the first treatment on the market for ATTR-CM.

Risks related to our business and industry

Our future success depends on our ability to retain key employees, directors, consultants and advisors and to attract, retain and motivate qualified personnel.

We are highly dependent on the management, research and development, clinical, financial and business development expertise of our executive officers, our directors, our Management Committee as well as the other members of our scientific and clinical teams. However, some of these executive officers, directors and other personnel split their time between BridgeBio and certain of our other subsidiaries. For instance, Neil Kumar serves as chief executive officer and a director both to us and Eidos; Uma Sinha serves as chief scientific officer to us and Eidos; Eric Aguiar and Ali Satvat each serve as a director both to us and Eidos; Eric David serves as chief executive officer of both Adrenas Therapeutics, Inc. and Aspa Therapeutics, Inc.; Neil Kirby serves as chief executive officer of both Origin Biosciences, Inc. and Phoenix Tissue Repair, Inc. As a result, these executive officers, directors and members of our Management Committee may not be able to devote their full attention to us, which could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy.

While we believe that we have put in place policies and procedures to identify such conflicts and any such policies and procedures were negotiated at arm's length in conformity with fiduciary duties, such conflicts of interest may nonetheless arise. The existence and consequences of such potential conflicts could expose us to loss of profits, claims by our investors and creditors, and harm our business and our results of operations. The risks related to our dependence upon Dr. Kumar are compounded by Dr. Kumar's significant ownership percentage and Dr. Kumar's role in both our company and our subsidiaries, including Eidos. If we were to lose Dr. Kumar or any of our other executives or key personnel, we may not be able to find appropriate replacements on a timely basis. In addition, because certain of our employees provide a centralized source of support across multiple subsidiaries, the loss of any of these employees could negatively affect the operations of the affected subsidiaries, and our financial condition and results of operations could be materially adversely affected.

Furthermore, each of our executive officers may terminate their employment with us at any time. We do not maintain "key person" insurance for any of our executives or employees. Recruiting and retaining qualified scientific and clinical personnel and, if we progress the development of our drug pipeline toward scaling up for commercialization, sales and marketing personnel, will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval for and commercialize our product candidates. Competition to hire qualified personnel in our industry is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. Furthermore, to the extent we hire personnel from competitors, we may be subject to allegations that they have been improperly solicited or that they have divulged proprietary or other confidential information, or that their former employers own their research output. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions.

In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

Our reliance on a central team consisting of a limited number of employees who provide various administrative, research and development and other services across our organization, and on dedicated teams at the subsidiary level presents operational challenges that may adversely affect our business.

As of December 31, 2019, we had 42 employees who are employed by our wholly-owned subsidiary, BridgeBio Services, Inc., upon which we rely for various administrative, research and development and other support services shared among us. While we believe this structure enables us to reduce certain infrastructure costs, the small size of our central team may cause us to be unable to devote adequate personnel, time and resources to support the operations of all of our subsidiaries, including their research and development activities, employee recruiting and retention efforts and the management financial and accounting and reporting matters. From time to

time, members of our central team may not have access to adequate information regarding aspects of the business and operations of our subsidiaries to sufficiently manage these affairs. Additionally, because our dedicated subsidiary-level employees and management are primarily incentivized at the subsidiary level, these employees and management team members may not be sufficiently incentivized to maximize the overall value of our entire organization. If our central team fails to provide adequate administrative, research and development or other services across our entire organization, or our subsidiary-level employees and management do not perform in a manner that aligns with the interests of our entire organization, our business, financial condition and results of operations could be harmed.

Changes in funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products or take action with respect to other regulatory matters can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved, or for other actions to be taken, by relevant government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Similarly, a prolonged government shutdown could prevent the timely review of our patent applications by the United States Patent and Trademark Office, or USPTO, which could delay the issuance of any U.S. patents to which we might otherwise be entitled. Future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

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, 2019, we had 248 full-time employees across all of our companies. As we mature, we expect to expand our full-time employee base and to hire more consultants and contractors. Our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time toward 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 revenues 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.

Because we have multiple programs and product candidates in our development pipeline and are pursuing a variety of target indications and treatment modalities, we may expend our limited resources to pursue a particular product candidate and fail to capitalize on development opportunities or product candidates that may be more profitable or for which there is a greater likelihood of success.

We focus on the development of product candidates to address Mendelian diseases and genetically driven cancers, regardless of the treatment modality or the particular target indication within this space. Because we have limited financial and personnel resources, we may forgo or delay pursuit of opportunities with potential target indications or product candidates that later prove to have greater commercial potential than our current and planned

development programs and product candidates. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and other future product candidates for specific indications may not yield any commercially viable future product candidates. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may be required to relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such future product candidates.

Additionally, we may pursue additional in-licenses or acquisitions of development-stage assets or programs, which entails additional risk to us. Identifying, selecting and acquiring promising product candidates requires substantial technical, financial and human resources expertise. Efforts to do so may not result in the actual acquisition or license of a successful product candidate, potentially resulting in a diversion of our management's time and the expenditure of our resources with no resulting benefit. For example, if we are unable to identify programs that ultimately result in approved products, we may spend material amounts of our capital and other resources evaluating, acquiring and developing products that ultimately do not provide a return on our investment.

Product liability lawsuits against us could cause us to incur substantial liabilities and could limit commercialization of any product candidates that we may develop.

We face an inherent risk of product liability exposure related to the testing of product candidates in human clinical trials and will face an even greater risk if we commercially sell any medicines that we may develop. If we cannot successfully defend ourselves against claims that our product candidates or medicines caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or medicines that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue; and
- the inability to commercialize our product candidates.

Although we maintain product liability insurance, including coverage for clinical trials that we sponsor, it may not be adequate to cover all liabilities that we may incur. We anticipate that we will need to increase our insurance coverage as we commence additional clinical trials and if we successfully commercialize any product candidates. The market for insurance coverage is increasingly expensive, and the costs of insurance coverage will increase as our clinical programs increase in size. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of fraud, misconduct or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and negligent conduct that fails to: comply with the laws of the FDA and comparable foreign regulatory authorities; provide true, complete and accurate information to the FDA and comparable foreign regulatory authorities; comply with manufacturing standards we have established; comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws; or report financial information or data accurately or to disclose unauthorized activities. If we obtain FDA approval of our product candidates and begin commercializing those products in the United States, our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. In particular, research, sales, marketing, education and other business arrangements in the healthcare industry are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, educating, marketing and promotion, sales

and commission, certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. We intend to adopt a code of business conduct and ethics, but it is not always possible to identify and deter misconduct by employees and third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

If 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 harm our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.

Our ability to invest in and expand our business and meet our financial obligations, to attract and retain third-party contractors and collaboration partners and to raise additional capital depends on our operating and financial performance, which, in turn, is subject to numerous factors, including the prevailing economic and political conditions and financial, business and other factors beyond our control, such as the rate of unemployment, the number of uninsured persons in the United States, political influences and inflationary pressures. For example, an overall decrease in or loss of insurance coverage among individuals in the United States as a result of unemployment, underemployment or the repeal of certain provisions of the ACA, may decrease the demand for healthcare services and pharmaceuticals. If fewer patients are seeking medical care because they do not have insurance coverage, we may experience difficulties in any eventual commercialization of our product candidates and our business, results of operations, financial condition and cash flows could be adversely affected.

In addition, our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets upon which pharmaceutical and biopharmaceutical companies such as us are dependent for sources of capital. In the past, global financial crises have caused extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn could result in a variety of risks to our business, including a reduced ability to raise additional capital when needed on acceptable terms, if at all, and weakened demand for our product candidates. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

Our internal computer systems, or those used by our third-party research institution collaborators, CROs or other contractors or consultants, may fail or suffer security breaches.

Despite the implementation of security measures, our internal computer systems and those of our current and future CROs and other contractors and consultants may be vulnerable to damage from computer viruses and unauthorized access. Although to our knowledge we have not experienced any such material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of development programs and business operations. For example, the loss of clinical trial data from completed, ongoing or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties for research and development, the manufacture and supply of drug product and drug substance and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or systems, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our product candidates could be delayed. We also rely on third-party service providers for aspects of our internal control over financial reporting, and such service providers may experience a material system failure or fail to carry out their obligations in other respects, which may impact our ability to produce accurate and timely financial statements, thus harming our operating results, our ability to operate our business, and our investors' view of us.

Certain data breaches must also be reported to affected individuals and the government, and in some cases to the media, under provisions of HIPAA, as amended by HITECH, other U.S. federal and state law, and requirements of non-U.S. jurisdictions, including the European Union General Data Protection Regulation, and financial penalties may also apply.

Our insurance policies may not be adequate to compensate us for the potential losses arising from breaches, failures or disruptions of our infrastructure, catastrophic events and disasters or otherwise. In addition, such insurance may not be available to us in the future on economically reasonable terms, or at all. Further, our insurance may not cover all claims made against us and defending a suit, regardless of its merit, could be costly and divert management's attention.

Furthermore, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on other third parties for the manufacture of our product candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business.

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

Earthquakes, outbreak of disease, or other natural disasters could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as the manufacturing facilities of our third-party CMOs, or that 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 originated in Wuhan, China. Since the manufacturing facilities of some of our third-party CMOs are in China, an outbreak of communicable diseases in China or elsewhere, 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 China, forcing temporary closure of facilities that we rely upon or increasing the costs associated with obtaining 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. The disaster recovery and business continuity plans we have in place currently are limited and are unlikely to prove adequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business.

Our international operations may expose us to business, regulatory, political, operational, financial, pricing and reimbursement and economic risks associated with doing business outside of the United States.

We currently have no employees outside the United States, but we are conducting clinical trials internationally through a global CRO and our business strategy incorporates potential international expansion to target patient populations outside the United States. If we receive regulatory approval for and commercialize any of our product candidates in patient populations outside the United States, we may hire sales representatives and conduct physician and patient association outreach activities outside of the United States. Doing business internationally involves a number of risks, including, but not limited to:

- multiple, conflicting, and changing laws and regulations such as privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements, and other governmental approvals, permits, and licenses;
- failure by us to obtain and maintain regulatory approvals for the use of our products in various countries;
- additional potentially relevant third-party patent rights;
- complexities and difficulties in obtaining protection and enforcing our intellectual property;
- difficulties in staffing and managing foreign operations;
- complexities associated with managing multiple payor reimbursement regimes, government payors, or patient self-pay systems;
- limits in our ability to penetrate international markets;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our products, and exposure to foreign currency exchange rate fluctuations;
- natural disasters, political and economic instability, including wars, terrorism, and political unrest, outbreak of disease (such as the outbreak of the novel strain of coronavirus in December 2019), boycotts, curtailment of trade, and other business restrictions;
- certain expenses including, among others, expenses for travel, translation, and insurance; and
- regulatory and compliance risks that relate to maintaining accurate information and control over sales and activities that may fall within the purview of the U.S. Foreign Corrupt Practices Act, its books and records provisions, or its anti-bribery provisions.

Any of these factors could significantly harm our potential international expansion and operations and, consequently, our results of operations.

We have identified material weaknesses in our internal control over financial reporting. If our remediation of the material weaknesses is not effective, or if we experience additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls in the future, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our common stock.

We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, the Sarbanes-Oxley Act and the rules and regulations of the Nasdaq Stock Market. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal controls over financial reporting. Prior to our IPO, we were a private company with limited accounting personnel to adequately execute our accounting processes and other supervisory resources with which to address our internal control over financial reporting and, as a result, we may experience difficulty in meeting these reporting requirements in a timely manner. To date, we have never conducted a review of our internal controls for the purpose of providing the reports required by the Sarbanes-Oxley Act. During our review and testing, we may identify deficiencies and be unable to remediate them before we must provide the required reports.

In connection with the preparation of our 2017 combined and consolidated financial statements, we and our independent auditors identified material weaknesses in our internal control over financial reporting. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim consolidated financial statements will not be prevented or detected on a timely basis.

These material weaknesses related to the following:

- We do not have sufficient staffing to enable segregation of duties within accounting functions and do not have sufficient written policies and procedures for accounting and financial reporting. These factors contributed to the lack of a formalized process or controls for our management's timely review and approval of journal entries and related financial statement analysis.
- We do not have finance and accounting staff with the appropriate U.S. GAAP technical expertise to identify, evaluate and account for complex and non-routine transactions. As a result, we did not design and maintain formal accounting policies, processes and controls related to complex transactions necessary for an effective financial reporting process.

As of December 31, 2019, these material weaknesses have been remediated. As the hiring of additional finance and accounting personnel becomes economically feasible, we intend to take appropriate and reasonable steps to continue to strengthen our internal controls through the implementation of appropriate segregation of duties and formalization of accounting policies and controls. However, we cannot assure you that these measures will significantly improve our internal controls or prevent further material weaknesses in the future.

In addition, in connection with the audit of the consolidated financial statements for the year ended December 31, 2018 of our subsidiary Eidos, which is a public company subject to the reporting requirements of the Exchange Act and the rules and regulations of the Nasdaq Stock Market, Eidos and its independent registered public accounting firm identified a material weakness in Eidos' internal control over financial reporting related to a deficiency in the operation of Eidos' internal controls over the accounting for complex debt and equity transactions and ineffective disclosure controls. Although this material weakness was remediated as of December 31, 2019, we can give no assurance that additional material weaknesses or significant deficiencies in our or Eidos' internal control over financial reporting will not be identified in the future.

We may discover additional weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our consolidated financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are not able to comply with the requirements of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls over financial reporting, we may not be able to produce timely and accurate financial statements. If that were to happen, our investors could lose confidence in our reported financial information, the market price of our stock could decline, and we could be subject to sanctions or investigations by the SEC or other regulatory authorities.

If we fail to maintain an effective system of disclosure controls and internal control over financial reporting, our ability to produce timely and accurate financial statements or comply with applicable regulations could be impaired.

As a public company, are required to maintain internal control over financial reporting and to report any material weaknesses in such internal controls. The Sarbanes-Oxley Act, requires that we evaluate and determine the effectiveness of our internal control over financial reporting and, beginning with our second annual report following our IPO, provide a management report on internal control over financial reporting. In addition, once we are no longer an emerging growth company, we will be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm.

Any failure to develop or maintain effective controls, or any difficulties encountered in their implementation or improvement, could harm our results of operations, cause us to fail to meet our reporting obligations, result in a restatement of our financial statements for prior periods, or adversely affect the results of management evaluations and independent registered public accounting firm audits of our internal control over financial reporting that we will eventually be required to include in our periodic reports that will be filed with the SEC. In addition, to the extent we acquire or establish additional consolidated subsidiaries and VIEs, the financial statements of such entities may not be initially prepared by us, and we will not have direct control over their financial statement preparation. As a result, we will, for our financial reporting, depend on what these entities report to us, which could result in our adding monitoring and audit processes, and increase the difficulty of implementing and maintaining adequate controls over our financial processes and reporting in the future, which could lead to delays in our external reporting. In particular, this may occur where we are establishing such entities with partners that do not have sophisticated financial accounting processes in place, or where we are entering into new relationships at a rapid pace, straining our integration capacity. Furthermore, during the course of the audit of Eidos' financial statements for the fiscal year ended December 31, 2018, Eidos discovered certain errors related to the accounting for complex debt and equity transactions, which required Eidos to restate its unaudited financial information for the quarterly periods ended March 31, 2018, June 30, 2018 and September 30, 2018. If we or any of our publicly listed subsidiaries are required to restate previously issued financial statements for any additional periods, our reputation could be impaired which could cause a loss of investor confidence and adversely materially affect our business, operating results and financial condition. Additionally, if we do not receive the information from the consolidated subsidiaries or controlled VIEs on a timely basis, it could cause delays in our external reporting. Ineffective disclosure controls and procedures and internal controls over financial reporting could also cause investors to lose confidence in our reported financial and other information, which would likely have a negative effect on the trading price of our common stock.

Historically, we have relied upon and expect to continue to rely upon third-party contracted service providers to assist with our financial reporting. We are in the process of designing and implementing the internal control over financial reporting required to comply with the Sarbanes-Oxley Act. This process will be time consuming, costly, and complicated. If we are unable to assert that our internal control over financial reporting is effective or when required in the future, if our independent registered public accounting firm issues an adverse opinion on the effectiveness of our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could be adversely affected and we could become subject to investigations by the stock exchange on which our securities are listed, the SEC, or other regulatory authorities, which could require additional financial and management resources.

Risks Related to our Common Stock

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

We are an "emerging growth company" as defined in the JOBS Act, and we intend to take advantage of some of the exemptions from reporting requirements that are applicable to other public companies that are not emerging growth companies, including:

- being permitted to provide only two years of audited financial statements prior to our first filing of our Annual Report on Form 10-K, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's discussion and analysis of financial condition and results of operations" disclosure;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- not being required to hold a non-binding advisory vote on executive compensation or obtain stockholder approval of any golden parachute payments not previously approved.

We cannot predict if investors will find our common stock less attractive because we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the earlier of (1) December 31, 2024, (2) the last day of the fiscal year in which we have total annual gross revenue of at least $1.07 billion, or (3) the date on which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th and (4) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

Under Section 107(b) of the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. Pursuant to Section 107(b) of the JOBS Act, we have elected to use the extended transition period for complying with new or revised accounting standards under Section 102(b)(2) of The JOBS Act. This election allows us to delay the adoption of new or revised accounting standards that have different effective dates for public and private companies until those standards apply to private companies. As a result, our financial statements may not be comparable to companies that comply with public company effective dates, and our stockholders and potential investors may have difficulty in analyzing our operating results if comparing us to such companies.

The market price of our common stock may be highly volatile, and purchasers of our common stock could incur substantial losses.

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

- adverse results or delays in our preclinical studies or clinical trials;
- reports of AEs or other negative results in clinical trials of third parties' product candidates that target our product candidates' target indications;
- inability for us to obtain additional funding on reasonable terms or at all;
- any delay in filing an IND, BLA or NDA for our product candidates and any adverse development or perceived adverse development with respect to the FDA's review of that IND, BLA or NDA;
- failure to develop successfully and commercialize our product candidates;
- announcements we make regarding our current product candidates, acquisition of potential new product candidates and companies and/or in-licensing;
- failure to maintain our existing license arrangements or enter into new licensing and collaboration agreements;
- failure by us or our licensors to prosecute, maintain or enforce our intellectual property rights;
- changes in laws or regulations applicable to future products;
- inability to obtain adequate clinical or commercial supply for our product candidates or the inability to do so at acceptable prices;
- adverse regulatory decisions, including failure to reach agreement with applicable regulatory authorities on the design or scope of our planned clinical trials;
- failure to obtain and maintain regulatory exclusivity for our product candidates;
- regulatory approval or commercialization of new products or other methods of treating our target disease indications by our competitors;
- failure to meet or exceed financial projections we may provide to the public or to 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, our strategic collaboration partner 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 our key scientific or management personnel;
- significant lawsuits, including patent or stockholder litigation, against us;
- changes in the market valuations of similar companies;
- sales or potential sales of substantial amounts of our common stock; and
- trading volume of our common stock.

In addition, companies trading in the stock market in general, and Nasdaq, in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance.

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

We will need additional capital in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. These sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

Pursuant to our 2019 Stock Option and Incentive Plan, or the 2019 Plan, we are authorized to grant stock options and other stock-based awards to our employees, directors and consultants. In addition, pursuant to our 2019 Inducement Equity Plan, we are authorized to grant stock options and other stock-based awards to prospective officers and employees who are not currently employed by us or one of our subsidiaries. If our board of directors elects to increase the number of shares available for future grant and our stockholders approve of such an increase at our annual meeting, our stockholders may experience additional dilution, and our stock price may fall.

A significant portion of our total outstanding shares is restricted from immediate resale but may be sold into the market in the near future, which could cause the market price of our common stock to decline significantly.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, upon the expiration of the market standoff agreement, the early release of this agreement, or the perception in the market that the holders of a large number of shares of common stock intend to sell shares, could reduce the market price of our common stock.

Shares of unvested restricted stock and common stock issued and outstanding as of the Reorganization will become available for sale immediately upon the vesting of such shares, as applicable, and the expiration of any applicable market standoff agreement. Shares issued upon the exercise of stock options outstanding under our equity incentive plans or pursuant to future awards granted under those plans will become available for sale in the public market to the extent permitted by the provisions of applicable vesting schedules, any applicable market standoff agreement, and Rule 144 and Rule 701 under the Securities Act of 1933, as amended, or the Securities Act.

Certain holders of our common stock have rights, subject to conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We also filed a registration statements on Form S-8 registering the issuance of shares of common stock issued or reserved for future issuance under our equity compensation and equity inducement plans. Shares registered under these registration statements on Form S-8 can be freely sold in the public market upon issuance and once vested, subject to volume limitations applicable to affiliates. If any of these additional shares are sold, or if it is perceived that they will be sold, in the public market, the market price of our common stock could decline.

If securities analysts do not publish research or reports about our business or if they publish negative evaluations of our stock, the price of our stock could decline.

The trading market for our common stock relies in part on the research and reports that industry or financial analysts publish about us or our business. If one or more of the analysts covering our business downgrade their evaluations of our stock, the price of our stock could decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price to decline.

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

Based upon our common stock outstanding as of December 31, 2019, KKR Genetic Disorder L.P., or together with its affiliates, KKR, Viking Global Opportunities Illiquid Investments Sub-Master LP and Neil Kumar, our chief executive officer, beneficially own 50.8% of our outstanding common stock. These stockholders will have the ability to influence us through their ownership positions. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders, acting together, may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may believe are in your best interest as one of our stockholders.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders or remove our current management.

Our amended and restated certificate of incorporation and amended and restated bylaws and Delaware law contain provisions that may have the effect of delaying or preventing a change in control of us or changes in our management. Our amended and restated certificate of incorporation and amended and restated bylaws include provisions that:

- authorize “blank check” preferred stock, which could be issued by our board of directors without stockholder approval and may contain voting, liquidation, dividend and other rights superior to our common stock;
- create a classified board of directors whose members serve staggered three-year terms;
- specify that special meetings of our stockholders can be called only by our board of directors or stockholders holding at least 25% of our outstanding voting stock;
- prohibit stockholder action by written consent;
- establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors;
- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even if less than a quorum, or by the holders of a majority of the outstanding shares of capital stock then entitled to vote at an election of directors;
- specify that no stockholder is permitted to cumulate votes at any election of directors;

- expressly authorize our board of directors to modify, alter or repeal our amended and restated bylaws; and
- require supermajority votes of the holders of our common stock to amend specified provisions of our amended and restated certificate of incorporation and amended and restated bylaws.

These provisions, alone or together, could delay or prevent hostile takeovers and changes in control or changes in our management.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which limits the ability of stockholders owning in excess of 15% of our outstanding voting stock to merge or combine with us. Any provision of our amended and restated certificate of incorporation or amended and restated bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

Our amended and restated bylaws will designate specific courts as the exclusive forum for certain litigation that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us.

Pursuant to our amended and restated bylaws, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if the Chancery Court does not have jurisdiction, the federal district court for the District of Delaware or other state courts of the State of Delaware) will be the sole and exclusive forum for state law claims for (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a claim of breach of a fiduciary duty or other wrongdoing by any of our directors, officers, employees or agents to us or our stockholders; (iii) any action asserting a claim against us arising pursuant to any provision of the Delaware General Corporation Law or our certificate of incorporation or bylaws; (iv) any action to interpret, apply, enforce or determine the validity of our certificate of incorporation or bylaws; or (v) any action asserting a claim governed by the internal affairs doctrine. This exclusive forum provision will not apply to any causes of action arising under the Securities Act or the Exchange Act. The forum selection clauses in our amended and restated bylaws may limit our stockholders' ability to obtain a favorable judicial forum for disputes with us.

We are party to a loan and security agreement that contains operating and financial covenants that may restrict our business and financing activities.

In June 2018, we entered into a loan and security agreement, or the Loan and Security Agreement, with Hercules Capital, Inc., or Hercules, pursuant to which we were extended a term loan in the aggregate principal amount of up to $35.0 million. In December 2018, we entered into an amendment to the Loan and Security Agreement with Hercules, pursuant to which we were extended an additional term loan in the aggregate principal amount of up to $20.0 million. In May 2019, we entered into a second amendment to the Loan and Security Agreement with Hercules, pursuant to which we were extended a second additional term loan in the aggregate principal amount of up to $20.0 million, increasing the total principal amount outstanding to $75.0 million under the Loan and Security Agreement, as amended to date, or the Amended and Restated Loan and Security Agreement. The Amended and Restated Loan and Security Agreement may restrict our ability, among other things, to:

- sell, transfer or otherwise dispose of any of our business or property, subject to limited exceptions;
- make material changes to our business;
- enter into transactions resulting in significant changes to the voting control of our stock;
- make certain changes to our organizational structure;
- consolidate or merge with other entities or acquire other entities;
- incur additional indebtedness or create encumbrances on our assets;
- pay dividends, or make distributions on and, in certain cases, repurchase our stock;

- enter into transactions with our affiliates;
- repay subordinated indebtedness; or
- make certain investments.

In addition, we are required under our Amended and Restated Loan and Security Agreement to comply with various operating covenants and default clauses that may restrict our ability to finance our operations, engage in business activities or expand or fully pursue our business strategies. A breach of any of these covenants or clauses could result in a default under the Amended and Restated Loan and Security Agreement, which could cause all of the outstanding indebtedness under the facility to become immediately due and payable.

If we are unable to generate sufficient cash to repay our debt obligations when they become due and payable, we may not be able to obtain additional debt or equity financing on favorable terms, if at all, which may negatively affect our business operations and financial condition.

Under the Amended and Restated Loan and Security Agreement, we also have an obligation to pledge our equity interests in our subsidiaries. In addition, certain of our non-operating subsidiaries, which are subsidiaries other than those predominantly involved in advancing our development programs are also obligated to enter into a joinder agreement, whereby they are also required to comply with the terms of the Amended and Restated Loan and Security Agreement. In addition, our subsidiary, Eidos Therapeutics, Inc. is also party to a loan and security agreement with Silicon Valley Bank and Hercules Capital, Inc., under which the lenders have agreed to loan to Eidos up to $55.0 million and Eidos is required to make and maintain certain financial covenants, representations and warranties and other customary agreements and is subject to customary events of default. Any breach by us or Eidos of, or any event of default under, our respective loan agreements could result in a material adverse effect on our business, financial condition and operating results.

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or our guidance.

Our quarterly and annual operating results may fluctuate significantly in the future, which makes it difficult for us to predict our future operating results. Our operating results may fluctuate due to a variety of factors, many of which are outside of our control and may be difficult to predict, including but not limited to the following:

- the timing, results and cost of, and level of investment in, our clinical development activities for BBP-265, BBP-831, BBP-454 and BBP-631, and any other product candidates we may identify and pursue, which may change from time to time;
- the cost of manufacturing BBP-009 and the related materials or other product candidates that we may identify, which may vary depending on the quantity of production and the terms of agreements with manufacturers;
- our ability to conduct clinical trials of BBP-265, BBP-831, BBP-454 and BBP-631 in accordance with our plans and to obtain regulatory approval for BBP-265, BBP-831, BBP-454 and BBP-631 or other product candidates that we may identify, and the timing and scope of any such approvals we may receive;
- the timing and success or failure of clinical trials for competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners;
- expenditures that we or will or may incur to acquire or develop additional product candidates and technologies;
- our ability to attract, hire and retain qualified personnel;
- the level of demand for BBP-265, BBP-831, BBP-454, BBP-631 or other product candidates that we may identify, should they receive approval, which may vary significantly;
- future accounting pronouncements or changes in our accounting policies;

- the risk/benefit profile, cost and reimbursement policies with respect to BBP-265, BBP-831, BBP-454, BBP-631 or other product candidates that we may identify, if approved, and existing and potential future drugs that compete with our product candidates; and
- the changing and volatile U.S., European and global economic environments.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially.

Our future ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.

We have incurred substantial losses during our history and we do not expect to become profitable in the near future and we may never achieve profitability. To the extent that we continue to generate taxable losses, unused losses will carry forward to offset a portion of future taxable income, if any, subject to expiration of such carryforwards in the case of carryforwards generated prior to 2018. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, if a corporation undergoes an "ownership change," generally defined as a greater than 50 percentage point change (by value) in its equity ownership over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards, or NOLs, and other pre-change tax attributes (such as research and development tax credits) to offset its post-change income or taxes may be limited. Our prior equity offerings and other changes in our stock ownership may have resulted in such ownership changes. In addition, we may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which are outside of our control. As a result, if we earn net taxable income, our ability to use our pre-change NOLs to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. Additional limitations on our ability to utilize our NOLs to offset future taxable income may arise as a result of our corporate structure whereby NOLs generated by certain of our subsidiaries or controlled entities may not be available to offset taxable income earned by other subsidiaries, controlled entities or BridgeBio. In addition, under the Tax Act, the amount of post-2017 NOLs that we are permitted to deduct in any taxable year is limited to 80% of our taxable income in such year. The Tax Act generally eliminates the ability to carry back any NOLs to prior taxable years, while allowing post-2017 unused NOLs to be carried forward indefinitely. There is a risk that due to changes under the Tax Act, regulatory changes, or other unforeseen reasons, our existing NOLs could expire or otherwise be unavailable to offset future income tax liabilities. At the state level, there may also be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. For these reasons, we may not be able to realize a tax benefit from the use of our NOLs, even if we attain profitability.

Comprehensive tax reform legislation could adversely affect our business and financial condition.

On December 22, 2017, the Tax Act was signed into law. The Tax Act, among other things, contains significant changes to corporate taxation, including (i) reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, (ii) limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), (iii) limitation of the deduction for net operating losses to 80% of current year taxable income in respect of net operating losses generated during or after 2018 and elimination of net operating loss carrybacks, (iv) one-time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, (v) immediate deductions for certain new investments instead of deductions for depreciation expense over time, and (vi) modifying or repealing many business deductions and credits. Any federal net operating loss incurred in 2018 and in future years may now be carried forward indefinitely pursuant to the Tax Act. It is uncertain if and to what extent various states will conform to the newly enacted federal tax law. We will continue to examine the impact the Tax Act may have on our business.

We have never and do not currently intend to pay dividends on our common stock, and, consequently, our stockholders' ability to achieve a return on their investment will depend on appreciation in the price of our common stock.

We have never paid cash dividends on any of our capital stock and do not currently intend to pay any cash dividends on our common stock for the foreseeable future. In addition, pursuant to the Amended and Restated Loan and Security Agreement with Hercules, we are not permitted to declare or pay any cash dividends or make cash distributions on any class of our capital stock or any other equity interest, except in limited circumstances. We currently intend to invest our future earnings, if any, to fund our growth. Therefore, you are not likely to receive any dividends on your common stock for the foreseeable future. Since we do not intend to pay dividends, your ability to receive a return on your investment will depend on any future appreciation in the market value of our common stock. There is no guarantee that our common stock will appreciate or even maintain the price at which our holders have purchased it.

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

As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company. We are subject to the reporting requirements of the Exchange Act, which requires, among other things, that we file with the SEC, annual, quarterly and current reports with respect to our business and financial condition and that of our consolidated subsidiaries. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and Nasdaq to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices.

Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation-related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as "say on pay" and proxy access. Recent legislation permits emerging growth companies to implement many of these requirements over a longer period and up to five years from the pricing of our IPO. We intend to take advantage of this new legislation, but cannot guarantee that we will not be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

We expect the rules and regulations applicable to us as a public company to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition and results of operations. The increased costs will decrease our net income or increase our net loss, and may require us to reduce costs in other areas of our business, including our subsidiaries. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

As of December 31, 2019, the following are the material properties that we occupy:

Property Description	Location	Square Footage	Owned or Leased	Initial Lease Term End Date	Lease Extension Options
Office space	Palo Alto, CA	3,900	Leased	2020	Extended through 2023 in 2019
Office space	San Francisco, CA	10,552	Leased	2026	None
Office space	San Francisco, CA	10,000	Leased	2021	Three-year option to extend
Laboratory facility	Raleigh, NC	11,376	Leased	2024	Five-year option to extend

ITEM 3. LEGAL PROCEEDINGS

As of the date of this Annual Report on Form 10-K, we were not party to any material legal proceedings. In the future, we may become party to legal proceedings and claims arising in the ordinary course of business. Although the results of litigation and claims cannot be predicted with certainty, we do not believe we are party to any claim or litigation the outcome of which, if determined adversely to us, would individually or in the aggregate be reasonably expected to have a material adverse impact on our financial position, results of operations or cash flows. Regardless of the outcome, litigation can have an adverse effect 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

Our common stock began trading on Nasdaq under the symbol "BBIO" on June 27, 2019. Prior to that date, there was no public trading market for shares of our common stock.

Holders

As of February 24, 2020, there were 27 stockholders of record of our common stock. As many of our shares of common stock are held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of stockholders represented by these record holders.

Dividend Policy

We have never declared or paid any dividends and do not anticipate paying any dividends on our common stock in the foreseeable future.

Securities Authorized for Issuance Under Equity Compensation Plans

Information about our equity compensation plans in Item 12 of Part III of this Annual Report on Form 10-K is incorporated herein by reference.

Stock Performance Graph

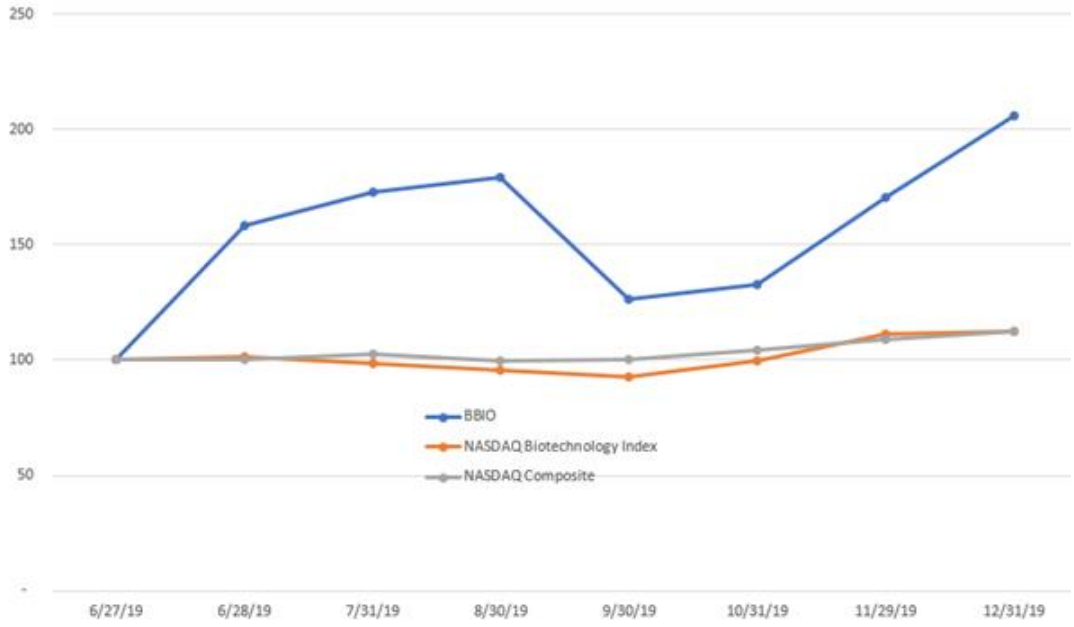
The graph set forth below compares the cumulative total stockholder return on our common stock for the period commencing on June 27, 2019 and ending on December 31, 2019, with the cumulative total return of the Nasdaq Composite Index and the Nasdaq Biotechnology Index over the same period. This graph assumes the investment of $100.00 on June 27, 2019 in each of our common stock at the IPO price, the Nasdaq Composite Index, and the Nasdaq Biotechnology Index, and assumes the reinvestment of dividends.

The comparisons shown in the graph below are based upon historical data. We caution that the stock price performance shown in the graph below is not necessarily indicative of, nor is it intended to forecast, the potential future performance of our common stock. Information used in the graph was obtained from sources believed to be reliable including Nasdaq, Bloomberg and Reuters, but we are not responsible for any errors or omissions in such information.

Notwithstanding anything to the contrary set forth in any of our previous or future filings under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, that might incorporate this Annual Report on Form 10-K or future filings made by us under those statutes, this Stock Performance Graph section is not "soliciting material," shall not be deemed filed with the SEC and shall not be deemed incorporated by reference into any of those prior filings or into any future filings made by us under those statutes.

COMPARISON OF CUMULATIVE TOTAL RETURN*

Among BridgeBio Pharma, Inc. the Nasdaq Composite Index, and Nasdaq Biotechnology Index



* $100 invested on June 27, 2019 in stock or index, including reinvestment of dividends.

Sales of Unregistered Securities

During the year ended December 31, 2019, we did not issue or sell any unregistered securities.

Issuer Purchases of Equity Securities

We have not made any purchases of our own equity securities for the year ended December 31, 2019.

ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA

The selected consolidated financial data below should be read in conjunction with Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" and Part II, Item 8, "Financial Statements and Supplementary Data," in this Annual Report on Form 10-K. The historical results are not necessarily indicative of the results to be expected in any future period.

	Year Ended December 31,		
	2019	2018	2017
	(in thousands, except share and per share data)		
Consolidated Statements of Operations Data:			
License revenue	$ 40,560	$ —	$ —
Operating expenses:			
Cost of license revenue	2,500	—	—
Research and development	209,947	140,073	30,556
General and administrative	94,353	43,587	13,302
Total operating expenses	306,800	183,660	43,858
Loss from operations	(266,240)	(183,660)	(43,858)
Other income (expense), net:			
Interest income	8,915	2,004	39
Interest expense	(8,765)	(2,547)	(13)
Gain on deconsolidation of PellePharm	—	19,327	—
Loss from ML Bio asset acquisition	(416)	—	—
Share in net loss of equity method investments	(20,869)	(275)	—
Other expense	(1,210)	(4,300)	—
Total other income (expense), net	(22,345)	14,209	26
Net loss	(288,585)	(169,451)	(43,832)
Net loss attributable to redeemable convertible noncontrolling interests and noncontrolling interests	27,998	38,702	13,267
Net loss attributable to common stockholders of BridgeBio	$ (260,587)	$ (130,749)	$ (30,565)
Net loss per share, basic and diluted	$ (2.48)	$ (2.12)	$ (1.00)
Weighted-average shares used in computing net loss per share, basic and diluted	105,099,089	61,767,414	30,598,983

	As of December 31,		
	2019	2018	2017
	(in thousands)		
Consolidated Balance Sheet Data:			
Cash and cash equivalents and marketable securities	$ 577,137	$ 436,086	$ 91,995
Working capital(1)	508,237	412,646	88,581
Total assets	631,679	464,941	98,044
Term loans, noncurrent	91,791	54,507	—
Other liabilities	3,527	495	312
Redeemable convertible noncontrolling interests	2,243	122	833
Common stock	124	92	51
Additional paid-in capital	848,107	494,231	134,495
Accumulated other comprehensive income	254	—	—
Accumulated deficit	(440,031)	(179,444)	(48,695)
Noncontrolling interests	65,279	62,361	2,498
Total stockholders' equity	473,733	377,240	88,349

(1) We define working capital as current assets less current liabilities. Refer to our consolidated balance sheets and notes to our financial statements for further details regarding our current assets and current liabilities.

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

You should read the following discussion and analysis of our financial condition and results of operations together with "Item 6. Selected Financial Data" and the financial statements and related notes included elsewhere in this Annual Report on Form 10-K.

This Annual Report on Form 10-K contains "forward-looking statements" within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended, (the "Exchange Act"). In some cases, you can identify these statements by forward-looking words such as "may," "will," "expect," "believe," "anticipate," "intend," "could," "should," "estimate," or "continue," and similar expressions or variations. Such forward-looking statements are subject to risks, uncertainties and other factors that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified below, and those discussed in the section titled "Risk Factors" included in this Annual Report on Form 10-K. The forward-looking statements in this Annual Report on Form 10-K represent our views as of the date of this Annual Report on Form 10-K. Except as may be required by law, we assume no obligation to update these forward-looking statements or the reasons that results could differ from these forward-looking statements. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Annual Report on Form 10-K.

Overview

We are a team of experienced drug discoverers, developers, and innovators working to create life-altering medicines that target well-characterized genetic diseases at their source. We founded BridgeBio in 2015 to identify and advance transformative medicines to treat patients who suffer from Mendelian diseases, which are diseases that arise from defects in a single gene, and cancers with clear genetic drivers. Our pipeline of over 20 development programs includes product candidates ranging from early discovery to late-stage development. Several of our programs target indications that we believe present the potential for our product candidate, if approved, to target portions of market opportunities of at least $1.0 billion in annual sales. We have initiated a rolling NDA submission for one of our product candidates, and have three product candidates in clinical trials that, if positive, we believe could support the filing of an application for marketing authorization.

We focus on genetic diseases because they exist at the intersection of high unmet patient need and tractable biology. Our approach is to translate research pioneered at academic laboratories and leading medical institutions into products that we hope will ultimately reach patients. We are able to realize this opportunity through a confluence of scientific advances: (i) identification of the genetic underpinnings of disease as more cost-efficient genome and exome sequencing becomes available; (ii) progress in molecular biology; and (iii) the development and maturation of longitudinal data and retrospective studies that enable the linkage of genes to diseases. We believe that this early-stage innovation represents one of the greatest practical sources for new drug creation.

Since our inception in 2015, we have focused substantially all of our efforts and financial resources on acquiring and developing product and technology rights, building our intellectual property portfolio and conducting research and development activities for our product candidates within our wholly-owned subsidiaries and controlled entities, including partially-owned subsidiaries and subsidiaries we consolidate based on our deemed majority control of such entities as determined using either the variable interest entity, or VIE model, or the voting interest entity, or VOE model. To support these activities, we and our wholly-owned subsidiary, BridgeBio Services, Inc., (i) identify and secure new programs, (ii) set up new wholly-owned subsidiaries and controlled entities, (iii) recruit key management team members, (iv) raise and allocate capital across the portfolio and (v) provide certain shared services, including accounting and human resources, as well as workspaces. We do not have any products approved for sale and have not generated any revenue from product sales. To date, we have funded our operations with proceeds from the sale of our equity securities and, to a lesser extent, debt borrowings.

On July 1, 2019, immediately prior to the completion of the initial public offering of our common stock (the IPO), we engaged in a series of transactions whereby BridgeBio Pharma LLC, or BBP LLC, became a wholly-owned subsidiary of BridgeBio Pharma, Inc., or BBP Inc., collectively with BBP LLC, BridgeBio. As part of the transactions, holders of Preferred Units, Founder Units, Common Units and Management Incentive Units of BBP LLC exchanged all outstanding units for an aggregate of 99,999,967 shares of common stock of BBP Inc.

On July 1, 2019, we completed the IPO. As part of the IPO, we issued and sold 23,575,000 shares of our common stock, which included 3,075,000 shares sold pursuant to the exercise of the underwriters' over-allotment option, at a public offering price of $17.00 per share. In July 2019, we received net proceeds of approximately $366.2 million from the IPO, after deducting underwriters' discounts and commissions of $28.1 million and offering costs of $6.5 million. As of December 31, 2019, we had cash, cash equivalents and marketable securities of $577.1 million or $385.9 million excluding Eidos.

Since our inception, we have incurred significant operating losses. For the years ended December 31, 2019, 2018 and 2017, we incurred net losses of $288.6 million, $169.5 million and $43.8 million, respectively. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of our product candidates at our wholly-owned subsidiaries and controlled entities. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years.

Financial Highlights

The following table summarizes our financial results:

	Year Ended December 31,			Change	
	2019	2018	2017	2019 vs 2018	2018 vs 2017
	(in thousands)				
License revenue	$ 40,560	$ —	$ —	$ 40,560	$ —
Total operating expenses	306,800	183,660	43,858	123,140	139,802
Loss from operations	(266,240)	(183,660)	(43,858)	(82,580)	(139,802)
Net loss	(288,585)	(169,451)	(43,832)	(119,134)	(125,619)
Net loss attributable to common stockholders of BridgeBio	(260,587)	(130,749)	(30,565)	(129,838)	(100,184)
Cash, cash equivalents and marketable securities	577,137	436,086	91,995	141,051	344,091

License revenue increased by $40.6 million in 2019 due mainly to the upfront payment received by Eidos upon execution of the Alexion License Agreement.

Total operating expenses and loss from operations increased by $123.1 million and $82.6 million, respectively, in 2019 and $139.8 million in 2018 mainly attributed to increase in external-related costs to support the progression in our research and development programs, which also contributed primarily to the increase in net loss and net loss attributable to common stockholders of BridgeBio.

During 2019, we received net proceeds of $366.2 million from the BridgeBio IPO, $36.9 million from term loans and $23.9 million from Eidos' at-the-market issuance of shares. In 2018, we received total net proceeds of $487.0 million from the Eidos IPO, issuances of our convertible preferred units and availment of term loans. As of December 31, 2019, we had cash, cash equivalents and marketable securities of $385.9 million excluding Eidos.

Basis of Presentation and Consolidation

Since our inception, we have created wholly-owned subsidiaries or made investments in certain controlled entities, including partially-owned subsidiaries for which we have majority voting interest under the VOE model or for which we are the primary beneficiary under the VIE model, which we refer to collectively as our consolidated entities. Ownership interests in entities over which we have significant influence, but not a controlling financial interest, are accounted for as cost and equity method investments. Ownership interests in consolidated entities that are held by entities other than us are reported as redeemable convertible noncontrolling interests and noncontrolling interests in our consolidated balance sheets. Losses attributed to redeemable convertible noncontrolling interests and noncontrolling interests are reported separately in our consolidated statements of operations.

We have either created or made investments in entities that are either wholly or partially-owned subsidiaries and VIEs. Refer to Note 2 to our consolidated financial statements for a list of our VIEs.

Factors Affecting Comparability

Our historical financial condition and results of operations for the periods presented may not be comparable, either between periods or going forward due to the factors described below.

Eidos Therapeutics, Inc. Transactions:

In February 2018, we entered into a note and warrant purchase agreement with Eidos pursuant to which Eidos issued a convertible promissory note, or the Eidos Note, with the principal amount of $10.0 million and a warrant to purchase a number of shares of preferred stock equal to $4.0 million at the price paid by investors in the next equity financing, or the Eidos Warrant. In March 2018, we transferred 10% or $1.0 million of our interest in the Eidos Note and the Eidos Warrant to a minority stockholder of Eidos. In March 2018, the Eidos Note was redeemed into shares of Series B redeemable convertible preferred stock of Eidos at a 30% discount to the price paid by other investors. In conjunction with these transactions, Eidos recognized a preferred stock warrant liability, tranche liability and an embedded derivative, which were recorded at fair value at inception and remeasured to fair value at each subsequent reporting date until the instruments were settled. For the year ended December 31, 2018, we recorded $1.3 million in other income (expense), net in the consolidated statements of operations related to these 2018 Eidos financing transactions. All of these Eidos financial instruments were settled during 2018.

In June 2018, Eidos completed its initial public offering, or the Eidos IPO. All redeemable convertible preferred stock of Eidos was converted into common stock at the closing of the Eidos IPO. As part of the Eidos IPO, we purchased common stock in the amount of $17.0 million. The Eidos Warrant was also net exercised upon the completion of the Eidos IPO. We previously determined that Eidos was a controlled VIE as of December 31, 2017 and through its initial public offering in June 2018, at which time we determined that Eidos is no longer a VIE. In May 2019, we purchased 1,103,848 shares of Eidos common stock from an existing Eidos stockholder for $28.6 million in a private purchase transaction. In July 2019, we purchased 882,353 shares of Eidos common stock from an existing Eidos investor for $26.4 million in a private purchase transaction. Subsequent to the Eidos IPO and through December 31, 2019, we held a majority voting interest in Eidos and consolidate Eidos under the VOE model.

PellePharm, Inc. Transactions:

PellePharm entered into a series of agreements, or the LEO Agreement, with LEO Pharma A/S, or LEO, in November 2018. As part of the LEO Agreement, we granted LEO an exclusive, irrevocable option, or the LEO Call Option, to acquire all of PellePharm’s shares held by us. The LEO Call Option is exercisable by LEO on or before the occurrence of certain events relating to PellePharm’s clinical development programs and no later than July 30, 2021. We account for the LEO Call Option as a current liability in our consolidated financial statements because we are obligated to sell our shares in PellePharm to LEO at a pre-determined price, if the option is exercised. The fair value of the LEO Call Option on issuance in November 2018 was $1.9 million and increased to $3.0 million as of December 31, 2018 and to $4.1 million as of December 31, 2019. We will remeasure the LEO Call Option to fair value at each subsequent balance sheet date until the LEO Call Option is either exercised or expires. We previously determined that we were the primary beneficiary of PellePharm, as of December 31, 2017 and through the date of execution of the LEO Agreement in November 2018. At the time of execution, we concluded that we are no longer the primary beneficiary of, and thus deconsolidated, PellePharm. Subsequent to the LEO Agreement, we account for our retained investment in common and preferred stock of PellePharm under the equity method and cost method,

respectively. Upon adoption ASU 2016-01 in 2019 (see Note 2 to our consolidated financial statements), we concluded that our investment in preferred stock of PellePharm did not have a readily available fair value. As a result we started to measure the adjusted cost basis of our retained investment in PellePharm's preferred stock of PellePharm at cost less impairment plus or minus observable price changes. Since our investment in common stock was reduced to zero during the first quarter of 2019 as a result of applying the equity method, we subsequently adjusted the cost basis of our preferred stock investment by recording our percentage of net losses consistent with our preferred stock ownership percentage of 61.9% until the adjusted cost basis was also reduced to zero during the remaining period of 2019.

Results of Operations

License Revenue

License revenue includes the recognition of upfront payments received in connection with our license agreements. The level of license revenue to be recognized depends in part upon the estimated recognition period of the upfront payments allocated to continuing performance obligations, the achievement of milestones and other contingent events, the amount of research and development work, and entering into new collaboration agreements, if any.

License revenue for 2019 was $40.6 million arising primarily from the recognition of the upfront payment received by Eidos upon execution of the Alexion License Agreement. Eidos determined that the exclusive license granted to Alexion was a distinct performance obligation and, as of the effective date, Eidos had provided all necessary information to Alexion to benefit from the license and the license term had begun. There were no revenues in 2018 and 2017.

Operating Expenses

Cost of License Revenue

Cost of license revenue represents sublicensing fees payable under the Stanford License in connection with the Alexion License Agreement and was $2.5 million in 2019. There were no costs of license revenue in 2018 and 2017.

Research and Development Expenses

	Year Ended December 31,			Change	
	2019	2018	2017	2019 vs 2018	2018 vs 2017
			(in thousands)		
Research and development	$ 209,947	$ 140,073	$ 30,556	$ 69,874	$ 109,517

Research and development costs consist primarily of external costs, such as fees paid to consultants, contractors, CMOs and CROs in connection with our preclinical and clinical development activities and are tracked on a program-by-program basis. License fees and other costs incurred after a product candidate has been designated and that are directly related to the product candidate are included in the specific program expense. License fees and other costs incurred prior to designating a product candidate are included in early stage research programs.

The following table summarizes our research and development expenses by program incurred for the following periods:

	Year Ended December 31,		
	2019	2018	2017
	(in thousands)		
BBP-265 (Eidos)(1)	$ 46,662	$ 28,539	$ 9,286
BBP-831 (QED)	65,096	42,726	444
BBP-870 (Origin)	19,501	7,532	—
BBP-631 (Adrenas)	14,744	8,848	446
BBP-812 (ASPA)	14,612	3,333	—
BBP-589 (PTR)	8,001	3,329	2,005
BBP-454 (TheRas)	5,853	3,663	997
BBP-009 (PellePharm)(2)	—	17,975	10,995
Other programs including early stage	35,478	24,128	6,383
Total	$ 209,947	$ 140,073	$ 30,556

(1) Amounts presented above may differ from the financial statements of Eidos due to intercompany income and expenses, which are eliminated in the consolidated financial statements of BridgeBio for all periods presented.

(2) Results for PellePharm are not included in our research and development expenses subsequent to the deconsolidation date in November 2018.

Research and development expense increased by $69.9 million in 2019 and $109.5 million in 2018 primarily due to increase in external-related costs to support progression in our research and development programs including increasing research pipeline.

General and Administrative Expenses

	Year Ended December 31,			Change	
	2019	2018	2017	2019 vs 2018	2018 vs 2017
	(in thousands)				
General and administrative	$ 94,353	$ 43,587	$ 13,302	$ 50,766	$ 30,285

General and administrative expenses increased by $50.8 million in 2019 and $30.3 million in 2018 due to increase in headcount to support the growth of our operations and external-related costs incurred as a result of preparation for the SEC listing and continuing compliance as a public company. General and administrative expenses increased by $30.3 million in 2018 mainly due to increase in professional and consulting services largely due to our expanding operations.

Other Income (Expense), Net

Interest Income

Interest income consists of interest income earned on our cash equivalents and marketable securities and the increase of $6.9 million in 2019 and $2.0 million in 2018 was attributed primarily to the additional income earned from higher investment balances following the initial public and debt offerings.

Interest Expense

Interest expense consists primarily of interest expense incurred under our term loans with Hercules Capital, Inc., or Hercules and the increase of $6.2 million in 2019 and $2.5 million in 2018 was primarily attributed to increase in term loan amounts.

(Loss) Gain from Equity Investments

	Year Ended December 31,			Change	
	2019	2018	2017	2019 vs 2018	2018 vs 2017
			(in thousands)		
Gain on deconsolidation of PellePharm	$ —	$ 19,327	$ —	$ (19,327)	$ 19,327
Share in net loss of equity method investments	(20,869)	(275)	—	(20,594)	(275)
Total	$ (20,869)	$ 19,052	$ —	(39,921)	19,052

Loss from equity investments increased by $20.6 million in 2019 and $0.3 million in 2018 primarily due to our share of losses from our investment in PellePharm totaling $17.1 million in 2019 and $0.3 million in 2018. We recognize our share of losses from the PellePharm equity method investment as incurred. After our equity method investment was reduced to zero during the three months ended March 31, 2019, we recognized our percentage of net losses consistent with our preferred stock ownership percentage until the investment was also reduced to zero during the remaining period of 2019.

In 2018, after the execution of the LEO Agreement, we concluded that PellePharm should be deconsolidated and we recorded our retained interest in PellePharm at fair value, resulting in a gain of $19.3 million being recognized during the year ended December 31, 2018. There were no such transactions in 2017.

Other Expense

Other expense consists mainly of changes in fair value of the LEO Call Option liability. We account for the LEO Call Option as a current liability as we have the obligation to sell our PellePharm shares to LEO at a pre-determined price if the LEO Call Option is exercised. The LEO Call Option can be exercised at any time through the maturity date. The LEO Call Option was recorded at fair value on the date the option agreement was entered into with LEO in November 2018. The LEO Call Option is subject to remeasurement to fair value at each balance sheet date until the LEO Call Option is either exercised or expires. The LEO call option expense decrease of $1.9 million in 2019 was due to change in fair value. The increase of $3.0 million in 2018 was due to initial recognition and change in fair value.

Other expense in 2018 consists primarily of the change in fair value of the Eidos financial instruments issued and settled in 2018 and other miscellaneous expenses unrelated to our core operations.

Income Taxes

Prior to the tax-free reorganization, BBP LLC was treated as a pass-through entity for U.S. federal income tax purposes, and as such, was generally not subject to U.S. federal income tax at the entity level. Rather, the tax liability with respect to its taxable income was passed through to its unitholders. Therefore, no provision or liability for federal income tax has been included in our consolidated financial statements prior to the reorganization. For our consolidated entities, income taxes are accounted for under the asset and liability method as described below.

Upon the Reorganization on July 1, 2019, we became subject to typical corporate U.S. federal and state income taxation. To the extent we incur operating losses in the periods in which we are treated as a corporation for tax purposes, net operating loss carryforwards may generally be used by us to offset cash taxes on future taxable income, subject to applicable tax laws.

As of December 31, 2019, we had net operating losses of approximately $393.4 million and $160.0 million for federal and state income tax purposes, respectively, available to reduce future taxable income, if any. The federal net operating losses generated prior to 2018 will begin to expire in 2037 and losses generated after 2018 will carryover indefinitely. State net operating losses will generally begin to expire in 2037. As of December 31, 2019, we had federal research and development credit carryforwards of $17.6 million, which will expire beginning in 2037 if not utilized. As of December 31, 2019, we had state research and development credit carryforwards of $2.6 million. The state research and development tax credits have no expiration date.

A valuation allowance is provided for deferred tax assets where the recoverability of the assets is uncertain. The determination to provide a valuation allowance is dependent upon the assessment of whether it is more likely than not that sufficient future taxable income will be generated to utilize the deferred tax assets. Based on the weight of the available evidence, which includes our consolidated entities' historical operating losses and forecast of future losses, we have provided a full valuation allowance against the deferred tax assets resulting from the tax loss and credits carried forward.

Utilization of the net operating loss and credit carryforwards may be subject to a substantial annual limitation due to an ownership change limitation as provided by section 382 of the Code, and similar state provisions. The annual limitation may result in the expiration of net operating losses and credits before utilization. In the event that we have a change of ownership, utilization of the net operating loss and tax credit carryforwards may be restricted.

Net Loss Attributable to Redeemable Convertible Noncontrolling Interests and Noncontrolling Interests

Net loss attributable to redeemable convertible noncontrolling interests and noncontrolling interests in our consolidated statements of operations consists of the portion of the net loss of those consolidated entities that is not allocated to us. Changes in the amount of net loss attributable to noncontrolling interests are directly impacted by changes in the net loss of our consolidated entities and are the result of ownership percentage changes. Refer to Note 7 to our consolidated financial statements.

Net loss attributable to redeemable convertible noncontrolling interests and noncontrolling interests was $28.0 million in 2019, compared to $38.7 million in 2018 and $13.3 million in 2017.

Liquidity and Capital Resources

We have historically financed our operations primarily through the sale of our equity securities, debt borrowings and revenue from collaboration arrangements. As of December 31, 2019, we had cash, cash equivalents and marketable securities of $577.1 million or $385.9 million excluding Eidos. The funds that were held by our wholly-owned subsidiaries and controlled entities are available for specific entity usage, except in limited circumstances. The cash, cash equivalents and marketable securities of $191.2 million as of December 31, 2019 belonging to Eidos may only be used solely by Eidos or its subsidiaries, if any. As of December 31, 2019, our outstanding debt was $91.8 million, net of debt issuance costs and accretion or $75.7 million excluding Eidos.

Since our inception, we have incurred significant operating losses. For the years ended December 31, 2019, 2018 and 2017, we incurred net losses of $288.6 million, $169.5 million and $43.8 million, respectively. We had an accumulated deficit as of December 31, 2019 of $440.0 million. We expect to continue to incur net losses over the next several years as we continue our drug discovery efforts and incur significant preclinical and clinical development costs related to our current research and development programs as well as costs related to commercial launch readiness. In particular, to the extent we advance our programs into and through later-stage clinical studies without a partner, we will incur substantial expenses.

Our current business plan is also subject to significant uncertainties and risks as a result of, among other factors, our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of our product candidates at our consolidated entities.

We expect our cash and cash equivalents and marketable securities will fund our operations for at least the next 12 months based on current operating plans and financial forecasts. If our current operating plans or financial forecasts change, we may require additional funding sooner in the form of public or private equity offerings, debt financings or additional collaborations and licensing arrangements. However, future financing may not be available in amounts or on terms acceptable to us, if at all.

Sources of Liquidity

Initial public offerings

In June 2018, our controlled subsidiary, Eidos, completed its U.S. initial public offering of its common stock of which net proceeds received were $95.5 million. As of December 31, 2019, we held 24,575,501 shares of common stock of Eidos. All cash and cash equivalents held by Eidos are restricted and can be applied solely to fund the operations of Eidos.

On July 1, 2019, we completed the IPO of our common stock. As part of the IPO, we issued and sold 23,575,000 shares of our common stock, which included 3,075,000 shares sold pursuant to the exercise of the underwriters' over-allotment option, at a public offering price of $17.00 per share. We received net proceeds of approximately $366.2 million from the IPO, after deducting underwriters' discounts and commissions of $28.1 million and offering costs of $6.5 million.

Term Loans

Hercules Loan and Security Agreement

In June 2018, we executed a Loan and Security Agreement with Hercules Capital, Inc. ("Hercules"), under which we borrowed $35.0 million ("Tranche I"). The term of the loan was approximately 42 months, with a maturity date of January 1, 2022 (the "Maturity Date"). No principal payments were due during an interest-only period, commencing on the initial borrowing date and continuing through July 1, 2020 (the "Amortization Date"). The outstanding balance of the loan was to be repaid monthly beginning on the Amortization Date and extending through the Maturity Date. The term loan bears interest at a floating rate equal to the greater of: (i) the prime rate as reported in the Wall Street Journal plus 4.35% and (ii) 9.35% (9.85% as of December 31, 2018 based on the prime rate as of that date), payable monthly.

In December 2018, we executed the First Amendment to the Loan and Security Agreement, whereby we borrowed an additional $20.0 million ("Tranche II") to increase the total principal balance outstanding to $55.0 million. Upon draw of the additional $20.0 million, the interest-only period on the entire facility was extended until January 1, 2021 (the "Amended Amortization Date"). The outstanding balance of the original loan of $35.0 million and the additional borrowing of $20.0 million is to be repaid monthly beginning on the Amended Amortization Date and extending through July 1, 2022 (the "Amended Maturity Date"). The additional $20.0 million loan bears interest at a floating rate equal to the greater of: (i) the prime rate as reported in the Wall Street Journal plus 3.35% and (ii) 9.10% (9.10% as of December 31, 2018), payable monthly.

On the earliest to occur of (i) the Amended Maturity Date, (ii) the date we prepay the outstanding principal amount of the Amended Hercules Term Loan or (iii) the date the outstanding principal amount of the Amended Hercules Term Loan otherwise becomes due, we will owe Hercules an end of term charge equal to 6.35% of the principal amount of the original $35.0 million term loan, or $2.2 million, and 5.75% of the principal amount of the incremental $20.0 million term loan, or $1.2 million. These amounts will be accrued over the term of the loan using the effective-interest method.

In May 2019, we executed the Second Amendment to the Loan and Security Agreement (the "Amended Hercules Term Loan") whereby we borrowed an additional $20.0 million ("Tranche III") to increase the total principal balance outstanding to $75.0 million.

In July 2019, the completion of our IPO triggered certain provisions of the Amended Hercules Term Loan. We received an option to pay up to 1.5% of scheduled cash pay interest on the entire facility as payment in kind, or PIK Interest, with such cash pay interest paid as PIK Interest at a 1:1.2 ratio. The interest-only period will continue through July 1, 2021 (the "Amended Amortization Date") and the entire facility received a maturity date of January 1, 2023 (the "Amended Maturity Date"). The outstanding balance of the Amended Hercules Term Loan is to be repaid by us on a monthly basis beginning on the Amended Amortization Date and extending through the Amended Maturity Date.

The interest rate for the Amended Hercules Term Loan was established as follows: (1) Tranche I bears interest at a floating rate equal to the greater of: (i) the prime rate as reported in the Wall Street Journal plus 3.85% and (ii) 8.85% (8.85% as of December 31, 2019 based on the prime rate as of that date), payable monthly; (2) Tranche II bears interest at a floating rate equal to the greater of: (i) the prime rate as reported in the Wall Street Journal plus 2.85% and (ii) 8.60% (8.60% as of December 31, 2019), payable monthly; and (3) Tranche III bears interest at a floating rate equal to the greater of: (i) the prime rate as reported in the Wall Street Journal plus 3.10% and (ii) 9.10% (9.10% as of December 31, 2019), payable monthly.

The Amended Hercules Term Loan contains customary representations and warranties, events of default, and affirmative and negative covenants for a term loan facility of this size and type. However, Hercules imposes no liquidity covenants on us and Hercules cannot limit or restrict our ability to dispose of assets, make investments, or make acquisitions. As pledged collateral for our obligations under the Amended Hercules Term Loan, we granted Hercules a security interest in all our assets or personal property , including all equity interests owned or hereafter acquired by us. Further, at Hercules' sole discretion we must make a mandatory prepayment equal to 75% of net cash proceeds received from the sale or licensing of any pledged or collateral assets, including intellectual property, of a consolidated entity owned by us, or the repurchase or redemption of any pledged collateral by certain specified operating companies. None of our consolidated entities are a party to, nor provide any credit support or other security in connection with the Amended Hercules Term Loan.

Silicon Valley Bank (SVB) and Hercules Loan Agreement

On November 13, 2019, Eidos entered into the SVB and Hercules Loan Agreement. The SVB and Hercules Loan Agreement provides for up to $55.0 million in term loans to be drawn in three tranches as follows: (i) Tranche A loan of $17.5 million, (ii) Tranche B loan of up to $22.5 million which is available to be drawn until October 31, 2020, and (iii) Tranche C loan of up to $15.0 million available to be drawn upon a clinical trial milestone. The Tranche C loan is available to be drawn until September 30, 2021. The Tranche A loan of $17.5 million was drawn on November 13, 2019. There have not been any additional draws on the other tranches as of December 31, 2019.

The Tranche A loan bears interest at a fixed rate equal to the greater of either (i) 8.50% or (ii) 3.25% plus the prime rate as reported in The Wall Street Journal (8.50% as of December 31, 2019). The Tranche A loan repayment schedule provides for interest only payments until November 1, 2021, followed by consecutive equal monthly payments of principal and interest commencing on this date continuing through the maturity date of October 2, 2023.

The Tranche A loan also provides for a $0.3 million commitment fee that was paid at closing and a final payment charge equal to 5.95% multiplied by the amount funded to be paid when the loan becomes due or upon prepayment of the facility. If Eidos elects to prepay the Tranche A loan, there is also a prepayment fee of between 0.75% and 2.50% of the principal amount being prepaid depending on the timing and circumstances of prepayment. The Tranche A loan is secured by substantially all of Eidos' assets, except Eidos' intellectual property, which is the subject of a negative pledge.

Cash Flows

The following table summarizes our cash flows during the periods indicated:

	Year Ended December 31,			Change	
	2019	2018	2017	2019 vs 2018	2018 vs 2017
	(in thousands)				
Net cash used in operating activities	$ (253,587)	$ (136,643)	$ (40,488)	$ (116,944)	$ (96,155)
Net cash used in investing activities	(217,253)	(21,036)	(464)	(196,217)	(20,572)
Net cash provided by financing activities	398,792	501,548	112,983	(102,756)	388,565
Net (decrease) increase in cash and cash equivalents and restricted cash	$ (72,048)	$ 343,869	$ 72,031	$ (415,917)	$ 271,838

Net Cash Flows Used in Operating Activities

Net cash used in operating activities was $253.6 million in 2019, consisting primarily of net loss of $288.6 million, adjusted for non-cash items such as $21.4 million in stock-based compensation expense and $20.9 million for our share of losses of our equity method investments as well as net cash outflow of $10.9 million related to changes in operating assets and liabilities. The $10.9 million net cash outflow related to changes in operating assets and liabilities was attributed mainly to an increase of $16.9 million in other assets, an increase of $13.5 million in prepaid expenses and other assets and a decrease of $4.7 million in accounts payable mostly due to payments of CROs' and CMOs' expenses for increased research activities, offset by changes in liabilities primarily due to an increase in accrued research and development liabilities of $12.0 million and an increase in accrued compensation and benefits of $9.3 million.

Net cash used in operating activities was $136.6 million in 2018, consisting primarily of net loss of $169.5 million, adjusted for non-cash charges such as $19.3 million gain on the deconsolidation of PellePharm, $17.9 million acquired in-process research and development assets, $6.1 million stock-based compensation expense and $3.0 million of expense related to the LEO Call Option as well as net cash inflow of $22.5 million related to changes in operating assets and liabilities. The $22.5 million net cash inflow related to changes in operating assets and liabilities was primarily due to an increase of $16.7 million in accounts payable and an increase of $5.8 million in accrued research and development liabilities as a result of increased research and development activities and timing of payments to vendors.

Net cash used in operating activities was $40.5 million in 2017, consisting primarily of net loss of $43.8 million, adjusted for non-cash charges of $1.8 million stock-based compensation expense and net cash inflow of $1.2 million related to changes in operating assets and liabilities.

Net Cash Flows Used in Investing Activities

Net cash used in investing activities was $217.3 million in 2019, consisting primarily of $212.9 million used to purchase marketable securities, $2.6 million related to purchase of property and equipment and $2.5 million paid for in-progress research and development assets acquired in connection with asset acquisitions.

Net cash used in investing activities was $21.0 million in 2018, consisting primarily of $16.0 million paid for in-progress research and development assets acquired through asset acquisitions, $2.2 million related to purchase of property and equipment and $2.9 million decrease in cash and cash equivalents resulting from the deconsolidation of PellePharm.

Net cash used in investing activities was $0.5 million in 2017 due to purchases of property and equipment.

Net Cash Flows Provided by Financing Activities

Net cash provided by financing activities was $398.8 million in 2019, consisting primarily of the net proceeds from our IPO of $366.2 million, availment of term loans of $36.9 million, at-the-market issuance of noncontrolling interest by Eidos of $23.9 million, issuance of noncontrolling interest in Eidos to Alexion of $23.3 million and stock option exercises of $1.8 million, offset by $55.0 million payment in relation to our purchase of common stock of Eidos from a noncontrolling interest holder.

Net cash provided by financing activities was $501.5 million in 2018, consisting primarily of the net proceeds from the issuance of our redeemable convertible preferred units of $335.0 million, the issuance of common stock in connection with the Eidos IPO of $95.5 million, third-party investors redeemable noncontrolling interests of $58.4 million and term loans of $56.4 million, offset by our purchase of a noncontrolling interest in Eidos for $44.2 million. The net cash proceeds from the Eidos IPO may only be used solely by Eidos or its subsidiaries, if any.

Net cash provided by financing activities was $113.0 million in 2017, consisting primarily of the net proceeds from the issuance of our redeemable convertible preferred units of $107.0 million and issuance of promissory notes of $4.0 million.

Contractual Obligations

The following table summarizes our contractual obligations as of December 31, 2019:

	Payments Due by Period				
	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years	Total
	(in thousands)				
Operating lease obligations	$ 2,811	$ 4,327	$ 2,758	$ 1,815	$ 11,711
Build-to-suit lease obligation	8,000	—	—	—	8,000
Term loans	—	80,903	11,597	—	92,500
Interest on term loans and final end of term payments	8,260	11,609	5,885	—	25,754
Total contractual obligations	$ 19,071	$ 96,839	$ 20,240	$ 1,815	$ 137,965

In March 2019, Eidos entered into an amendment to its office lease. The amended lease commenced in August 2019 and Eidos increased its rentable facilities to 10,552 square feet. The amended lease is for 87 months and has $6.4 million of payments under this lease.

In May 2019, we executed the Second Amendment to the Loan and Security Agreement (the “Amended Hercules Term Loan”) whereby we borrowed an additional $20.0 million (“Tranche III”) to increase the total principal balance outstanding to $75.0 million.

In July 2019, the completion of our IPO triggered certain provisions of the Amended Hercules Term Loan. The outstanding balance of the Amended Hercules Term Loan is to be repaid by us monthly beginning on July 1, 2021 and extending through January 1, 2023. Immediately prior to completion of our IPO, these dates were January 1, 2021 and July 1, 2022, respectively.

In November 2019, Eidos entered into the SVB and Hercules Loan Agreement. The SVB and Hercules Loan Agreement provides for up to $55.0 million in term loans to be drawn in three tranches. The Tranche A loan of $17.5 million was drawn on November 13, 2019. There have not been any additional draws on the other tranches as of December 31, 2019.

We have performance-based milestone compensation arrangements with certain employees, whose vesting is contingent upon meeting various regulatory and development milestones, with fixed monetary amounts known at inception that can be settled in the form of cash or fully vested common stock of the Company at our sole election, upon achievement of each contingent milestones. As of December 31, 2019, the potential milestone compensation amount is up to $34.0 million. Since the timing of the payments is contingent on the occurrence of these performance-based milestones, these payments are not included in the contractual obligations above.

In December 2019, we entered into a manufacturing agreement in which we agreed to pay a one-time fee of $10.0 million for a dedicated manufacturing suite. The amount included in the table above as ‘Build-to-suit lease obligation’ pertains to the unpaid portion of as of December 31, 2019.

We have certain payment obligations under various license and collaboration agreements. Under these agreements we are required to make milestone payments upon successful completion and achievement of certain intellectual property, clinical, regulatory and sales milestones. The payment obligations under the license and collaboration agreements are contingent upon future events such as our achievement of specified development, clinical, regulatory and commercial milestones, and we will be required to make development milestone payments and royalty payments in connection with the sale of products developed under these agreements. As the achievement and timing of these future milestone payments are not probable or estimable, such amounts have not been included in our consolidated balance sheet as of December 31, 2019, or in the contractual obligations table above.

In addition, we enter into agreements in the normal course of business with contract research organizations and other vendors for clinical trials and with vendors for preclinical studies and other services and products for operating purposes, which are generally cancelable upon written notice. These payments are not included in the contractual obligations table above.

Off-Balance Sheet Arrangements

During the periods presented, we did not have any off-balance sheet arrangements. While we have investments classified as VIEs, their purpose is not to provide off-balance sheet financing.

Critical Accounting Polices and Estimates

Our management’s discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with United States generally accepted accounting principles. The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, as well as revenues and expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our consolidated financial statements for the periods in this report.

Licensing Arrangements

When we enter into licensing agreements with pharmaceutical and biotechnology partners, we assess whether the arrangements fall within the scope of Accounting Standards Codification (ASC) 808, *Collaborative Arrangements* (ASC 808) based on whether the arrangements involve joint operating activities and whether both parties have active participation in the arrangement and are exposed to significant risks and rewards. To the extent that the arrangement falls within the scope of ASC 808, we assess whether the payments between us and our partner fall within the scope of other accounting literature. If we conclude that payments from the partner to us represent consideration from a customer, such as license fees and contract research and development activities, we account for those payments within the scope of ASC 606, *Revenue from Contracts with Customers*. However, if we conclude that our partner is not a customer for certain activities and associated payments, such as for certain collaborative research, development, manufacturing and commercial activities, we record such payments as a reduction of research and development expense or general and administrative expense, based on where we record the underlying expense.

Revenue Recognition

We recognize license revenue based on the facts and circumstances of each contractual agreement and includes recognition of upfront fees and milestone payments. At the inception of each agreement, we determine which promises represent distinct performance obligations, for which management must use significant judgment. Additionally, at inception and at each reporting date thereafter, we must determine and update, as appropriate, the transaction price, which includes variable consideration such as development milestones. We must use judgment to determine when to include variable consideration in the transaction price such that inclusion of such variable consideration will not result in a significant reversal of revenue recognized when the contingency surrounding the variable consideration is resolved. We must also allocate the arrangement consideration to performance obligations based on their relative standalone selling prices, which we generally base on our best estimates and which require significant judgment. For example, in estimating the standalone selling prices for granting licenses for our drug candidate, our estimates may include revenue forecasts, clinical development timelines and costs, discount rates and probabilities of clinical and regulatory success. For performance obligations satisfied over time, we recognize revenue based on our estimates of expected future costs or other measures of progress.

Research and Development Expenses

Research and development costs are expensed as incurred. Research and development costs consist of salaries, benefits, and other personnel related costs, including stock-based compensation expense, laboratory supplies, preclinical studies, clinical trials and related clinical manufacturing costs, costs related to manufacturing preparations, fees paid to other entities to conduct certain research and development activities on our behalf, and allocated facility and other related costs. Non-refundable advance payments for goods or services that will be used or rendered for future research and development activities are deferred and capitalized as either prepaid expenses or other noncurrent assets depending on the timing of delivery of the goods or performance of the services.

Accrued Research and Development Liabilities

We record accruals for estimated costs of research and development activities conducted by third-party service providers, which include the conduct of preclinical studies and clinical trials, and contract manufacturing activities. We record the estimated costs of research and development activities based upon the estimated amount of services provided but not yet invoiced, and include these costs in accrued research and development liabilities in the consolidated balance sheet and within research and development expense in the consolidated statements of operations. These costs are a significant component of our research and development expenses.

Examples of estimated research and development expenses that we accrue include:

- fees paid to CROs in connection with preclinical and toxicology studies and clinical studies;
- fees paid to investigative sites in connection with clinical studies;
- fees paid to CMOs in connection with the production of product and clinical study materials; and
- professional service fees for consulting and related services.

We base our expense accruals related to clinical studies on our estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and CROs that conduct and manage clinical studies on our behalf. The financial terms of these agreements vary from contract to contract and may result in uneven payment flows. Payments under some of these contracts depend on factors, such as the successful enrollment of patients and the completion of clinical study milestones. Our service providers generally invoice us monthly in arrears for services performed. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If we do not identify costs that we have begun to incur or if we underestimate or overestimate the level of services performed or the costs of these services, our actual expenses could differ from our estimates. We record advance payments to service providers as prepaid assets.

We record accruals for the estimated costs of our contract manufacturing activities performed by third parties. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows to our vendors. Payments under the contracts include upfront payments and milestone payments, which depend on factors such as the achievement of the completion of certain stages of the manufacturing process. For purposes of recognizing expense, we assess whether we consider the production process sufficiently defined to be considered the delivery of a good or the delivery of a service, where processes and yields are developing and less certain. If we consider the process to be the delivery of a good, we recognize expense when the drug product is delivered, or we otherwise bear risk of loss. If we consider the process to be the delivery of a service, we recognize expense based on our best estimates of the contract manufacturer's progress towards completion of the stages in the contract. We base our estimates on the best information available at the time. However, additional information may become available to us which may allow us to make a more accurate estimate in future periods. In this event, we may be required to record adjustments to research and development expenses in future periods when the actual level of activity becomes more certain. Any increases or decreases in cost are generally considered to be changes in estimates and will be reflected in research and development expenses in the period identified.

To date, we have not experienced significant changes in our estimates of accrued research and development liabilities after a reporting period. However, due to the nature of estimates, there is no assurance that we will not make changes to our estimates in the future as we become aware of additional information about the status or conduct of our clinical studies and other research activities.

VIE and VOE

We consolidate those entities in which we have a direct or indirect controlling financial interest based on either the VIE model or the VOE model.

VIEs are entities that, by design, either: (i) lack sufficient equity to permit the entity to finance its activities without additional support from other parties; or (ii) have equity holders that do not have the ability to make significant decisions relating to the entity's operations through voting rights, or do not have the obligation to absorb the expected losses, or do not have the right to receive the residual returns of the entity.

The primary beneficiary of a VIE is required to consolidate the assets and liabilities of the VIE. The primary beneficiary is the party that has both the power to direct the activities of the VIE that most significantly impact the VIE's economic performance and the obligation to absorb losses or the right to receive benefits from the VIE that could potentially be significant to the VIE through its interest in the VIE.

To assess whether we have the power to direct the activities of a VIE that most significantly impact the VIE's economic performance, we consider all of the facts and circumstances, including our role in establishing the VIE and our ongoing rights and responsibilities. Our assessment includes identifying the activities that most significantly impact the VIE's economic performance and identifying which party, if any, has power over those activities. In general, the parties that make the most significant decisions affecting the VIE (management and representation on the board of directors) and have the right to unilaterally remove those decision-makers are deemed to have the power to direct the activities of a VIE.

To assess whether we have the obligation to absorb losses of the VIE or the right to receive benefits from the VIE that could potentially be significant to the VIE, we consider all of our economic interests, which primarily include equity investments in preferred and common stock and issuance of notes that are convertible into preferred stock, that are deemed to be variable interests in the VIE. This assessment requires us to apply judgment in determining whether these interests, in the aggregate, are considered potentially significant to the VIE. Factors considered in assessing the significance include: the design of the VIE, including its capitalization structure; subordination of interests; payment priority; relative share of interests held across various classes within the VIE's capital structure; and the reasons why the interests are held by us.

At the VIE inception, we determine whether we are the primary beneficiary and if the VIE should be consolidated based on the facts and circumstances. We then perform ongoing reassessments at each reporting period on whether changes in the facts and circumstances regarding our involvement with the VIE results in a change to our consolidation conclusion.

Entities that do not qualify as a VIE are assessed for consolidation under the VOE model. Under the VOE model, we consolidate an entity if we determine that we, directly or indirectly, have greater than 50% of the voting shares and that other equity holders in such entities do not have substantive voting, participating or liquidation rights.

Stock-Based Compensation

Prior to the IPO, because there was no public market for our units as we were a private company, our board of managers determined the fair value of management incentive units and common units by considering a number of objective and subjective factors, including having contemporaneous and retrospective valuations of our equity performed by a third-party valuation specialist, valuations of comparable peer public companies, sales of our redeemable convertible preferred units, operating and financial performance, the lack of liquidity of our units, and general and industry-specific economic outlook. The fair value of our management incentive unit and common unit were determined by our board of managers until the IPO. Following our IPO, the closing sale price per share of our common stock as reported on the Nasdaq Global Select Market on the date of grant is used to determine the exercise price per share of our stock-based awards to purchase common stock.

Stock-based compensation is measured at the grant date for all stock-based awards made to employees and non-employees based on the fair value of the awards and is recognized as an expense on a straight-line basis over the requisite service period, which is generally the vesting period. We have elected to recognize the actual forfeitures by reducing the stock-based compensation in the same period as the forfeitures occur. Stock-based compensation for awards made to non-employees was measured as per ASC 505-50 until we early adopted Accounting Standards Update, or ASU, *2018-07 Compensation-Stock Compensation (Topic 718)* on January 1, 2017. We remeasured our equity-classified non-employee awards for which a measurement date had not been established at their adoption-based fair-value based measurement (January 1, 2017), and determined there was no cumulative-effect adjustment to our opening accumulated deficit. Subsequent to the adoption of ASU 2018-07, we account for non-employee awards similar to employee awards.

Prior to the IPO, we granted management incentive units and common units to employees and non-employees. These awards generally have only a service condition and vest over a period of up to five years. The awards have accelerated vesting upon a fundamental transaction, which is defined as (i) a merger, recapitalization or other business combination, (ii) a sale, transfer, exclusive license or disposition of BBP LLC or (iii) a final liquidation, dissolution, winding-up or termination of BBP LLC. Our consolidated entities have granted stock options that are exercisable in the underlying entity's equity and have issued restricted stock awards in the underlying entity's equity to employees and non-employees. None of the awards issued by the consolidated entities are issued for BBP LLC members' capital. These awards generally have only a service condition and generally vest over a period of up to four years.

On June 22, 2019, we adopted the 2019 Stock Option and Incentive Plan (the "2019 Plan"), which became effective on June 25, 2019. The 2019 Plan provides for the grant of stock-based incentive awards, including common stock options and other stock-based awards.

On November 13, 2019, we adopted the 2019 Inducement Equity Plan (the "2019 Inducement Plan"). The 2019 Inducement Plan provides for the grant stock-based awards to induce highly-qualified prospective officers and employees who are not currently employed by BridgeBio or its Subsidiaries to accept employment and to provide them with a proprietary interest in the Company, including common stock options and other stock-based awards. We were authorized to issue 1,000,000 shares of common stock for inducement awards under the 2019 Inducement Plan, which may be allocated among stock options, awards of restricted common stock, restricted common units and other stock-based awards.

Milestone Compensation Arrangements with Employees

We have performance-based milestone compensation arrangements with certain employees, whose vesting is contingent upon meeting various regulatory and development milestones, with fixed monetary amounts known at inception that can be settled in the form of cash or fully vested common stock of the Company at our sole election, upon achievement of each contingent milestones. Compensation expense arising from each milestone is recognized when the specific contingent milestone is probable of achievement and is measured at each reporting period. Under ASC 718, *Compensation – Stock Compensation*, we will classify the milestone compensation arrangements as liability-classified awards when it is probable of achievement because of the possible fixed monetary amounts settlement outcomes. The arrangements would also result in settlement with a variable number of shares based on the then-current stock price at grant date should we elect to settle in equity.

Income Taxes

Prior to the tax-free reorganization, BBP LLC was treated as a pass-through entity for U.S. federal income tax purposes, and as such, was generally not subject to U.S. federal income tax at the entity level. Rather, the tax liability with respect to its taxable income was passed through to its unitholders. Therefore, no provision or liability for federal income tax has been included in our consolidated financial statements prior to the reorganization. For our consolidated entities, income taxes are accounted for under the asset and liability method as described below.

Upon the Reorganization on July 1, 2019, we became subject to typical corporate U.S. federal and state income taxation. To the extent we incur operating losses in the periods in which we are treated as a corporation for tax purposes, net operating loss carryforwards may generally be used by us to offset cash taxes on future taxable income, subject to applicable tax laws.

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax base and net operating loss and tax credit carryforwards. Deferred tax assets and liabilities are determined based upon the difference between the consolidated financial statement carrying amounts and the tax basis of assets and liabilities and are measured using the enacted tax rate expected to apply to taxable income in the years in which the differences are expected to be reversed. Deferred tax assets are reduced by a valuation allowance if it is more likely than not that some portion or all of the deferred tax asset will not be realized.

For U.S. federal income tax purposes, we are required to file separate U.S. federal income tax returns for the consolidated entities. We are required to assess stand-alone valuation allowances separately in each entity even though we consolidate their financial results in our consolidated financial statements. We continue to file combined state tax returns in most jurisdictions. As a result, we continue to assess the state portion of our valuation allowance for those jurisdictions on a consolidated basis.

We evaluate our deferred tax assets regularly to determine whether adjustments to the valuation allowance are appropriate due to changes in facts or circumstances, such as changes in expected future pre-tax earnings, tax law, interactions with taxing authorities and developments in case law. In making this evaluation, we rely on our recent history of pre-tax earnings. Our material assumptions are our forecasts of future pre-tax earnings and the nature and timing of future deductions and income represented by the deferred tax assets and liabilities, all of which involve the exercise of significant judgment. Although we believe our estimates are reasonable, we are required to use significant judgment in determining the appropriate amount of valuation allowance recorded against our deferred tax assets.

We recognize uncertain income tax positions at the largest amount that is more likely than not to be sustained upon audit by the relevant taxing authority. Changes in recognition or measurement are reflected in the period in which judgment occurs. BridgeBio’s consolidated entities’ policy is to recognize interest and penalties related to the underpayment of income taxes as a component of the provision for income taxes. To date, there have been no interest or penalties recorded in relation to unrecognized tax benefits.

JOBS Act and Emerging Growth Company Status

We are an emerging growth company, as defined in the JOBS Act. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have elected to use the extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that (i) we are no longer an emerging growth company or (ii) we affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our consolidated financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

We will remain an emerging growth company until the earliest of (i) December 31, 2024, (ii) the last day of our first fiscal year in which we have total annual gross revenues of $1.07 billion or more, (iii) the date on which we have issued more than $1.0 billion of non-convertible debt instruments during the previous three fiscal years, or (iv) the date on which we are deemed a “large accelerated filer” under the rules of the SEC with at least $700.0 million of outstanding equity securities held by non-affiliates as of the immediately preceding June 30.

Recent Accounting Pronouncements

See Note 2, “Summary of Significant Accounting Policies—Recently Adopted Accounting Pronouncements” to our consolidated financial statements appearing under Part II, Item 8 for more information.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate sensitivities. The primary objective of our investment activities is to preserve our capital to fund our operations. We also seek to maximize income from our investments without assuming significant risk. To achieve our objectives, we maintain a portfolio of cash equivalents and investments in a variety of marketable securities of high credit quality.

As of December 31, 2019, we held cash, cash equivalents and marketable securities of $577.1 million. Our cash equivalents consist of amounts invested in money market accounts, such as money market funds and overnight repurchase agreements collateralized with securities issued by the U.S. government or its agencies. Our marketable securities consisted of commercial paper, corporate debt securities and U.S. government agency securities. We do not enter into investments for trading or speculative purposes and have not used any derivative financial instruments to manage our interest rate risk exposure. We have not been exposed nor do we anticipate being exposed to material risks due to changes in interest rates. A hypothetical 100 basis point change in interest rate during any of the periods presented would not have had a material impact on our financial statements. We do not believe that our cash, cash equivalents or marketable securities have a significant risk of default or illiquidity.

As of December 31, 2019, we had $75.0 million in variable rate debt outstanding. The Amended Hercules Term Loan matures in January 2023, with interest-only monthly payments until July 2021. Tranche I bears interest at a floating rate equal to the greater of: (i) the prime rate as reported in the Wall Street Journal plus 3.85% and (ii) 8.85% (8.85% as of December 31, 2019); Tranche II bears interest at a floating rate of equal to the greater of: (i) the prime rate as reported in the Wall Street Journal plus 2.85% and (ii) 8.60% (8.60% as of December 31, 2019); and Tranche III bears interest at a floating rate of equal to the greater of: (i) the prime rate as reported in the Wall Street Journal plus 3.10% and (ii) 9.10% (9.10% as of December 31, 2019).

The Silicon Valley Bank and Hercules Loan Agreement entered into by Eidos had a principal balance of $17.5 million as of December 31, 2019 and bears interest at a fixed rate. Our cash flows on this debt are not subject to variability as a result of changes in interest rates.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

	Page
Consolidated Balance Sheets as of December 31, 2019 and December 31, 2018	142
Consolidated Statements of Operations for each of the three years in the period ended December 31, 2019	143
Consolidated Statements of Comprehensive Loss for each of the three years in the period ended December 31, 2019	144
Consolidated Statements of Redeemable Convertible Noncontrolling Interests and Stockholders' Equity for each of the three years in the period ended December 31, 2019	145
Consolidated Statements of Cash Flows for each of the three years in the period ended December 31, 2019	146
Notes to Consolidated Financial Statements	147
Supplementary Financial Data (unaudited)	197
Report of Independent Registered Public Accounting Firm	198

BRIDGEBIO PHARMA, INC.

Consolidated Balance Sheets
(in thousands, except shares and per share amounts)

	December 31,	
	2019	**2018**
Assets		(1)
Current assets:		
Cash and cash equivalents	$ 363,773	$ 436,086
Short-term marketable securities	182,220	—
Prepaid expenses and other current assets	22,629	9,137
Total current assets	568,622	445,223
Property and equipment, net	5,625	1,575
Long-term marketable securities	31,144	—
Investments in nonconsolidated entities	—	17,050
Other assets	26,288	1,093
Total assets	$ 631,679	$ 464,941
Liabilities, Redeemable Convertible Noncontrolling Interests and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 8,852	$ 13,509
Accrued compensation and benefits	13,317	4,047
Accrued research and development liabilities	20,896	8,915
Accrued professional services	2,222	772
Accrued distributions to stockholders	—	997
LEO call option liability	4,078	3,009
Build-to-suit lease obligation	8,000	—
Other accrued liabilities	3,020	1,328
Total current liabilities	60,385	32,577
Term loans, noncurrent	91,791	54,507
Other liabilities	3,527	495
Total liabilities	155,703	87,579
Commitments and contingencies (Note 9)		
Redeemable convertible noncontrolling interests	2,243	122
Stockholders' equity:		
Undesignated preferred stock, $0.001 par value; 25,000,000 and no shares authorized as of December 31, 2019 and 2018; no shares issued and outstanding as of December 31, 2019 and 2018	—	—
Common stock, $0.001 par value; 500,000,000 and 97,412,870 shares authorized as of December 31, 2019 and 2018, respectively; 123,658,287 and 92,057,704 shares issued and outstanding as of December 31, 2019 and 2018, respectively	124	92
Additional paid-in capital	848,107	494,231
Accumulated other comprehensive income	254	—
Accumulated deficit	(440,031)	(179,444)
Total BridgeBio stockholders' equity	408,454	314,879
Noncontrolling interests	65,279	62,361
Total stockholders' equity	473,733	377,240
Total liabilities, redeemable convertible noncontrolling interests and stockholders' equity	$ 631,679	$ 464,941

The accompanying notes are an integral part of these consolidated financial statements.

(1) The consolidated balance sheet as of December 31, 2018 is derived from the audited consolidated financial statements as of that date and was retroactively adjusted, including shares and per share amounts, as a result of the Reorganization. See Note 3 to the consolidated financial statements for additional details.

BRIDGEBIO PHARMA, INC.

Consolidated Statements of Operations
(in thousands, except shares and per share amounts)

	Year Ended December 31,		
	2019	**2018**	**2017**
License revenue	$ 40,560	$ —	$ —
Operating expenses:			
Cost of license revenue	2,500	—	—
Research and development	209,947	140,073	30,556
General and administrative	94,353	43,587	13,302
Total operating expenses	306,800	183,660	43,858
Loss from operations	(266,240)	(183,660)	(43,858)
Other income (expense), net:			
Interest income	8,915	2,004	39
Interest expense	(8,765)	(2,547)	(13)
Gain on deconsolidation of PellePharm	—	19,327	—
Loss from ML Bio asset acquisition	(416)	—	—
Share in net loss of equity method investments	(20,869)	(275)	—
Other expense	(1,210)	(4,300)	—
Total other income (expense), net	(22,345)	14,209	26
Net loss	(288,585)	(169,451)	(43,832)
Net loss attributable to redeemable convertible noncontrolling interests and noncontrolling interests	27,998	38,702	13,267
Net loss attributable to common stockholders of BridgeBio	$ (260,587)	$ (130,749)	$ (30,565)
Net loss per share, basic and diluted	$ (2.48)	$ (2.12)	$ (1.00)
Weighted-average shares used in computing net loss per share, basic and diluted (2)	105,099,089	61,767,414	30,598,983

The accompanying notes are an integral part of these consolidated financial statements.

(2) The weighted-average shares used in computing net loss per share, basic and diluted were retroactively adjusted as a result of the Reorganization. See Note 3 to the consolidated financial statements for additional details.

BRIDGEBIO PHARMA, INC.

Consolidated Statements of Comprehensive Loss
(in thousands)

	Year Ended December 31,		
	2019	**2018**	**2017**
Net loss	$ (288,585)	$ (169,451)	$ (43,832)
Other comprehensive income:			
Unrealized gain on available-for-sale securities	254	—	—
Comprehensive loss	(288,331)	(169,451)	(43,832)
Comprehensive loss attributable to redeemable convertible noncontrolling interests and noncontrolling interests	27,998	38,702	13,267
Comprehensive loss attributable to common stockholders of BridgeBio	$ (260,333)	$ (130,749)	$ (30,565)

The accompanying notes are an integral part of these consolidated financial statements.

BRIDGEBIO PHARMA, INC.
Consolidated Statements of Redeemable Convertible Noncontrolling Interests and Stockholders' Equity
(in thousands, except shares and per share amounts)

	Redeemable Convertible Noncontrolling Interests	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total BridgeBio Stockholders' Equity	Noncontro-lling Interests	Total Stockholders' Equity
Balances as of December 31, 2016 (1)	$ 1,520	21,043,992	$ 21	$ 32,998	$ —	$ (18,130)	$ 14,889	$ 2,595	$ 17,484
MyoKardia distributions	—	—	—	(2,148)	—	—	(2,148)	—	(2,148)
Issuance and vesting of restricted common stock and related stock-based compensation expense	—	1,316,657	1	540	—	—	541	—	541
Issuance of common stock at $2.22 per share, net of issuance costs of $0	—	5,417,297	5	12,015	—	—	12,020	—	12,020
Issuance of common stock at $4.21 per share, net of issuance costs of $818	—	22,595,374	23	95,159	—	—	95,182	—	95,182
Issuance of common stock at $4.25 per share through conversion of promissory note	—	941,474	1	3,999	—	—	4,000	—	4,000
Capital transaction upon Merger	—	—	—	4,532	—	—	4,532	—	4,532
Deemed dividends to common stockholders	—	—	—	(4,532)	—	—	(4,532)	—	(4,532)
Repayment on nonrecourse notes	—	—	—	132	—	—	132	—	132
Issuance (repurchase) of noncontrolling interest	2,839	—	—	—	—	—	—	1,444	1,444
Transfers to (from) and conversion of noncontrolling interest	(769)	—	—	(8,200)	—	—	(8,200)	8,969	769
Net loss	(2,757)	—	—	—	—	(30,565)	(30,565)	(10,510)	(41,075)
Balances as of December 31, 2017 (1)	833	51,314,794	51	134,495	—	(48,695)	85,851	2,498	88,349
Vesting of restricted common stock and related stock-based compensation expense	—	1,827,623	2	3,181	—	—	3,183	—	3,183
Issuance of common stock at $4.29 per share, net of issuance costs of $0	—	8,455,861	8	36,291	—	—	36,299	—	36,299
Issuance of common stock at $9.82 per share, net of issuance costs of $541	—	30,459,426	31	298,668	—	—	298,699	—	298,699
Issuance (repurchase) of noncontrolling interest	62,363	—	—	—	—	—	—	55,245	55,245
Transfers to (from) noncontrolling interest	(51,698)	—	—	21,596	—	—	21,596	30,102	51,698
Deconsolidation of PellePharm	1,154	—	—	—	—	—	—	688	688
Net loss	(12,530)	—	—	—	—	(130,749)	(130,749)	(26,172)	(156,921)
Balances as of December 31, 2018 (1)	122	92,057,704	92	494,231	—	(179,444)	314,879	62,361	377,240
Issuance of common stock and restricted stock awards and associated stock-based compensation expense	—	7,960,917	8	10,894	—	—	10,902	—	10,902
Repayment of nonrecourse notes	—	—	—	179	—	—	179	—	179
Stock-based compensation expense related to stock-option and incentive plan	—	—	—	3,937	—	—	3,937	—	3,937
Stock-based compensation expense related to employee stock ownership plan	—	—	—	351	—	—	351	—	351
Issuance of common stock at $17.00 per share in connection with the initial public offering, net of underwriter discounts and issuance costs of $34,538	—	23,575,000	24	366,213	—	—	366,237	—	366,237
Exercise of common stock options	—	949	—	16	—	—	16	—	16
Issuance of common stock under ESPP	—	63,717	—	921	—	—	921	—	921
Unrealized gains on available-for-sale securities	—	—	—	—	254	—	254	—	254
Issuance (repurchase) of noncontrolling interest	3,196	—	—	—	—	—	—	1,206	1,206
Transfers to (from) noncontrolling interest	1,803	—	—	(28,635)	—	—	(28,635)	26,832	(1,803)
Net loss	(2,878)	—	—	—	—	(260,587)	(260,587)	(25,120)	(285,707)
Balances as of December 31, 2019	$ 2,243	123,658,287	$ 124	$ 848,107	$ 254	$ (440,031)	$ 408,454	$ 65,279	$ 473,733

The accompanying notes are an integral part of these consolidated financial statements.

(1) The consolidated balances as of December 31, 2018, 2017 and 2016 are derived from the audited consolidated financial statements as of that date and were retroactively adjusted, including shares and per share amounts, as a result of the Reorganization. See Note 3 to the consolidated financial statements for additional details.

BRIDGEBIO PHARMA, INC.

Consolidated Statements of Cash Flows
(in thousands)

	Year Ended December 31,		
Operating activities:	**2019**	**2018**	**2017**
Net loss	$ (288,585)	$ (169,451)	$ (43,832)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation	21,374	6,067	1,841
Gain on deconsolidation of PellePharm	—	(19,327)	—
Share in net loss of equity method investments	20,869	275	—
Fair value of equity method investment	(3,819)	—	—
Accretion of term loans and convertible promissory notes	1,509	783	—
Acquired in-process research and development assets	3,560	17,922	—
LEO call option expense	1,069	3,009	—
Change in fair value of Eidos financial instruments	—	1,146	—
Other noncash adjustments	1,351	442	260
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	(13,492)	(6,100)	(4,301)
Other assets	(16,929)	(843)	(92)
Accounts payable	(4,657)	16,700	1,577
Accrued compensation and benefits	9,270	3,396	1,131
Accrued research and development liabilities	11,981	5,785	2,650
Accrued professional services	1,450	454	(346)
Other accrued liabilities	1,527	2,917	356
Other liabilities	(65)	182	268
Net cash used in operating activities	(253,587)	(136,643)	(40,488)
Investing activities			
Purchases of marketable securities	(212,899)	—	—
Decrease in cash and cash equivalents resulting from deconsolidation of PellePharm	—	(2,858)	—
Cash paid for in-process research and development assets acquired	(2,500)	(16,000)	—
Cash and cash equivalents acquired in ML Bio asset acquisition	784	—	—
Purchases of property and equipment	(2,638)	(2,178)	(464)
Net cash used in investing activities	(217,253)	(21,036)	(464)
Financing activities			
Proceeds from issuance of common stock in connection with the initial public offering of the Corporation in 2019 and Eidos in 2018, net of underwriting discounts and commissions	366,237	95,536	—
Proceeds from issuance of noncontrolling interest to Alexion (Note 13)	23,309	—	—
Proceeds from issuance of promissory notes	—	1,000	4,000
Proceeds from repayment of nonrecourse notes	179	—	132
Proceeds from term loans, net of issuance costs	36,939	56,438	—
Proceeds from at-the-market issuance of noncontrolling interest by Eidos	23,927	—	—
Proceeds from the issuance of redeemable convertible preferred units, net of issuance costs	—	334,998	107,019
Proceeds from third-party investors in redeemable convertible noncontrolling interests	1,500	58,430	2,839
Proceeds from repayment of the loans received by noncontrolling interest shareholder	—	37	—
MyoKardia distributions	(997)	—	(1,151)
Repurchase of noncontrolling interest	(55,011)	(44,234)	—
Repayment of term loans	—	(1,097)	—
Proceeds from BridgeBio common stock issuances under ESPP	921	—	—
Proceeds from stock option exercises	1,788	440	144
Net cash provided by financing activities	398,792	501,548	112,983
Net (decrease) increase in cash, cash equivalents and restricted cash	(72,048)	343,869	72,031
Cash, cash equivalents and restricted cash at beginning of period	436,245	92,376	20,345
Cash, cash equivalents and restricted cash at end of period	$ 364,197	$ 436,245	$ 92,376
Supplemental Disclosures of Cash Flow Information:			
Cash paid for interest	$ 6,092	$ 1,574	$ —
Supplemental Disclosures of Non-Cash Investing and Financing Information:			
Tenant improvement paid by landlord	$ 2,097	$ —	$ —
Conversion of promissory note upon issuance of Series C redeemable convertible preferred units	$ —	$ —	$ 4,000
Transfers (from) to noncontrolling interest (Note 7)	$ (28,635)	$ 21,596	$ (8,200)
Build-to-suit funding liability accrual (Note 14)	$ 8,000	$ —	$ —
Fair value of success fee derivative at issuance of Eidos Term Loan	$ 1,148	$ —	$ —
Conversion of redeemable noncontrolling interest into noncontrolling interest	$ —	$ 12,252	$ —
Conversion of promissory note into redeemable convertible noncontrolling interest	$ —	$ 1,005	$ —
Capital transaction upon Merger	$ —	$ —	$ 4,532
Fair value of redeemable convertible noncontrolling interest issued for acquired in-process research and development assets	$ —	$ 1,922	$ —

The accompanying notes are an integral part of these consolidated financial statements.

1. Organization and Description of Business

BridgeBio Pharma, Inc. (the "Corporation") was formed as a Delaware corporation on May 17, 2019 for the purpose of completing an initial public offering of the Corporation's common stock (the "IPO") and related organizational transactions (the "Reorganization") in order to carry on the business of BridgeBio Pharma LLC ("BBP LLC"). The Corporation, the reporting entity in these consolidated financial statements, and BBP LLC, the predecessor reporting entity before the completion of the Reorganization and the Corporation's wholly-owned subsidiary after the completion of the Reorganization, are collectively referred to as BridgeBio.

Since inception, BridgeBio has either created wholly-owned subsidiaries or has made investments in certain controlled entities, including partially-owned subsidiaries for which BridgeBio has a majority voting interest and variable interest entities ("VIEs") for which BridgeBio is the primary beneficiary (collectively, "we", "our", "us"). BridgeBio is headquartered in Palo Alto, California.

BridgeBio was established to identify and advance transformative medicines to treat patients who suffer from Mendelian diseases, which are diseases that arise from defects in a single gene, and cancers with clear genetic drivers. BridgeBio's pipeline of programs spans early discovery to late-stage development.

Reorganization and Initial Public Offering

On July 1, 2019, the Corporation closed the IPO of its common stock. As part of the IPO, the Corporation issued and sold 23,575,000 shares of its common stock, which included 3,075,000 shares sold pursuant to the exercise of the underwriters' over-allotment option, at a public offering price of $17.00 per share. The Corporation received net proceeds of approximately $366.2 million from the IPO, after deducting underwriters' discounts and commissions of $28.1 million and offering costs of $6.5 million.

Upon the closing of the IPO on July 1, 2019, BridgeBio completed the Reorganization, whereby all unitholders of BBP LLC exchanged their units for shares of common stock of the Corporation, and BBP LLC became a wholly-owned subsidiary of the Corporation. Subsequent to the Reorganization, as the sole managing member, the Corporation operates and controls all of BBP LLC's businesses and affairs. See Note 3 for additional details.

The results of operations and cash flows prior to the IPO closing on July 1, 2019 relate to BBP LLC, its subsidiaries and controlled entities. Subsequent to the IPO closing, the information relates to the Corporation, its subsidiaries and controlled entities. All share and per share amounts in these consolidated financial statements and related notes have been retroactively adjusted, where applicable, for all periods presented to give effect to the exchange ratio applied in connection with the Reorganization. See Note 3 for additional details.

2. Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

The consolidated financial statements include the accounts of BridgeBio Pharma, Inc., its wholly owned subsidiaries and controlled entities, all of which are denominated in U.S. dollars. All intercompany balances and transactions have been eliminated in consolidation.

The consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States ("GAAP") and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for a fair statement of our financial position, our results of operations and comprehensive loss, and our cash flows for the periods presented. The results of operations for the years ended December 31, 2019, 2018 and 2017 are not necessarily indicative of the results to be expected for the year ending December 31, 2020 or for any other future annual or interim period.

Factors Affecting Comparability

Our historical financial condition and results of operations for the periods presented may not be comparable, either between periods or going forward due to the factors described below.

Eidos Therapeutics, Inc. Transactions:

In February 2018, we entered into a note and warrant purchase agreement with Eidos pursuant to which Eidos issued a convertible promissory note, or the Eidos Note, with the principal amount of $10.0 million and a warrant to purchase a number of shares of preferred stock equal to $4.0 million at the price paid by investors in the next equity financing, or the Eidos Warrant. In March 2018, we transferred 10% or $1.0 million of our interest in the Eidos Note and the Eidos Warrant to a minority stockholder of Eidos. In March 2018, the Eidos Note was redeemed into shares of Series B redeemable convertible preferred stock of Eidos at a 30% discount to the price paid by other investors. In conjunction with these transactions, Eidos recognized a preferred stock warrant liability, tranche liability and an embedded derivative, which were recorded at fair value at inception and remeasured to fair value at each subsequent reporting date until the instruments were settled. For the year ended December 31, 2018, we recorded $1.3 million in other income (expense), net in the consolidated statements of operations related to these 2018 Eidos financing transactions. All of these Eidos financial instruments were settled during 2018.

In June 2018, Eidos completed its initial public offering, or the Eidos IPO. All redeemable convertible preferred stock of Eidos was converted into common stock at the closing of the Eidos IPO. As part of the Eidos IPO, we purchased common stock in the amount of $17.0 million. The Eidos Warrant was also net exercised upon the completion of the Eidos IPO. We previously determined that Eidos was a controlled VIE as of December 31, 2017 and through its initial public offering in June 2018, at which time we determined that Eidos is no longer a VIE. In May 2019, we purchased 1,103,848 shares of Eidos common stock from an existing Eidos stockholder for $28.6 million in a private purchase transaction. In July 2019, we purchased 882,353 shares of Eidos common stock from an existing Eidos investor for $26.4 million in a private purchase transaction. Subsequent to the Eidos IPO and through December 31, 2019, we held a majority voting interest in Eidos and consolidate Eidos under the VOE model.

PellePharm, Inc. Transactions:

PellePharm entered into a series of agreements, or the LEO Agreement, with LEO Pharma A/S, or LEO, in November 2018. As part of the LEO Agreement, we granted LEO an exclusive, irrevocable option, or the LEO Call Option, to acquire all of PellePharm's shares held by us. The LEO Call Option is exercisable by LEO on or before the occurrence of certain events relating to PellePharm's clinical development programs and no later than July 30, 2021. We account for the LEO Call Option as a current liability in our consolidated financial statements because we are obligated to sell our shares in PellePharm to LEO at a pre-determined price, if the option is exercised. The fair value of the LEO Call Option on issuance in November 2018 was $1.9 million and increased to $3.0 million as of December 31, 2018 and increased to $4.1 million as of December 31, 2019. The change in fair value of the LEO Call Option is recorded as part of other expense in our consolidated statements of operations. We remeasure the LEO Call Option to fair value at each subsequent balance sheet date until the LEO Call Option is either exercised or expires. We previously determined that we were the primary beneficiary of PellePharm, as of December 31, 2017 and through the date of execution of the LEO Agreement in November 2018. At the time of execution, we concluded that we are no longer the primary beneficiary of, and thus deconsolidated, PellePharm. Subsequent to the LEO Agreement, we account for our retained investment in common and preferred stock of PellePharm under the equity method and cost method, respectively. Upon adoption ASU 2016-01 in 2019 (see *Recently Adopted Accounting Pronouncements*), we concluded that our investment in preferred stock of PellePharm did not have a readily available fair value. As a result we started to measure the adjusted cost basis of our retained investment in PellePharm's preferred stock at cost less impairment plus or minus observable price changes. Since our investment in common stock was reduced to zero during the first quarter of 2019 as a result of applying the equity method, we subsequently adjusted the cost basis of our preferred stock investment by recording our percentage of net losses consistent with our preferred stock ownership percentage of 61.9% until the adjusted cost basis was also reduced to zero during the remaining period of 2019.

Variable Interest Entities and Voting Interest Entities

BridgeBio consolidates those entities in which it has a direct or indirect controlling financial interest based on either the Variable Interest Entity ("VIE") model or the Voting Interest Entity ("VOE") model.

VIEs are entities that, by design, either (i) lack sufficient equity to permit the entity to finance its activities without additional subordinated financial support from other parties; or (ii) have equity investors that do not have the ability to make significant decisions relating to the entity's operations through voting rights, or do not have the obligation to absorb the expected losses, or do not have the right to receive the residual returns of the entity.

The primary beneficiary of a VIE is required to consolidate the assets and liabilities of the VIE. The primary beneficiary is the party that has both (i) the power to direct the activities of the VIE that most significantly impact the VIE's economic performance; and (ii) the obligation to absorb losses or the right to receive benefits from the VIE that could potentially be significant to the VIE through its interest in the VIE.

To assess whether BridgeBio has the power to direct the activities of a VIE that most significantly impact the VIE's economic performance, BridgeBio considers all the facts and circumstances, including its role in establishing the VIE and its ongoing rights and responsibilities. This assessment includes identifying the activities that most significantly impact the VIE's economic performance and identifying which party, if any, has power over those activities. In general, the parties that make the most significant decisions affecting the VIE (management and representation on the Board of Directors) and have the right to unilaterally remove those decision-makers are deemed to have the power to direct the activities of a VIE.

To assess whether BridgeBio has the obligation to absorb losses of the VIE or the right to receive benefits from the VIE that could potentially be significant to the VIE, BridgeBio considers all of its economic interests, which primarily include equity investments in preferred and common stock and issuance of notes that are convertible into preferred stock, that are deemed to be variable interests in the VIE. This assessment requires BridgeBio to apply judgment in determining whether these interests, in the aggregate, are considered potentially significant to the VIE. Factors considered in assessing the significance include: the design of the VIE, including its capitalization structure; subordination of interests; payment priority; relative share of interests held across various classes within the VIE's capital structure; and the reasons why the interests are held by BridgeBio.

At the VIE's inception, BridgeBio determines whether it is the primary beneficiary and if the VIE should be consolidated based on the facts and circumstances. BridgeBio then performs on-going reassessments of the VIE based on reconsideration events and reevaluates whether a change to the consolidation conclusion is required each reporting period. Refer to Note 6.

Entities that do not qualify as a VIE are assessed for consolidation under the VOE model. Under the VOE model, BridgeBio consolidates the entity if it determines that it, directly or indirectly, has greater than 50% of the voting shares and that other equity holders do not have substantive voting, participating or liquidation rights. Refer to Note 6.

We have either created or made investments in entities that are either wholly or partially-owned subsidiaries and VIEs. The following are the VIEs as of December 31, 2019 and 2018:

Variable Interest Entities	Relationship as of December 31, 2019	Date Control First Acquired	Ownership % as of December 31, 2019 (unaudited)	Ownership % as of December 31, 2018
Fortify Therapeutics, Inc. (”Fortify”)	Controlled VIE	June 2018	99.7%	100.0%
Calcilytix Therapeutics, Inc. ("Calcilytix")	Controlled VIE	December 2018	98.9%	100.0%
Audition Therapeutics, Inc. ("Audition")	Controlled VIE	May 2019	64.5%	—
Molecular Skin Therapeutics, Inc. (”MOST”)	Controlled VIE	July 2016	64.8%	61.7%
TheRas, Inc. (”Theras”)	Controlled VIE	August 2016	99.6%	100.0%
Quartz Therapeutics, Inc. (”Quartz”)	Controlled VIE	October 2016	89.0%	89.0%
PellePharm, Inc. (”PellePharm”)(1)	VIE	December 2016	43.3%	43.3%
Navire Pharma, Inc. (”Navire”)	Controlled VIE	February 2017	78.6%	78.8%
CoA Therapeutics, Inc. (”CoA”)	Controlled VIE	February 2017	99.5%	99.5%
Dermecular Therapeutics, Inc. (”Dermecular”)	Controlled VIE	April 2017	87.6%	87.6%
Phoenix Tissue Repair, Inc. (”PTR”)	Controlled VIE	July 2017	65.5%	56.7%
QED Therapeutics, Inc. (”QED”)	Controlled VIE	January 2018	97.8%	94.4%
Adrenas Therapeutics, Inc. (”Adrenas”)	Controlled VIE	January 2018	90.1%	90.1%
Orfan Biotech, Inc. (”Orfan”)	Controlled VIE	January 2018	91.7%	85.1%
Ferro Therapeutics, Inc. (”Ferro”)	Controlled VIE	March 2018	90.9%	89.4%
Origin Biosciences, Inc. (”Origin”)	Controlled VIE	April 2018	99.6%	100.0%
Venthera, Inc. (”Venthera”)	Controlled VIE	April 2018	83.2%	82.0%
Aspa Therapeutics, Inc. (”Aspa”)	Controlled VIE	June 2018	91.0%	92.5%
ML Bio Solutions, Inc. (”ML Bio”)	Controlled VIE	July 2019	50.6%	—

(1) Subsequent to the execution of a series of agreements (the “LEO Agreement”) with LEO Pharma A/S and LEO Spiny Merger Sub, Inc. (“LEO”) in November 2018, BridgeBio determined that it is no longer the primary beneficiary of PellePharm, Inc. (“PellePharm”) and deconsolidated PellePharm. Refer to Note 8.

Not included in the above list is Eidos, which is a partially-owned subsidiary that we consolidate under the VOE model.

Equity Method and Other Investments in Equity Method Investees

We utilize the equity method to account for investments when we possess the ability to exercise significant influence, but not control, over the operating and financial decisions of the investee. Generally, the ability to exercise significant influence is presumed when the investor possesses more than 20% of the voting interests of the investee. This presumption may be overcome based on specific facts and circumstances that demonstrate that the ability to exercise significant influence is restricted. We apply the equity method to investments in common stock and to other investments in entities that have risk and reward characteristics that are substantially similar to an investment in the investee’s common stock.

In applying the equity method, we record the investment at cost unless the initial recognition is the result of the deconsolidation of a subsidiary, in which case it is recorded at fair value. We subsequently increase or decrease the carrying amount of the investment by our proportionate share of the net earnings or losses and other comprehensive income of the investee based on our percentage of common stock ownership during the respective reporting period. Payments to investees such as additional investments, loans and expenses incurred on behalf of investees, as well as payments from investees such as dividends, distributions and repayments of loans are recorded as adjustments to the carrying value of the investment. In the event that net losses of the investee reduce the carrying amount to zero, additional net losses may be recorded if we have other investment in the investee not accounted for under the equity method, have guaranteed obligations of the investee, or we are otherwise committed to provide further financial support for the investee.

We account for investments at fair value when we do not have significant influence over the investee. In the absence of readily available fair value, we measure the investment at cost less impairment plus or minus observable price changes, if any. We recognize income for any dividends declared from the distribution of the investee's earnings.

As of December 31, 2019 and 2018, we have an equity method and equity security investments in PellePharm, which are presented in the consolidated financial statements as part of single line item titled "Investments in nonconsolidated entities." The equity security investments in PellePharm are without a readily determinable fair value and is carried at cost less impairment plus or minus observable price changes. Refer to Note 8 for further discussion on the PellePharm investment. We have an equity method investment in another third party for ordinary shares representing 10% of the third party's fully-diluted equity (see Note 13). The amount of the investment was reduced to zero as of December 31, 2019 after recognizing our equity share in the net losses on the investment for the year ended December 31, 2019.

Under the equity method of accounting, our investments are reviewed for indicators of impairment at each reporting period and are written down to fair value if there is evidence of a loss in value that is other-than-temporary. Factors that may be indicative of an impairment include a series of operating losses of an investee, the absence of an ability to recover the carrying amount of the investment, the inability of the investee to sustain an earnings capacity and a current fair value of an investment that is less than its carrying amount. Indicators that a decline in value may be other-than-temporary include the length of time and the extent to which the estimated fair value or market value has been below the carrying value, the financial condition and the near-term prospects of the investee, the intent and our ability to retain our investment in the investee for a period of time sufficient to allow for any anticipated recovery in market value and general market conditions. The estimation of fair value and whether an other-than-temporary impairment has occurred requires the application of significant judgment and future results may vary from current assumptions. No impairment charge was recognized during the years ended December 31, 2019 and 2018 related to our equity method investments.

Concentration of Credit Risk and Other Risks and Uncertainties

Financial instruments that subject us to significant concentrations of credit risk consist primarily of cash, cash equivalents and restricted cash. Our cash, cash equivalents and restricted cash are held in financial institutions in the United States. Amounts on deposit may at times exceed federally insured limits. Management believes that the financial institutions are financially sound and, accordingly, minimal credit risk exists with respect to the financial institutions.

We are subject to certain risks and uncertainties and we believe that changes in any of the following areas could have a material adverse effect on future financial position or results of operations: ability to obtain future financing; regulatory approval and market acceptance of, and reimbursement for, product candidates; performance of third-party clinical research organizations and manufacturers upon which we rely; development of sales channels; protection of our intellectual property; litigation or claims against us based on intellectual property, patent, product, regulatory or other factors; and our ability to attract and retain employees necessary to support our growth.

We are dependent on third-party manufacturers to supply products for research and development activities in our programs. In particular, we rely and expects to continue to rely on a small number of manufacturers to supply us with our requirements for the active pharmaceutical ingredients and formulated drugs related to these programs. These programs could be adversely affected by a significant interruption in the supply of active pharmaceutical ingredients and formulated drugs.

Restricted Cash

Under certain lease agreements and letters of credit, we have pledged cash and cash equivalents as collateral. As of December 31, 2019 and 2018, restricted cash related to such agreements was $0.4 million and $0.2 million, respectively and is classified in other assets in our consolidated balance sheets.

Cash, Cash Equivalents and Investments

We consider all highly liquid investments purchased with original maturities of 90 days or less from the purchase date to be cash equivalents. Cash equivalents consist primarily of amounts invested in money market instruments, such as money market funds and repurchase agreements collateralized with securities issued by the U.S. government or its agencies.

We invest in marketable securities, primarily corporate notes, government, government agency, and municipal bonds. We classify our marketable securities as available-for-sale securities and report them at fair value in cash equivalents or marketable securities on the consolidated balance sheets with related unrealized gains and losses included as a component of shareholders' equity. We classify our marketable securities as either short-term or long-term based on each instrument's underlying contractual maturity date. The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity, which is included in interest income on the consolidated statements of operations. Realized gains and losses and declines in value judged to be other-than-temporary, if any, on available-for-sale securities are included in other expense. The cost of securities sold is based on the specific identification method. Interest and dividends on securities classified as available-for-sale are included in interest income.

Our cash, cash equivalents, investments are exposed to credit risk in the event of default by the third parties that hold or issue such assets. Our cash, cash equivalents, investments are held by financial institutions that management believes are of high credit quality. Our investment policy limits investments to fixed income securities denominated and payable in U.S. dollars such as corporate bonds, corporate commercial paper, U.S. government obligations, and money market funds and places restrictions on maturities and concentrations by type and issuer.

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the consolidated balance sheets that sum to the total of the amounts shown in the consolidated statements of cash flows:

	December 31,		
	2019	2018	2017
	(in thousands)		
Cash and cash equivalents	$ 363,773	$ 436,086	$ 91,995
Restricted cash	424	159	381
Total cash, cash equivalents and restricted cash shown in the consolidated statements of cash flows	$ 364,197	$ 436,245	$ 92,376

Fair Value Measurements

Assets and liabilities recorded at fair value on a recurring basis in the 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. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The authoritative guidance on fair value measurements establishes a three-tier fair value hierarchy for disclosure of fair value measurements as follows:

Level 1—Observable inputs such as unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date;

Level 2—Inputs (other than quoted prices included in Level 1) are either directly or indirectly observable for the asset or liability. These include quoted prices for similar assets or liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active; and

Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment we exercise in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

The carrying amounts reflected in the accompanying consolidated balance sheets for cash and cash equivalents, restricted cash, prepaid expenses and other current assets, accounts payable and accrued expenses approximate their fair values, due to their short-term nature.

Property and Equipment, net

Property and equipment are stated at cost, net of accumulated depreciation and amortization. Depreciation and amortization of property and equipment is calculated using the straight-line method over the estimated useful lives of the respective assets. Maintenance and repairs that do not improve or extend the life of the assets are expensed when incurred. Upon sale or retirement of assets, the cost and accumulated depreciation and amortization are removed from the consolidated balance sheet and any resulting gain or loss is reflected in the consolidated statement of operations in the period realized.

The estimated useful lives of our property and equipment are as follows:

Furniture and office equipment	3 - 5 years
Lab equipment	3 - 5 years
Leasehold improvements	Shorter of remaining lease term or estimated useful life

Depreciation and amortization expense were not material during the periods presented.

Asset Acquisitions

We measure and recognize asset acquisitions that are not deemed to be business combinations based on the cost to acquire the assets, which includes transaction costs. Goodwill is not recognized in asset acquisitions. In an asset acquisition, the cost allocated to acquire in-process research and development ("IPR&D") with no alternative future use is charged to research and development expense at the acquisition date.

Impairment of Long-Lived Assets

Long-lived assets are reviewed for impairment annually or whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability is measured by comparison of the carrying amount of an asset group to the future net undiscounted cash flows that the assets are expected to generate. If the carrying amount of an asset group exceeds its estimated future cash flows, an impairment charge is recognized in the amount by which the carrying amount of the asset group exceeds the fair value of the asset group. There was no impairment of long-lived assets for any of the periods presented.

Segments

We determined that we operate in a single segment, which is the business of identifying and advancing transformative medicines to treat patients. We operate in one segment because our business offerings have similar economics and other characteristics, including the nature of products and manufacturing processes, types of customers, distribution methods and regulatory environment. We are comprehensively managed as one business segment by our Chief Executive Officer and his management team. All of our capitalized property and equipment is located in the United States. Revenue from license and collaborative arrangements are attributed to regions based on the headquarters of the partner. For the year ended December 31, 2019, approximately 66% of our revenue is from Alexion Pharmaceuticals with headquarters located in the United States and 34% with a third-party biotech company with headquarters located in Shanghai, China.

Use of Estimates

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and the reported amounts of expenses during the reporting period. Significant estimates and assumptions made in the accompanying consolidated financial statements include, but are not limited to, the fair value of the LEO Call Option liability, the valuation of our stock-based awards, accruals for certain employees' performance-based milestones, accruals for research and development activities, accruals for contingent milestone payments in our license agreements and income tax uncertainties. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable. Actual results may differ from those estimates or assumptions.

License Arrangements and Multiple-Element Arrangements

Revenue from non-refundable, up-front license or technology access payments under license arrangements that are not dependent on any future performance by us is recognized when such amounts are earned. If we have continuing obligations to perform under the arrangement, such fees are recognized over the estimated period of continuing performance obligation.

When we enter into license agreements, we assess whether the arrangements fall within the scope of Accounting Standards Codification (ASC) 808, Collaborative Arrangements (ASC 808) based on whether the arrangements involve joint operating activities and whether both parties have active participation in the arrangement and are exposed to significant risks and rewards. To the extent that the arrangement falls within the scope of ASC 808, we assess whether the payments between us and our partner fall within the scope of other accounting literature. If we conclude that payments from the partner to us represent consideration from a customer, such as license fees and contract research and development activities, we account for those payments within the scope of ASC 606, Revenue from Contracts with Customers. However, if we conclude that our partner is not a customer for certain activities and associated payments, such as for certain collaborative research, development, manufacturing and commercial activities, we present such payments as a reduction of research and development expense or general and administrative expense, based on where we present the underlying expense.

Revenue Recognition

For elements of those arrangements that we determine should be accounted for under ASC 606, we assess which activities in our license or collaboration agreements are performance obligations that should be accounted for separately and determine the transaction price of the arrangement, which includes the assessment of the probability of achievement of future milestones and other potential consideration. For arrangements that include multiple performance obligations, such as granting a license or performing contract research and development activities or participation on joint steering or other committees, we allocate upfront and milestone payments under a relative standalone selling price method. Accordingly, we develop assumptions that require judgment to determine the standalone selling price for each performance obligation identified in the contract. These key assumptions may include revenue forecasts, clinical development timelines and costs, discount rates and probabilities of clinical and regulatory success.

License Fees: For arrangements that include a grant of a license to our intellectual property, we consider whether the license grant is distinct from the other performance obligations included in the arrangement. Generally, we would conclude that the license is distinct if the customer is able to benefit from the license with the resources available to it. For licenses that are distinct, we recognize revenues from nonrefundable, upfront payments and other consideration allocated to the license when the license term has begun and we have provided all necessary information regarding the underlying intellectual property to the customer, which generally occurs at or near the inception of the arrangement.

Milestone Payments: We are required to include additional consideration in the transaction price when it is probable. We include milestone payments for research and development services in the transaction price when they are achieved. We include these milestone payments when they are achieved because there is considerable uncertainty in the research and development processes that trigger these payments under our agreements. Similarly, we include approval milestone payments in the transaction price once the product is approved by the applicable

regulatory agency. We will recognize sales based milestone payments in the period we achieve the milestone under the sales-based royalty exception allowed under accounting rules. We recognize milestone payments that relate to an ongoing performance obligation over our period of performance. Conversely, we recognize in full those milestone payments that we earn based on our partners' activities when our partner achieves the milestone event.

Research and Development Expenses

Research and development costs are expensed as incurred. Research and development expenses consist of salaries, benefits and other personnel related costs including stock-based compensation expense, laboratory supplies, preclinical studies, clinical trials and related clinical manufacturing costs, costs related to manufacturing preparations, fees paid to other entities to conduct certain research and development activities on our behalf and allocated facility and other related costs. Non-refundable advance payments for goods or services that will be used or rendered for future research and development activities are deferred and capitalized as prepaid expenses until the related goods are delivered or services are performed.

Accrued Research and Development Liabilities

We record accruals for estimated costs of research and development activities conducted by third-party service providers, which include the conduct of preclinical studies and clinical trials, and contract manufacturing activities. We record the estimated costs of research and development activities based upon the estimated amount of services provided but not yet invoiced, and include these costs in accrued research and development liabilities in the consolidated balance sheet and within research and development expense in the consolidated statements of operations. These costs are a significant component of our research and development expenses.

- Examples of estimated research and development expenses that we accrue include:
- fees paid to CROs in connection with preclinical and toxicology studies and clinical studies;
- fees paid to investigative sites in connection with clinical studies;
- fees paid to CMOs in connection with the production of product and clinical study materials; and
- professional service fees for consulting and related services.

We base our expense accruals related to clinical studies on our estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and CROs that conduct and manage clinical studies on our behalf. The financial terms of these agreements vary from contract to contract and may result in uneven payment flows. Payments under some of these contracts depend on factors, such as the successful enrollment of patients and the completion of clinical study milestones. Our service providers generally invoice us monthly in arrears for services performed. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If we do not identify costs that we have begun to incur or if we underestimate or overestimate the level of services performed or the costs of these services, our actual expenses could differ from our estimates. We record advance payments to service providers as prepaid assets.

We record accruals for the estimated costs of our contract manufacturing activities performed by third parties. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows to our vendors. Payments under the contracts include upfront payments and milestone payments, which depend on factors such as the achievement of the completion of certain stages of the manufacturing process. For purposes of recognizing expense, we assess whether we consider the production process sufficiently defined to be considered the delivery of a good or the delivery of a service, where processes and yields are developing and less certain. If we consider the process to be the delivery of a good, we recognize expense when the drug product is delivered, or we otherwise bear risk of loss. If we consider the process to be the delivery of a service, we recognize expense based on our best estimates of the contract manufacturer's progress towards completion of the stages in the contract. We base our estimates on the best information available at the time. However, additional information may become available to us which may allow us to make a more accurate estimate in future periods. In this event, we may be required to record adjustments to research and development expenses in future periods when the actual level of activity becomes more certain. Any increases or decreases in cost are generally considered to be changes in estimates and will be reflected in research and development expenses in the period identified.

Stock-Based Compensation

Stock-based compensation arrangements include stock option grants, restricted stock awards (RSA) and restricted stock units (RSU) awards under our equity incentive plans, as well as shares issued under our Employee Stock Purchase Plan (ESPP), through which employees may purchase our common stock at a discount to the market price.

We use the Black-Scholes-Merton option pricing model to estimate the fair value of options granted under our equity incentive plans and rights to acquire shares granted under our employee share purchase plan ("ESPP"). The Black-Scholes-Merton option valuation model requires the use of assumptions, including the expected term of the award and the expected share price volatility. The Company uses the "simplified" method to estimate the expected option term.

Stock-based compensation is measured at the grant date for all stock-based awards made to employees and non-employees based on the fair value of the awards. Compensation expense for purchases under the ESPP is recognized based on the fair value of the award on the date of offering. Stock-based compensation is recognized as expense on a straight-line basis over the requisite service period, which is generally the vesting period.

The estimated fair value of performance-contingent equity awards is expensed using an accelerated method over the term of the award once we have determined that it is probable that performance milestones will be achieved. Compensation expense for equity awards that contain performance conditions is based on the grant date fair value of the award. Compensation expense is recorded over the requisite service period based on management's best estimate as to whether it is probable that the shares awarded are expected to vest. We assess the probability of the performance milestones being met on a continuous basis. The grant date fair value of awards with a market condition is determined using a Monte Carlo valuation model and the compensation expense is recognized over the implied service period.

We have elected to recognize the actual forfeitures by reducing the stock-based compensation in the same period as the forfeitures occur. Stock-based compensation for awards made to non-employees was measured as per ASC 505-50 until we early adopted Accounting Standards Update ("ASU") *2018-07 Compensation-Stock Compensation (Topic 718)* on January 1, 2017. We remeasured our equity-classified non-employee awards for which a measurement date had not been established at their adoption date fair-value based measurement (January 1, 2017) and determined there was no cumulative-effect adjustment to opening accumulated deficit. Subsequent to the adoption of ASU 2018-07, we account for non-employee awards similar to employee awards.

BBP LLC had granted Management Incentive Units and Common Units to employees and non-employees. These awards generally had only a service condition and vest over a period of up to five years. The awards had accelerated vesting upon a fundamental transaction (a "Fundamental Transaction") which is defined as (i) a merger, recapitalization or other business combination, (ii) a sale, transfer, exclusive license or disposition of the Company or (iii) a final liquidation, dissolution, winding-up or termination of the Company. The unvested outstanding management incentive units and common units of BBP LLC were exchanged for shares of the Corporation's unvested restricted stock, subject to the same time-based vesting conditions as the original management incentive units and common units terms and conditions (see Note 3).

Stock-based compensation is recorded in research and development expense, and general and administrative expense based on the function of the applicable employee and non-employee.

Milestone Compensation Arrangements with Employees

We have performance-based milestone compensation arrangements with certain employees, whose vesting is contingent upon meeting various regulatory and development milestones, with fixed monetary amounts known at inception that can be settled in the form of cash or fully vested common stock of the Company at our sole election, upon achievement of each contingent milestones. Compensation expense arising from each milestone is recognized when the specific contingent milestone is probable of achievement and is measured at each reporting period. Under *ASC 718, Compensation – Stock Compensation*, we will classify the milestone compensation arrangements as liability-classified awards when it is probable of achievement because of the possible fixed monetary amounts settlement outcomes. The arrangements would also result in settlement with a variable number of shares based on the then-current stock price at grant date should we elect to settle in equity.

Amortization of Debt Issuance Costs

Debt issuance costs are amortized to interest expense over the estimated life of the related debt based on the effective interest method.

Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax base and net operating loss and tax credit carryforwards. Deferred tax assets and liabilities are determined based upon the difference between the consolidated financial statement carrying amounts and the tax basis of assets and liabilities and are measured using the enacted tax rate expected to apply to taxable income in the years in which the differences are expected to be reversed. Deferred tax assets are reduced by a valuation allowance if it is more likely than not that some portion or all of the deferred tax asset will not be realized.

For U.S. federal income tax purposes, we are required to file separate U.S. federal income tax returns for the consolidated entities. We are required to assess stand-alone valuation allowances separately in each entity even though we consolidate their financial results in the consolidated financial statements. We continue to file combined state tax returns in most jurisdictions. As a result, we continue to assess the state portion of valuation allowance for those jurisdictions on a consolidated basis.

We evaluate our deferred tax assets regularly to determine whether adjustments to the valuation allowance are appropriate due to changes in facts or circumstances, such as changes in expected future pre-tax earnings, tax law, interactions with taxing authorities and developments in case law. In making this evaluation, we rely on our recent history of pre-tax earnings. Our material assumptions are our forecasts of future pre-tax earnings and the nature and timing of future deductions and income represented by the deferred tax assets and liabilities, all of which involve the exercise of significant judgment. Although we believe our estimates are reasonable, we are required to use significant judgment in determining the appropriate amount of valuation allowance recorded against deferred tax assets.

We recognize uncertain income tax positions at the largest amount that is more likely than not to be sustained upon audit by the relevant taxing authority. Changes in recognition or measurement are reflected in the period in which judgment occurs. Our policy is to recognize interest and penalties related to the underpayment of income taxes as a component of the provision for income taxes. To date, there have been no interest or penalties recorded in relation to unrecognized tax benefits.

LEO Call Option Liability

We have accounted for LEO Call Option as a current liability as we have the obligation to sell our PellePharm shares to LEO at a pre-determined price if the option is exercised. The LEO Call Option was recorded at fair value upon execution of the LEO Agreement. The LEO Call Option is subject to remeasurement to fair value at each balance sheet date until the LEO Call Option is either exercised or expires as it does not qualify for equity classification. Any change in the fair value of the LEO Call Option is recognized as a component of other income (expense), net in the consolidated statements of operations. Refer to Note 4 and Note 8 for further discussion.

Net Loss per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of shares of the Corporation’s common stock outstanding for the period, without consideration for potential dilutive shares of common stock, such as stock options, unvested restricted stock units and shares issuable under the employee stock purchase plan. Shares of common stock subject to repurchase are excluded from the weighted-average shares. Since we were in a loss position for all periods presented, basic net loss per share is the same as diluted net loss per share since the effects of potentially dilutive securities are antidilutive.

No adjustment for cumulative returns on BBP LLC's redeemable convertible preferred units has been applied to the calculation of basic and diluted net loss per share, since such units were retroactively adjusted as if the Reorganization occurred at the beginning of the earliest period to be presented in our financial statements for the year ending December 31, 2019. See Note 3 to for additional details.

Emerging Growth Company Status

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that it (i) is no longer an emerging growth company or (ii) affirmatively and irrevocably opts out of the extended transition period provided in the JOBS Act. As a result, these consolidated financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

As described in "Recently Adopted Accounting Pronouncements" below, we early adopted multiple accounting standards, as the JOBS Act does not preclude an emerging growth company from adopting a new or revised accounting standard earlier than the time that such standard applies to private companies. We expect to use the extended transition period for any other new or revised accounting standards during the period in which we remain an emerging growth company.

Recently Adopted Accounting Pronouncements

ASU 2015-17 Income Taxes (Topic 740). In November 2015, the FASB issued *ASU 2015-17 Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes ("ASU 2015-17")*, which simplifies the presentation of deferred taxes in a classified balance sheet by eliminating the requirement to separate deferred income tax liabilities and assets into current and noncurrent amounts. Instead, ASU 2015-17 requires that all deferred tax liabilities and assets be shown as noncurrent in a classified balance sheet. ASU 2015-17 is effective for fiscal years beginning after December 15, 2017 and may be applied either prospectively or retrospectively to all periods presented. We adopted this guidance on January 1, 2018. There is no impact to the consolidated balance sheets as of December 31, 2019 and December 31, 2018 because of the full valuation allowance position taken for deferred taxes.

ASU 2016-01 Recognition and Measurement of Financial Assets and Financial Liabilities. In January 2016, the FASB issued ASU 2016-01, which changes how companies recognize, measure, present and make disclosures about certain financial assets and financial liabilities. Under this guidance, entities have to measure equity investments (except those accounted for under the equity method, those that result in consolidation of the investee and certain other investments) at fair value and recognize any changes in fair value in net income. Entities can elect a measurement alternative for equity investments that do not have readily determinable fair values and do not qualify for the practical expedient in ASC 820 to estimate fair value using the net asset value per share (or its equivalent). ASU 2016-01 does not change the guidance for recognizing and measuring investments in debt securities. For public business entities, ASU 2016-01 is effective for financial statements issued for fiscal years beginning after December 15, 2017, and interim periods therein. For all other entities, ASU 2016-01 is effective for financial statements issued for fiscal years beginning after December 15, 2018, and interim periods within fiscal years beginning after December 15, 2019. We adopted this guidance for our fiscal year ending December 31, 2019. The adoption of ASU 2016-01 impacts how we account for our equity investments that do not qualify for equity method of accounting, that is, any unrealized change in fair value of these investments is recognized in our consolidated statements of operations.

ASU 2016-09 Stock Compensation—Improvements to Employee Share-Based Payment Accounting. In March 2016, the FASB issued *ASU 2016-09, Stock Compensation—Improvements to Employee Share-Based Payment Accounting ("ASU 2016-09")*. ASU 2016-09 was issued to simplify accounting guidance by identifying, evaluating, and improving areas for which cost and complexity can be reduced while maintaining or improving the usefulness of the information provided to users of financial statements. The areas affected by ASU 2016-09 include accounting for income taxes, classification of excess tax benefits in the statement of cash flows, minimum statutory tax withholding requirements, and classification of employee taxes paid in the statement of cash flows when an

employer withholds shares for tax-withholding purposes. In addition, under this guidance, an entity can make an accounting policy election to either estimate the number of awards that are expected to vest or account for forfeitures when they occur. ASU 2016-09 is effective for fiscal years beginning after December 15, 2017 and should be applied using a retrospective transition method to each period presented. Early adoption is permitted. Upon early adoption of this guidance on January 1, 2016, we changed our policy to account for forfeitures as they occur. The adoption of this guidance did not materially impact our consolidated financial statements.

ASU 2016-15 Statement of Cash Flows (Topic 230) Classification of Certain Cash Receipts and Cash Payments. In August 2016, the FASB issued *ASU 2016-15, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments ("ASU 2016-15")*. The areas affected by ASU 2016-15 are debt prepayment and debt extinguishment costs, settlement of zero-coupon debt instruments or other debt instruments with coupon interest rates that are insignificant in relation to the effective interest rate of the borrowing, contingent consideration payments made after a business combination, proceeds from the settlement of insurance claims, proceeds from the settlement of corporate-owned life insurance policies (including bank-owned life insurance policies), distributions received from equity method investees, beneficial interests in securitization transactions and separately identifiable cash flows and application of the predominance principle. Specifically, under this guidance, cash payments for debt prepayment or debt extinguishment costs will be classified as cash outflows for financing activities. The amendments in ASU 2016-15 are effective for fiscal years beginning after December 15, 2018 and interim periods within fiscal years beginning after December 15, 2019. Early adoption is permitted, including adoption in an interim period. If an entity early adopts the amendments in an interim period, any adjustments should be reflected as of the beginning of the fiscal year that includes that interim period. The adoption of this guidance did not materially impact our consolidated financial statements.

ASU 2016-16 Income Taxes: Intra-Entity Transfers of Assets Other Than Inventory. In October 2016, the FASB issued ASU 2016-16, *Income Taxes: Intra-Entity Transfers of Assets Other Than Inventory*. ASU 2016-16 will require the tax effects of intercompany transactions, other than sales of inventory, to be recognized currently, eliminating an exception under current GAAP in which the tax effects of intra-entity asset transfer are deferred until the transferred asset is sold to a third party or otherwise recovered through use. For public business entities, the guidance is effective for annual periods beginning after December 15, 2017, and interim periods within those annual periods. For all other entities, the guidance is effective for annual periods beginning after December 15, 2018, and interim periods within annual periods beginning after December 15, 2019. Early adoption is permitted for all entities as of the beginning of a fiscal year for which neither the annual or interim (if applicable) financial statements have been issued. If an entity chooses to early adopt the amendments in the ASU, it must do so in the first interim period of its annual financial statements (if the entity issues interim financial statements). That is, an entity cannot adopt the amendments in the ASU in a later interim period and apply them as if they were in effect as of the beginning of the year. The adoption of this guidance did not materially impact our consolidated financial statements.

ASU 2016-18 Statement of Cash Flows (Topic 230). In November 2016, the FASB issued *ASU 2016-18 Statement of Cash Flows (Topic 230) Restricted Cash—a consensus of the FASB Emerging Issues Task Force ("ASU 2016-18")*, which requires that amounts generally described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown in the statement of cash flows. ASU 2016-18 is effective for fiscal years beginning after December 15, 2018 and should be applied using a retrospective transition method to each period presented. Early adoption is permitted. We early adopted this guidance on January 1, 2017. The adoption of this guidance did not materially impact our consolidated financial statements.

ASU 2017-01 Business Combinations (Topic 805). In January 2017, the FASB issued *ASU 2017-01, Business Combinations (Topic 805): Clarifying the Definition of a Business ("ASU 2017-01")*. This ASU provides guidance to evaluate whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. If substantially all of the fair value of the gross assets acquired (or disposed of) is concentrated in a single asset or a group of similar assets, the assets acquired (or disposed of) are not considered a business. This guidance is effective for annual periods beginning after December 15, 2018, with early adoption permitted. We early adopted this guidance. As a result of applying this guidance, we accounted for our acquisition of PellePharm, Inc. in 2016 as an asset acquisition (see Note 8) and other asset acquisitions (see Note 12).

ASU 2017-09 Compensation—Stock Compensation (Topic 718). In May 2017, the FASB issued *ASU 2017-09, Compensation—Stock Compensation (Topic 718): Scope of Modification Accounting ("ASU 2017-09").* This ASU provides guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718. The guidance is effective for annual and interim periods beginning after December 15, 2017, with early adoption permitted. We early adopted this guidance on January 1, 2016. The adoption of this guidance did not materially impact our consolidated financial statements.

ASU 2017-11 Earnings Per Share (Topic 260) Distinguishing Liabilities from Equity (Topic 480) Derivatives and Hedging (Topic 815). In July 2017, FASB issued a two-part *ASU 2017-11, I. Accounting for Certain Financial Instruments with Down Round Features, and II. Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception ("ASU 2017-11").* ASU 2017-11 amends guidance in ASC 260, *Earnings Per Share* , ASC 480, *Distinguishing Liabilities from Equity*, and ASC 815, *Derivatives and Hedging.* Part I of this ASU changes the classification analysis of certain equity-linked financial instruments (or embedded features) with down round features and clarifies existing disclosure requirements. Part II does not have an accounting effect. The standard is effective for fiscal years beginning after December 15, 2019 with early adoption permitted. We early adopted this guidance effective January 1, 2016. The adoption of this guidance did not materially impact our consolidated financial statements.

ASU 2018-07 Compensation-Stock Compensation (Topic 718). In June 2018, the FASB issued *ASU No. 2018-07, Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting ("ASU 2018-07").* ASU 2018-07 is intended to reduce the cost and complexity and to improve financial reporting for nonemployee share-based payments. The ASU expands the scope of Topic 718, (which currently only includes share-based payments to employees) to include share-based payments issued to non-employees for goods or services. Consequently, the accounting for share-based payments to non-employees and employees will be substantially aligned. The standard is effective for fiscal years beginning after December 15, 2019. Early adoption is permitted, but no earlier than a company's adoption date of Topic 606. We early adopted this guidance effective January 1, 2017. The adoption of this guidance did not materially impact our consolidated financial statements.

Recently Issued Accounting Pronouncements Not Yet Adopted

ASU 2016-02 Leases (Topic 842). In February 2016, the FASB issued *ASU 2016-02, Leases (Topic 842) ("ASU 2016-02"*), which, for operating leases, requires the lessee to recognize a right-of-use asset and a lease liability, initially measured at the present value of the lease payments, in its balance sheet. The guidance also requires a lessee to recognize single lease costs, calculated so that the cost of the lease is allocated over the lease term, generally on a straight-line basis. In July 2018, the FASB issued *ASU 2018-10, Codification Improvements to Topic 842, Leases*. Additionally, the FASB issued *ASU 2018-11, Leases (Topic 842): Targeted Improvements*, which offers a practical expedient for transitioning at the adoption date. *ASU 2019-10, Financial Instruments — Credit Losses (Topic 326), Derivatives and Hedging (Topic 815), and Leases (Topic 842): Effective Dates*, issued in November 2019, delayed the effective date of Topic 842 for companies like us to January 1, 2021 but early adoption is still permitted. We plan to adopt these ASUs on January 1, 2020 and we have chosen to use the practical expedient and recognize a cumulative-effect adjustment to the opening balance of the accumulated deficit. We also plan to apply other practical expedients provided by the standard. We have commenced the implementation of this new standard, including the identification of our lease population and the implementation of changes to our existing processes that will be required to implement the new lease standard. We believe that the most significant changes to the financial statements will relate to the recognition of right-of-use assets and offsetting lease liabilities in the consolidated balance sheet for operating leases. The impact on the consolidated balance sheet will be based on the population of operating leases at adoption, which we are still analyzing. However, we do not expect the standard to have a material impact on the consolidated statement of cash flows or the consolidated statement of operations.

ASU 2016-13 Financial Instruments - Credit Losses. In June 2016, the FASB issued *ASU 2016-13, Financial Instruments - Credit Losses.* This update requires immediate recognition of management's estimates of current expected credit losses ("CECL"). Under the prior model, losses were recognized only as they were incurred. The new model is applicable to most financial assets and certain other instruments that are not measured at fair value through net income. The standard is effective for fiscal years beginning after December 15, 2019 for public entities. Early adoption is permitted. The delay in effective date for certain entities of *ASU 2016-13* by the issuance of *ASU 2019-10* in November 2019 does not apply to companies like us. We are currently assessing the impact of this update on our consolidated financial statements.

ASU 2018-13 Fair Value Measurement – Disclosure Framework (Topic 820). In August 2018, the FASB issued *ASU 2018-13, Fair Value Measurement - Disclosure Framework (Topic 820) ("ASU 2018-13").* The updated guidance improves the disclosure requirements on fair value measurements and is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. Early adoption is permitted upon issuance of the standard for disclosures modified or removed with a delay of adoption of the additional disclosures until their effective date. We are currently assessing the impact of this update on our consolidated financial statements.

3. Reorganization

On June 13, 2019, the Corporation formed BridgeBio Pharma Merger Sub LLC ("Merger Sub LLC"), a Delaware limited liability company and direct wholly-owned subsidiary. The Reorganization was executed on July 1, 2019, immediately prior to completion of the IPO of the Corporation's common stock. As part of the Reorganization, the existing ownership interest in BBP LLC held by all BBP LLC unitholders was transferred to Merger Sub LLC, and all outstanding units of BBP LLC were cancelled and exchanged for shares of common stock of the Corporation. Merger Sub LLC was then merged with and into BBP LLC, the surviving entity, which became a wholly-owned subsidiary of the Corporation. At the conclusion of the Reorganization, the Corporation became the reporting entity.

The number of shares of the Corporation's common stock issued to BBP LLC unitholders in the Reorganization is shown in the below table by unit class:

BBP LLC unit class	Number of the Corporation's Shares Issued
Series D Preferred Units	30,459,426
Series C Preferred Units	31,992,709
Series B Preferred Units	17,794,455
Series A Preferred Units	4,918,881
Founder Units	2,252,916
Common Units	1,794,823
Management Incentive Units	10,786,757
Total shares issued	99,999,967

Included in the amounts above, the unvested outstanding management incentive units and common units of BBP LLC were exchanged for 6,819,455 shares of the Corporation's unvested restricted stock, subject to the same time-based vesting conditions as the original management incentive units and common units terms and conditions. See Note 16 for additional details.

The Reorganization was accounted for as a reverse acquisition and recapitalization for financial reporting purposes. The assets and liabilities of the Corporation, the legal acquirer, were nominal and there were no material pre-combination activities. Therefore, BBP LLC, the legal acquiree, was determined to be the accounting acquirer. Accordingly, the historical financial statements of BBP LLC became the Corporation's historical financial statements, including the comparative prior periods. All share and per share amounts in these consolidated financial statements and related notes have been retroactively adjusted, where applicable, for all periods presented. The shares of the Corporation's common stock for periods prior to July 1, 2019 represent the outstanding BBP LLC units recalculated to give effect to the exchange ratio applied in connection with the Reorganization.

All BBP LLC units that were previously reported as temporary equity and were converted to common stock of the Corporation upon the execution of the Reorganization, have been reclassified to equity for all periods presented, as if the Reorganization occurred at the beginning of the earliest period presented in our financial statements for the year ending December 31, 2019, as follows:

	December 31, 2018		
	As Reported	Adjustment	As Adjusted
	(in thousands)		
Redeemable convertible preferred units	$ 478,865	$ (478,865)	$ —
Redeemable founder units	1,754	(1,754)	—
Redeemable common units	1,619	(1,619)	—
Management incentive units	3,221	(3,221)	—
Redeemable convertible noncontrolling interests	122	—	122
Stockholders' equity (Members' deficit):			
Undesignated preferred stock	—	—	—
Common stock	—	92	92
Additional paid-in capital	—	494,231	494,231
Accumulated deficit	(170,580)	(8,864)	(179,444)
Total BridgeBio stockholders' equity (Members' deficit)	(170,580)	485,459	314,879
Noncontrolling interests	62,361	—	62,361
Total stockholders' equity (Members' deficit)	$ (108,219)	$ 485,459	$ 377,240

	December 31, 2017		
	As Reported	Adjustment	As Adjusted
	(in thousands)		
Redeemable convertible preferred units	$ 143,867	$ (143,867)	$ —
Redeemable founder units	1,754	(1,754)	—
Redeemable common units	1,431	(1,431)	—
Management incentive units	226	(226)	—
Redeemable convertible noncontrolling interests	833	—	833
Stockholders' equity (Members' deficit):			
Undesignated preferred stock	—	—	—
Common stock	—	51	51
Additional paid-in capital	—	134,495	134,495
Accumulated deficit	(61,427)	12,732	(48,695)
Total BridgeBio stockholders' equity (Members' deficit)	(61,427)	147,278	85,851
Noncontrolling interests	2,498	—	2,498
Total stockholders' equity (Members' deficit)	$ (58,929)	$ 147,278	$ 88,349

	December 31, 2016		
	As Reported	Adjustment	As Adjusted
	(in thousands)		
Redeemable convertible preferred units	$ 31,280	$ (31,280)	$ —
Redeemable founder units	1,124	(1,124)	—
Redeemable common units	589	(589)	—
Management incentive units	26	(26)	—
Redeemable convertible noncontrolling interests	1,520	—	1,520
Stockholders' equity (Members' deficit):			
Undesignated preferred stock	—	—	—
Common stock	—	21	21
Additional paid-in capital	—	32,998	32,998
Accumulated deficit	(18,130)	—	(18,130)
Total BridgeBio stockholders' equity (Members' deficit)	(18,130)	33,019	14,889
Noncontrolling interests	2,595	—	2,595
Total stockholders' equity (Members' deficit)	$ (15,535)	$ 33,019	$ 17,484

4. Fair Value Measurement

The following table presents information about our financial assets and liabilities that are measured at fair value on a recurring basis and indicates the fair value hierarchy of the valuation:

	December 31, 2019			
	Total	Level 1	Level 2	Level 3
	(in thousands)			
Assets				
Cash equivalents:				
Money market funds	$ 248,736	$ 248,736	$ —	$ —
Repurchase agreements	59,000	59,000	—	—
Total cash equivalents	307,736	307,736	—	—
Short-term marketable securities:				
U.S. treasury notes	45,280	—	45,280	—
Commercial paper	65,626	—	65,626	—
Corporate debt securities	71,314	—	71,314	—
Total short-term marketable securities	182,220	—	182,220	—
Long-term marketable securities:				
U.S. treasury notes	15,307	—	15,307	—
Corporate debt securities	15,837	—	15,837	—
Total long-term marketable securities	31,144	—	31,144	—
Total cash equivalents and marketable securities	$ 521,100	$ 307,736	$ 213,364	$ —
Liabilities:				
LEO call option liability	$ 4,078	$ —	$ —	4,078
Embedded derivative	1,165	—	—	1,165
Total financial liabilities	$ 5,243	$ —	$ —	$ 5,243

	December 31, 2018			
	Total	Level 1	Level 2	Level 3
	(in thousands)			
Assets:				
Money market funds	$ 395,780	$ 395,780	$ —	$ —
Liabilities:				
LEO call option liability	$ 3,009	$ —	$ —	$ 3,009

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

Marketable Securities

The fair value of our marketable securities classified within Level 2 is based upon observable inputs that may include benchmark yields, reported trades, broker/dealer quotes, issuer spreads, two-sided markets, benchmark securities, bids, offers and reference data including market research publications.

LEO Call Option Liability

The valuation of the LEO Call Option (see Note 8) contains unobservable inputs that reflect management's own assumptions for which there is little, if any, market activity at the measurement date. Accordingly, the LEO Call Option liability is remeasured to fair value on a recurring basis using unobservable inputs that are classified as Level 3 inputs.

We estimated the fair value of the LEO Call Option by estimating the fair value of various clinical, regulatory, and sales milestones based on the estimated risk and probability of achievement of each milestone, and allocated the value using a Black-Scholes option pricing model with the following assumptions:

	December 31,	
	2019	2018
Probability of milestone achievement	12.0%-84.0%	12.0%-84.0%
Discount rate	1.6%-13.1%	2.7%-11.0%
Expected term (in years)	0.67-5.25	0.58-4.38
Expected volatility	60.0%-68.0%	67.0%-79.0%
Risk-free interest rate	2.34%-2.46%	2.51%-2.78%
Dividend yield	—	—

The following table sets forth a summary of the changes in the estimated fair value of the LEO Call Option:

	Total
	(in thousands)
Balance as of January 1, 2018	$ —
Initial fair value upon execution of the LEO Agreement in November 2018	1,879
Change in fair value upon remeasurement recognized in other income (expense), net	1,130
Balance as of December 31, 2018	3,009
Change in fair value upon remeasurement recognized in other income (expense), net	1,069
Balance as of December 31, 2019	$ 4,078

Term Loans

The fair value of our outstanding term loans with Hercules Capital, Inc. (see Note 10) is estimated using the net present value of the payments, discounted at an interest rate that is consistent with a market interest rate, which is a Level 2 input. The estimated fair value of our outstanding term loans approximates the carrying amount, as the term loan bears a floating rate that approximates the market interest rate.

Eidos Embedded Derivative Liability in Loan Agreement

For the SVB and Hercules Loan entered in November 2019 (see Note 10), Eidos determined that the requirement to pay a fee ("Success Fee") upon certain events is an embedded derivative liability to be measured at fair value. The fair value of the derivative was determined based on an income approach that identified the cash flows using a "with-and-without" valuation methodology. The inputs used to determine the estimated fair value of the derivative instrument were based primarily on the probability of an underlying event triggering the embedded derivative occurring and the timing of such event.

5. Cash Equivalents and Marketable Securities

We invest in certain money market funds and reverse repurchase agreements, classified as cash equivalents, which are collateralized by deposits in the form of U.S. treasury securities for an amount no less than 102% of their value. We do not record an asset or liability for the collateral as we do not intend to sell or re-pledge the collateral. The collateral has the prevailing credit rating of at least the U.S. government treasuries and agencies. We utilize a third-party custodian to manage the exchange of funds and ensure that collateral received is maintained at 102% of the value of the reverse repurchase agreements on a daily basis.

Cash equivalents and marketable securities classified as available-for-sale consisted of the following:

	December 31, 2019			
	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Fair Value
	(in thousands)			
Cash equivalents:				
Money market funds	$ 248,736	$ —	$ —	$ 248,736
Repurchase agreements	59,000	—	—	59,000
Total cash equivalents	307,736	—	—	307,736
Short-term marketable securities:				
U.S. treasury notes	45,224	56	—	45,280
Commercial paper	65,626	—	—	65,626
Corporate debt securities	71,231	83	—	71,314
Total short-term marketable securities	182,081	139	—	182,220
Long-term marketable securities:				
U.S. treasury notes	15,248	59	—	15,307
Corporate debt securities	15,781	56	—	15,837
Total long-term marketable securities	31,029	115	—	31,144
Total cash equivalents and marketable securities	$ 520,846	$ 254	$ —	$ 521,100

As of December 31, 2018, we had $395.8 million in money market funds and no marketable securities. There have been no significant realized gains or losses on available-for-sale securities for the periods presented. As of December 31, 2019, our short-term and long-term marketable securities have average contractual maturities of approximately eight months and 16 months, respectively.

6. Variable Interest Entities and Voting Interest Model

The entities consolidated by BridgeBio are comprised of wholly-owned subsidiaries and partially-owned entities consolidated under the VOE model and VIEs for which BridgeBio is the primary beneficiary under the VIE model. The results of operations of the consolidated entities are included within the BridgeBio consolidated financial statements for the years ended December 31, 2019, 2018 and 2017.

Upon the Reorganization, BBP LLC became a wholly-owned subsidiary of the Corporation through the series of transactions described in Note 3. At that time, the consolidation assessment was updated on behalf of the Corporation with no changes in the BridgeBio group composition, other than the merger of BBP LLC and Merger Sub LLC as a result of the Reorganization described in Note 3.

As of December 31, 2019 and 2018, there were no significant restrictions on the VIE assets or liabilities except for the cash held by our VIEs presented below. For VIEs, BridgeBio calculates the maximum exposure to loss to be equal to the amount invested in the equity of the VIE and the amount of outstanding convertible notes.

Included within Note 2 is a list of partially-owned entities that were determined to be under BridgeBio's control under the VIE model as of December 31, 2019 and December 31, 2018, with the exception of PellePharm as discussed in Note 8. At each reporting period, we reassess whether we have a majority voting interest for entities consolidated under the VOE model and whether we remain the primary beneficiary of the VIEs consolidated under the VIE model.

Eidos

Eidos is a clinical stage biopharmaceutical company focused on the development of BBP-265 to address the large and growing unmet need in diseases caused by transthyretin amyloidosis. In April 2016, we initially invested $1.0 million and determined that our investment in Eidos represented a variable interest. At that time, Eidos did not have sufficient resources to carry out its principal activities without additional financial support. BridgeBio was determined to be the primary beneficiary of Eidos as it controlled the activities that most significantly impacted Eidos' economic performance, controlled the most significant decisions affecting Eidos through its representation within management and Eidos' Board of Directors, and BridgeBio had a majority ownership interest.

In February 2018, BridgeBio entered into a note and warrant purchase agreement with Eidos, pursuant to which Eidos issued a convertible promissory note (the "Eidos Note") with the principal amount of $10.0 million and a warrant to purchase a number of shares of preferred stock equal to $4.0 million at the price paid by investors in the next equity financing (the "Eidos Warrant"). In March 2018, BridgeBio transferred 10% or $1.0 million of its interests in the Eidos Note and the Eidos Warrant to the minority stockholder of Eidos. In March 2018, the Eidos Note was redeemed into shares of Series B redeemable convertible preferred stock of Eidos at a 30% discount to the price paid by other investors.

In March 2018, Eidos entered into the Eidos Series B Preferred Stock Purchase Agreement for issuance of shares of Eidos Series B redeemable convertible preferred stock in two closings. As part of the March 2018 closing, Eidos also issued a freestanding tranche liability related to the obligation of Eidos to issue additional shares and the right to request investors to purchase additional shares. The tranche liability was recorded at fair value and remeasured through the settlement date in May 2018. In May 2018, BridgeBio contributed $11.2 million into Eidos in exchange for shares of Series B redeemable convertible preferred stock.

In June 2018, Eidos completed its initial public offering. All redeemable convertible preferred stock of Eidos was converted into common stock at the closing of the Eidos IPO. As part of the Eidos IPO, BridgeBio purchased common stock of $17.0 million. The Eidos Warrant was also net exercised upon the completion of the Eidos IPO.

From the date of BridgeBio's initial investment until June 22, 2018, the Eidos IPO closing date, Eidos was determined to be a VIE and BridgeBio consolidated Eidos as the primary beneficiary. Subsequent to the Eidos IPO, BridgeBio determined that Eidos was no longer a VIE due to it having sufficient equity at risk to finance its activities without additional subordinated financial support. From June 22, 2018 through December 31, 2019, BridgeBio determined that it held greater than 50% of the voting shares of Eidos and there were no other parties with substantive participating, liquidation or kick-out rights. BridgeBio consolidated Eidos under the VOE model as of December 31, 2019 and 2018 and during the years then ended.

In May 2019, BridgeBio purchased 1,103,848 shares of Eidos common stock from an existing Eidos stockholder for $28.6 million in a private purchase transaction. In July 2019, BridgeBio purchased 882,353 shares of Eidos common stock from an existing Eidos investor for $26.4 million in a private purchase transaction. In September 2019, Eidos issued 556,173 shares of Eidos common stock to a third-party, which is futher described in Note 13.

On August 2, 2019, Eidos filed a 2019 Shelf with the SEC in relation to the registration of common stock, preferred stock, warrants and units of any combination thereof. Eidos also simultaneously entered into an Open Market Sale Agreement with the Sales Agent, to provide for the offering, issuance and sale by Eidos of up to an aggregate offering price of $100.0 million of its common stock from time to time in "at-the-market" offerings under the 2019 Shelf and subject to the limitations thereof. Eidos will pay to the Sales Agent cash commissions of up to 3.0 percent of the gross proceeds of sales of common stock under the 2019 Sales Agreement. Eidos has issued 385,613 shares under this offering and received $23.9 million of net proceeds as of December 31, 2019.

Consolidated VIEs

The entities identified as a "Controlled VIE" in Note 2 are VIEs for which BridgeBio was determined to be the primary beneficiary as of December 31, 2019 and 2018. For each entity, the initial investment was determined to represent a variable interest as, at that time, the entity did not have sufficient resources to carry out its principal activities without additional financial support. BridgeBio was determined to be the primary beneficiary of each entity as it controlled the activities that most significantly impact the entity's economic performance and controlled the most significant decisions affecting the entity through its representation within management and the entity's board of directors. BridgeBio also had a majority ownership interest in these entities as of December 31, 2019 and December 31, 2018.

ML Bio is a biopharmaceutical company focused on developing BBP-418, an orally administered ribitol replacement therapy, for the treatment of Limb Girdle Muscular Dystrophy type 2i. In July 2019, BridgeBio purchased shares of preferred stock of ML Bio for $7.0 million. Upon the initial investment, BridgeBio received a majority ownership interest in ML Bio and it was determined that ML Bio is a VIE and BridgeBio is the primary beneficiary. BridgeBio controlled the activities that most significantly impact ML Bio's economic performance and, through its representation within management on ML Bio's Board of Directors, also controlled the most significant decisions affecting ML Bio. BridgeBio has consolidated ML Bio under the VIE model since the initial investment date in July 2019 through December 31, 2019. Refer to Note 12 for additional details with respect to this transaction.

MoST is a biopharmaceutical company focused on developing BBP-561, a series of topical KLK5/7 inhibitors, for the treatment of Netherton Syndrome. BridgeBio made investments in MoST of $1.4 million, $1.2 million and $1.5 million in 2019, 2018 and 2017, respectively, in exchange for shares of redeemable convertible preferred stock.

Quartz is a biopharmaceutical company focused on the development of effective therapies for patients suffering from RAS-driven cancers. BridgeBio made investments in Quartz of $4.0 million in 2017 in exchange for shares of redeemable convertible preferred stock. Quartz issued convertible notes to BridgeBio in 2019 and 2018 totaling $0.4 million and $1.1 million, respectively, that are outstanding as of December 31, 2019.

Navire is a biopharmaceutical company advancing our BBP-398 discovery program for small molecule inhibitors of SHP2 for the potential treatment of cancers driven by hyperactive receptor tyrosine kinase, or MAPK signaling. BridgeBio made investments in Navire of $4.5 million, $6.8 million and $3.2 million in 2019, 2018 and 2017, respectively, in exchange for shares of redeemable convertible preferred stock.

CoA is a biopharmaceutical company focused on the development of BBP-671, an oral small molecule, for the treatment of Pantothenate Kinase Associated Neurodegeneration, or PKAN. BridgeBio made investments in CoA of $5.1 million $7.0 million and $1.5 million in 2019, 2018 and 2017, respectively, in exchange for shares of redeemable convertible preferred stock.

Dermecular is a biopharmaceutical company focused on the development of BBP-321, an oral S1P lyase inhibitor, for the treatment of Darier Disease and Hailey-Hailey Disease. BridgeBio made investments in Dermecular of $0.7 million and $4.5 million in 2018 and 2017, respectively, in exchange for shares of redeemable convertible preferred stock.

PTR is a biopharmaceutical company focused on developing BBP-589, an IV-administered recombinant collagen type VII, protein replacement therapy, for the treatment of recessive dystrophic epidermolysis bullosa. BridgeBio made investments in PTR of $7.0 million, $10.5 million and $3.0 million in 2019, 2018 and 2017, respectively, in exchange for shares of redeemable convertible preferred stock.

Adrenas is a biopharmaceutical company focused on developing BBP-631, an adeno-associated virus, gene transfer product candidate, for the treatment of congenital adrenal hyperplasia, caused by 21-hydroxylase deficiency. BridgeBio made investments in Adrenas of $21.6 million and $13.4 million in 2019 and 2018, respectively, in exchange for shares of redeemable convertible preferred stock.

QED is a biopharmaceutical company focused on developing infigratinib, an oral FGFR1-3 selective tyrosine kinase inhibitor, for the treatment of FGFR-driven cancers. BridgeBio made investments in QED of $100.0 million and $50.0 million in 2019 and 2018, respectively, in exchange for shares of redeemable convertible preferred stock.

Orfan is a biopharmaceutical company focused on developing BBP-711, a series of oral small molecule inhibitors of glycolate oxidase, for the treatment of primary hyperoxaluria and recurrent kidney stone disease. BridgeBio made investments in Orfan of $9.7 million and $3.0 million in 2019 and 2018, respectively, in exchange for shares of redeemable convertible preferred stock.

Ferro is a biopharmaceutical company focused on developing BBP-954 for irreversible inhibitors of glutathione peroxidase 4, for the treatment of solid and hematological cancers. BridgeBio made investments in Ferro of $7.0 million and $3.0 million in 2019 and 2018, respectively, in exchange for shares of redeemable convertible preferred stock.

Venthera is a biopharmaceutical company focused on developing BBP-681, a transdermal PI3K inhibitor, for the treatment of cutaneous venous and lymphatic malformations. BridgeBio made investments in Venthera of $4.5 million and $5.5 million in 2019 and 2018, respectively, in exchange for shares of redeemable convertible preferred stock.

Aspa is a biopharmaceutical company focused on developing BBP-812, an adeno-associated virus, gene transfer therapy, for the treatment of Canavan Disease. BridgeBio made investments in Aspa of $15.6 million and $8.0 million in 2019 and 2018, respectively, in exchange for shares of redeemable convertible preferred stock.

Origin is a biopharmaceutical company focused on developing BBP-870, an IV formulation of synthetic cyclic pyranopterin monophosphate for the treatment of molybdenum cofactor deficiency Type A. BridgeBio made investments in Origin of $24.0 million and $10.0 million in 2019 and 2018, respectively, in exchange for shares of redeemable convertible preferred stock.

Theras is a biopharmaceutical company focused on developing BBP-454, a preclinical development program for small molecule inhibitors of KRAS for the treatment of pan-mutant KRAS-driven cancers. BridgeBio made investments in Theras of $14.0 million and $5.0 million in 2019 and 2018, respectively, in exchange for shares of redeemable convertible preferred stock.

The following table provides the assets and liabilities for all consolidated VIEs as of December 31, 2019:

	Adrenas	Aspa	ML Bio	QED	Theras	All Other	Total
				(in thousands)			
Assets:							
Current assets:							
Cash and cash equivalents	$ 6,453	$ 1,695	$ 7,432	$ 27,781	$ 6,351	$ 31,600	$ 81,312
Prepaid expenses and other current assets	906	758	17	7,282	2,555	2,416	13,934
Total current assets	7,359	2,453	7,449	35,063	8,906	34,016	95,246
Property and equipment, net	3,189	274	98	281	3	325	4,170
Other assets	—	10,000	—	11,313	—	637	21,950
Total assets	$ 10,548	$ 12,727	$ 7,547	$ 46,657	$ 8,909	$ 34,978	$ 121,366
Liabilities:							
Current liabilities:							
Accounts payable	$ 526	$ 219	$ 19	$ 1,443	$ 23	$ 1,341	$ 3,571
Accrued compensation and benefits	923	156	67	3,396	243	3,352	8,137
Accrued research and development liabilities	757	567	—	8,931	212	5,293	15,760
Accrued professional services	83	280	7	435	4	363	1,172
Build-to-suit lease obligation	—	8,000	—	—	—	—	8,000
Other accrued liabilities	290	38	—	180	33	592	1,133
Total current liabilities	2,579	9,260	93	14,385	515	10,941	37,773
Other liabilities	951	—	—	161	—	24	1,136
Total liabilities	$ 3,530	$ 9,260	$ 93	$ 14,546	$ 515	$ 10,965	$ 38,909

The following table provides the assets and liabilities for all consolidated VIEs as of December 31, 2018:

	Adrenas	Aspa	PTR	QED	Venthera	All Other	Total
				(in thousands)			
Assets:							
Current assets:							
Cash and cash equivalents	$ 3,046	$ 4,259	$ 6,934	$ 8,630	$ 2,913	$ 6,713	$ 32,495
Prepaid expenses and other current assets	665	1,722	28	3,240	—	321	5,976
Total current assets	3,711	5,981	6,962	11,870	2,913	7,034	38,471
Property and equipment, net	584	129	88	181	—	277	1,259
Other assets	7	—	41	—	—	28	76
Total assets	$ 4,302	$ 6,110	$ 7,091	$ 12,051	$ 2,913	$ 7,339	$ 39,806
Liabilities:							
Current liabilities:							
Accounts payable	$ 1,876	$ 1,187	$ 621	$ 3,537	$ 333	$ 1,737	$ 9,291
Accrued compensation and benefits	377	30	287	1,392	—	467	2,553
Accrued research and development liabilities	227	728	—	4,390	—	1,251	6,596
Other accrued liabilities	28	32	8	229	9	82	388
Total current liabilities	2,508	1,977	916	9,548	342	3,537	18,828
Other liabilities	—	—	—	150	—	29	179
Total liabilities	$ 2,508	$ 1,977	$ 916	$ 9,698	$ 342	$ 3,566	$ 19,007

VIEs included in the “All Other” category of the above table are not significant individually for separate presentation as of the respective dates presented. Going forward, BridgeBio may not provide any further investment in certain of these VIEs.

7. Noncontrolling Interests

As of December 31, 2019 and 2018, we had both redeemable convertible noncontrolling interests and noncontrolling interests in consolidated partially-owned entities, for which BridgeBio has a majority voting interest under the VOE model and for which BridgeBio is the primary beneficiary under the VIE model. These balances are reported as separate components outside stockholders’ equity in “Redeemable convertible noncontrolling interests” and as part of stockholders’ equity in “Noncontrolling interests” in the consolidated balance sheets.

We adjust the carrying value of noncontrolling interest to reflect the book value attributable to noncontrolling shareholders of consolidated partially-owned entities when there is a change in the ownership during the respective reporting period. During the years ended December 31, 2019, 2018 and 2017, such adjustments in the aggregate amounts of $(28.6) million, $21.6 million and ($8.2) million, respectively, are recorded to additional paid-in capital. All such adjustments are disclosed within the “Transfers to (from) noncontrolling interest” line item in the consolidated statements of redeemable convertible noncontrolling interests and stockholders’ equity.

Upon the Eidos IPO in June 2018, all outstanding shares of Eidos’ redeemable convertible preferred stock were converted into shares of common stock of Eidos. This transaction is reflected as conversion of redeemable noncontrolling interest into noncontrolling interest in the table below. The net exercise of the Eidos Warrants upon the Eidos IPO is presented as the issuance of noncontrolling interest in the table below.

The following table provides a rollforward of the redeemable convertible noncontrolling interests balance:

	Orfan	QED	ML Bio	Eidos	PellePharm	Total
			(in thousands)			
Balance as of January 1, 2017	$ —	$ —	$ —	$ 6	$ 1,514	$ 1,520
Issuance of redeemable convertible noncontrolling interest	—	—	—	—	2,839	2,839
Net loss attributable to redeemable convertible noncontrolling interest	—	—	—	(27)	(2,730)	(2,757)
Transfers to (from) redeemable convertible noncontrolling interest	—	—	—	26	(795)	(769)
Balance as of December 31, 2017	—	—	—	5	828	833
Issuance of redeemable convertible noncontrolling interest	187	1,735	—	51,012	9,429	62,363
Net loss attributable to redeemable convertible noncontrolling interest	(263)	(4,675)	—	(1,411)	(6,181)	(12,530)
Deconsolidation of PellePharm	—	—	—	—	1,154	1,154
Transfers to (from) and conversion of noncontrolling interest:						
Transfers to (from) redeemable convertible noncontrolling interest	84	3,054	—	(37,354)	(5,230)	(39,446)
Conversion of redeemable convertible noncontrolling interest to noncontrolling interest	—	—	—	(12,252)	—	(12,252)
Balance as of December 31, 2018	8	114	—	—	—	122
Issuance of redeemable convertible noncontrolling interest	—	—	3,196	—	—	3,196
Net loss attributable to redeemable convertible noncontrolling interest	(120)	(2,168)	(590)	—	—	(2,878)
Transfers to (from) redeemable convertible noncontrolling interest	186	2,666	(1,049)	—	—	1,803
Balance as of December 31, 2019	$ 74	$ 612	$ 1,557	$ —	$ —	$ 2,243

The following table provides a rollforward of the noncontrolling interests balance:

	Adrenas	Aspa	Eidos	PellePharm	PTR	Venthera	All Other	Total
				(in thousands)				
Balance as of January 1, 2017	$ —	$ —	$ 605	$ 1,990	$ —	$ —	$ —	$ 2,595
Issuance of noncontrolling interest	—	—	1,218	181	1	—	44	1,444
Transfers to (from) noncontrolling interest	—	—	2,157	2,272	2,242	—	2,298	8,969
Net loss attributable to noncontrolling interest	—	—	(3,214)	(3,560)	(2,016)	—	(1,720)	(10,510)
Balance as of December 31, 2017	—	—	766	883	227	—	622	2,498
Issuance of noncontrolling interest	5	7	98,765	239	7	14	442	99,479
Net loss attributable to noncontrolling interest	(1,548)	(416)	(13,457)	(4,541)	(2,716)	(612)	(2,882)	(26,172)
Deconsolidation of PellePharm	—	—	—	688	—	—	—	688
Repurchase of redeemable noncontrolling interest	—	—	(44,234)	—	—	—	—	(44,234)
Transfers to (from) and conversion of noncontrolling interest:								
Transfers to (from) noncontrolling interest	1,760	654	4,093	2,731	5,210	1,047	2,355	17,850
Conversion of redeemable convertible noncontrolling interest to noncontrolling interest	—	—	12,252	—	—	—	—	12,252
Balance as of December 31, 2018	217	245	58,185	—	2,728	449	537	62,361
Issuance (repurchase) of noncontrolling interest	15	17	(754)	—	73	6	1,849	1,206
Transfers to (from) noncontrolling interest	2,324	1,342	16,004	—	2,245	777	4,140	26,832
Net loss attributable to noncontrolling interest	(1,860)	(1,354)	(13,713)	—	(3,748)	(1,092)	(3,353)	(25,120)
Balance as of December 31, 2019	$ 696	$ 250	$ 59,722	$ —	$ 1,298	$ 140	$ 3,173	$ 65,279

8. PellePharm Investment

PellePharm is a clinical-stage biopharmaceutical company developing BBP-009, a topical gel formulation of patidegib, a hedgehog inhibitor, for the treatment of Gorlin Syndrome and High-Frequency Basal Cell Carcinoma. In July 2015, BridgeBio made an initial investment of $4.5 million in PellePharm and in a series of transactions through December 2016, we increased our ownership interest to greater than 50%. BridgeBio determined that its initial investment in PellePharm represented a variable interest, but that BridgeBio was not the primary beneficiary until December 2016.

On November 19, 2018, PellePharm entered into the LEO Agreement, pursuant to which LEO was granted an exclusive, irrevocable option to acquire PellePharm. The LEO Call Option is exercisable by LEO on or before the occurrence of certain events relating to PellePharm's clinical development programs and no later than July 30, 2021. We account for the LEO Call Option as a current liability in our consolidated financial statements because BridgeBio is obligated to sell its shares in PellePharm to LEO at a pre-determined price, if the option is exercised. We remeasure the LEO Call Option to fair value at each subsequent balance sheet date until the LEO Call Option is either exercised or expires.

The date the LEO Agreement was entered into was determined to be a VIE reconsideration event. Based on our assessment, BridgeBio concluded that PellePharm remains a VIE after the reconsideration event as it does not have sufficient equity at risk to finance its activities without additional subordinated financial support. However, based on changes to PellePharm's governance structure and Board of Directors composition as a result of the LEO Agreement, BridgeBio is no longer the primary beneficiary as it no longer has the power over the key decisions that most significantly impact PellePharm's economic performance. Accordingly, BridgeBio deconsolidated PellePharm on November 19, 2018. After the deconsolidation in November 2018, PellePharm is considered a related party of BridgeBio.

As a result of the deconsolidation of PellePharm in November 2018, BridgeBio recorded a gain of $19.3 million primarily related to the remeasurement of its common stock and preferred stock investment in PellePharm to its estimated fair value of $17.3 million. The gain is included in the accompanying consolidated statement of operations for the year ended December 31, 2018. We concluded that the deconsolidation of PellePharm did not qualify for presentation as discontinued operations.

The valuation technique used to measure the fair value of the retained investment in the PellePharm's common stock and preferred stock is the PWERM, which was based on the expected proceeds from either the acquisition of PellePharm by LEO or LEO not exercising its option to acquire PellePharm during the option period. As of the deconsolidation date, BridgeBio holds 8.0% of the outstanding PellePharm common stock and 61.9% of the outstanding PellePharm preferred stock. BridgeBio also has continuing involvement and significant influence in PellePharm through its participation on the PellePharm Board of Directors. The carrying amount of BridgeBio's investment in PellePharm in the consolidated balance sheets represents its maximum loss exposure related to its VIE investment in PellePharm.

As of the deconsolidation date, BridgeBio's investment in PellePharm had a fair value of $17.3 million, which is comprised of $0.5 million in PellePharm common stock that is accounted for as an equity method investment and $16.8 million in PellePharm preferred stock that was accounted for as a cost method investment. Subsequent to the adoption of ASU No. 2016-01, we accounted for the investment in PellePharm preferred stock as an equity security without a readily determinable fair value.

The following represents the amounts related to the PellePharm deconsolidation accounting:

	Amount (in thousands)
Working capital (1) (excluding cash and cash equivalents)	$ 6,134
Term loan	1,359
Property and equipment, net	(791)
Carrying value of noncontrolling interest	(688)
Carrying value of redeemable convertible noncontrolling interest	(1,154)
Fair value of interest retained by BridgeBio	17,325
Gain on deconsolidation of PellePharm	(19,327)
Decrease in cash and cash equivalents resulting from the deconsolidation of PellePharm	$ 2,858

(1) Working capital is defined as current assets less current liabilities.

After the deconsolidation of PellePharm in November 2018, BridgeBio accounted for its retained common stock investment as an equity method investment. BridgeBio's common stock investment valued at $0.5 million upon deconsolidation was compared to BridgeBio's percentage of underlying equity in net assets of PellePharm. BridgeBio concluded that there was no material basis difference.

For the year ended December 31, 2019 and for the period November 20 through December 31, 2018, BridgeBio's share of PellePharm's net losses amounted to $0.2 million and $0.3 million, respectively, based on its percentage of common stock ownership in PellePharm. As of December 31, 2019 and 2018, the aggregate carrying amount of our equity method investment in PellePharm is zero and $0.2 million, respectively. As of December 31, 2019 and 2018, the aggregate carrying amount of the equity security investment in PellePharm is zero and $16.8 million, respectively. After the equity method investment was reduced to zero during the three months ended March 31, 2019, BridgeBio has subsequently recorded its percentage of net losses consistent with its preferred stock ownership percentage of 61.9% until the equity security investment was also reduced to zero during the remaining period of 2019. The carrying amount of BridgeBio's investment in PellePharm in the consolidated balance sheets represents its maximum loss exposure related to its VIE investment in PellePharm. The aggregate carrying amount of the PellePharm investment is presented as a separate line item in the consolidated balance sheets as of December 31, 2019 and 2018 as part of "Investments in nonconsolidated entities". We did not recognize an impairment related to our PellePharm investment during the year ended December 31, 2019 and 2018.

9. Commitments and Contingencies

Operating Lease Commitments

We lease office space and laboratory facilities under noncancelable operating leases that have terms expiring through October 2026.

In March 2017, BridgeBio entered into a three-year agreement to rent 3,900 square feet of office space in Palo Alto, California. In May 2019, the lease was extended by three years through April 2023. The aggregate rent expense under the lease is $2.2 million.

In November 2017, Eidos entered into a five-year agreement to rent 4,659 square feet of office space in San Francisco, California. The aggregate rent expense under the lease was $1.7 million. In March 2019, Eidos entered into an amendment to the November 2017 lease and the amended lease commenced on August 2019. In connection with the amendment, Eidos leases 10,552 rentable square feet. The amended Eidos lease is for 87 months and has $6.4 million of future minimum lease payments.

In February 2018, QED entered into a thirty-seven-month agreement to rent 1,944 square feet of office space in San Francisco, California. The aggregate rent expense under the lease is $0.6 million. In October 2018, QED entered into a thirty-four-month agreement to rent 10,000 square feet of office space in San Francisco, California. The aggregate rent expense under the lease is $2.6 million.

In October 2019, Adrenas entered into a sixty-one-month agreement to rent 11,376 square feet of laboratory facility in Raleigh, North Carolina. The aggregate rent expense under the lease is $1.9 million.

We recognize rent expense on a straight-line basis over the noncancelable lease period and record the difference between cash payments and the recognition of rent expense as a deferred rent liability. Where leases contain escalation clauses, rent abatements and/or concessions, such as rent holidays and landlord or tenant incentives or allowances, we apply them in the determination of straight-line rent expense over the lease period.

As of December 31, 2019, future minimum lease payments for all noncancelable operating leases with remaining lease terms in excess of one year, are as follows:

	Amount (in thousands)
Year Ending December 31:	
2020	$ 2,811
2021	2,515
2022	1,812
2023	1,485
2024	1,272
Thereafter	1,816
Total future minimum lease payments	$ 11,711

Total rent expense for the years ending December 31, 2019, 2018 and 2017 was $2.8 million, $1.5 million and $0.4 million, respectively.

Milestone Compensation Arrangements with Employees

We have performance-based milestone compensation arrangements with certain employees, whose vesting is contingent upon meeting various regulatory and development milestones, with fixed monetary amounts known at inception that can be settled in the form of cash or fully vested common stock of the Company at our sole election, upon achievement of each contingent milestones. As of December 31, 2019, the potential milestone compensation amount under these arrangements is up to $34.0 million. Under these arrangements, there was no compensation expense recognized or liability recorded for the year ended December 31, 2019 because the performance milestones are not considered probable of achievement.

Other Research and Development Agreements

We may also enter into contracts in the normal course of business with clinical research organizations for clinical trials, with contract manufacturing organizations for clinical supplies and with other vendors for preclinical studies, supplies and other services and products for operating purposes. These contracts generally provide for termination on notice, with the exception of potential termination charges related to one of our contract manufacturing agreements in the event that certain minimum purchase volumes are not met. As of December 31, 2019 and 2018, there were no amounts accrued related to termination charges for minimum purchase volumes not being met.

Indemnification

In the ordinary course of business, we may provide indemnifications of varying scope and terms to vendors, lessors, business partners, board members, officers and other parties with respect to certain matters, including, but not limited to, losses arising out of breach of such agreements, services to be provided by us, our negligence or willful misconduct, violations of law, or intellectual property infringement claims made by third parties. In addition, we have entered into indemnification agreements with directors and certain officers and employees that will require us, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors, officers or employees. No demands have been made upon the us to provide indemnification under such agreements, and thus, there are no claims that we are aware of that could have a material effect on our consolidated balance sheets, statements of operations and comprehensive loss, or statements of cash flows.

We also maintain director and officer insurance, which may cover certain liabilities arising from our obligation to indemnify our directors. To date, we have not incurred any material costs and have not accrued any liabilities in the consolidated financial statements as a result of these provisions.

Contingencies

From time to time, we may become involved in legal proceedings arising in the ordinary course of business. We are not currently a party to any material legal proceedings.

10. Term Loans

Hercules Loan and Security Agreement

In June 2018, we executed a Loan and Security Agreement with Hercules Capital, Inc. ("Hercules"), under which we borrowed $35.0 million ("Tranche I"). The term of the loan was approximately 42 months, with a maturity date of January 1, 2022 (the "Maturity Date"). No principal payments were due during an interest-only period, commencing on the initial borrowing date and continuing through July 1, 2020 (the "Amortization Date"). The outstanding balance of the loan was to be repaid monthly beginning on the Amortization Date and extending through the Maturity Date. The term loan bears interest at a floating rate equal to the greater of: (i) the prime rate as reported in the Wall Street Journal plus 4.35% and (ii) 9.35% (9.85% as of December 31, 2018 based on the prime rate as of that date), payable monthly.

In December 2018, we executed the First Amendment to the Loan and Security Agreement, whereby we borrowed an additional $20.0 million ("Tranche II") to increase the total principal balance outstanding to $55.0 million. Upon draw of the additional $20.0 million, the interest-only period on the entire facility was extended until January 1, 2021 (the "Amended Amortization Date"). The outstanding balance of the original loan of $35.0 million and the additional borrowing of $20.0 million is to be repaid monthly beginning on the Amended Amortization Date and extending through July 1, 2022 (the "Amended Maturity Date"). The additional $20.0 million loan bears interest at a floating rate equal to the greater of: (i) the prime rate as reported in the Wall Street Journal plus 3.35% and (ii) 9.10% (9.10% as of December 31, 2018), payable monthly.

On the earliest to occur of (i) the Amended Maturity Date, (ii) the date we prepay the outstanding principal amount of the Amended Hercules Term Loan or (iii) the date the outstanding principal amount of the Amended Hercules Term Loan otherwise becomes due, we will owe Hercules an end of term charge equal to 6.35% of the principal amount of the original $35.0 million term loan, or $2.2 million, and 5.75% of the principal amount of the incremental $20.0 million term loan, or $1.2 million. These amounts will be accrued over the term of the loan using the effective-interest method.

In May 2019, we executed the Second Amendment to the Loan and Security Agreement (the "Amended Hercules Term Loan") whereby we borrowed an additional $20.0 million ("Tranche III") to increase the total principal balance outstanding to $75.0 million.

In July 2019, the completion of the Corporation's IPO triggered certain provisions of the Amended Hercules Term Loan. The Corporation received an option to pay up to 1.5% of scheduled cash pay interest on the entire facility as payment in kind, or PIK Interest, with such cash pay interest paid as PIK Interest at a 1:1.2 ratio. The interest-only period will continue through July 1, 2021 (the "Amended Amortization Date") and the entire facility received a maturity date of January 1, 2023 (the "Amended Maturity Date"). The outstanding balance of the Amended Hercules Term Loan is to be repaid by the Corporation monthly beginning on the Amended Amortization Date and extending through the Amended Maturity Date.

The interest rate for the Amended Hercules Term Loan was established as follows: (1) Tranche I bears interest at a floating rate equal to the greater of: (i) the prime rate as reported in the Wall Street Journal plus 3.85% and (ii) 8.85% (8.85% as of December 31, 2019 based on the prime rate as of that date), payable monthly; (2) Tranche II bears interest at a floating rate equal to the greater of: (i) the prime rate as reported in the Wall Street Journal plus 2.85% and (ii) 8.60% (8.60% as of December 31, 2019), payable monthly; and (3) Tranche III bears interest at a floating rate equal to the greater of: (i) the prime rate as reported in the Wall Street Journal plus 3.10% and (ii) 9.10% (9.10% as of December 31, 2019), payable monthly.

The Amended Hercules Term Loan contains customary representations and warranties, events of default, and affirmative and negative covenants for a term loan facility of this size and type. However, Hercules imposes no liquidity covenants on us and Hercules cannot limit or restrict our ability to dispose of assets, make investments, or make acquisitions. As pledged collateral for our obligations under the Amended Hercules Term Loan, we granted Hercules a security interest in all our assets or personal property, including all equity interests owned or hereafter acquired by us. Further, at Hercules' sole discretion we must make a mandatory prepayment equal to 75% of net cash proceeds received from the sale or licensing of any pledged or collateral assets, including intellectual property, of a consolidated entity owned by us, or the repurchase or redemption of any pledged collateral by certain specified operating companies. None of our consolidated entities are a party to, nor provide any credit support or other security in connection with the Amended Hercules Term Loan.

During the years ended December 31, 2019 and 2018, we recognized interest expense related to the Amended Hercules Term Loan of $8.3 million and $2.4 million, respectively, of which $1.4 and $0.5 million, respectively, relates to amortization of debt discount.

The term loans balance is as follows:

	December 31,	
	2019	2018
	(in thousands)	
Principal value of term loans	$ 75,000	$ 55,000
Debt issuance costs and debt accretion	679	(493)
Term loans, noncurrent	$ 75,679	$ 54,507

Future minimum payments of principal and estimated payments of interest on our outstanding variable rate borrowings as of December 31, 2019 are as follows:

	Amount
	(in thousands)
Year Ending December 31:	
2020	$ 6,748
2021	28,825
2022	50,939
2023	8,861
Total future payments	95,373
Less amounts representing interest	(15,850)
Less final end of term payment	(4,523)
Total principal amount of term loan payments	$ 75,000

Silicon Valley Bank and Hercules Loan Agreement

On November 13, 2019, Eidos entered into a Loan and Security Agreement with Silicon Valley Bank and Hercules Capital, Inc. (the "SVB and Hercules Loan Agreement"). The SVB and Hercules Loan Agreement provides for up to $55.0 million in term loans to be drawn in three tranches as follows: (i) Tranche A loan of $17.5 million, (ii) Tranche B loan of up to $22.5 million which is available to be drawn until October 31, 2020, and (iii) Tranche C loan of up to $15.0 million available to be drawn upon the achievement of a clinical data milestone. The Tranche C loan is available to be drawn until September 30, 2021. The Tranche A loan of $17.5 million was drawn on November 13, 2019. There have not been any additional draws on the other tranches as of December 31, 2019.

The Tranche A loan bears interest at a fixed rate equal to the greater of either (i) 8.50% or (ii) 3.25% plus the prime rate as reported in The Wall Street Journal (8.50% as of December 31, 2019). The Tranche A loan repayment schedule provides for interest only payments until November 1, 2021, followed by consecutive equal monthly payments of principal and interest commencing on this date continuing through the maturity date of October 2, 2023.

The Tranche A loan also provides for a $0.3 million commitment fee that was paid at closing and a final payment charge equal to 5.95% multiplied by the amount funded to be paid when the loan becomes due or upon prepayment of the facility. If Eidos elects to prepay the Tranche A loan, there is also a prepayment fee of between 0.75% and 2.50% of the principal amount being prepaid depending on the timing and circumstances of prepayment. The Tranche A loan is secured by substantially all of Eidos' assets, except Eidos' intellectual property, which is the subject of a negative pledge.

Embedded derivatives and debt discounts

On issuance, the net carrying value of the Tranche A loan was $16.1 million after deducting for various discounts on issuance of $2.5 million. The discounts relate to the recognition of a bifurcated compound embedded derivative liability of $1.1 million, the final payment charge of $1.0 million due on maturity, the $0.3 million commitment fee paid at closing and $0.1 million in other debt issuance costs. The debt discounts are being amortized to interest expense over the life of the Tranche A loan using the effective interest rate method.

Eidos determined that the requirement in its SVB and Hercules Loan Agreement to pay a Success Fee in certain events is an embedded derivative liability requiring bifurcation from the Tranche A loan proceeds and separate accounting. The Success Fee amount is $1.0 million if conditions are met prior to November 13, 2021 and $2.0 million if conditions are met after November 13, 2021. Eidos also determined that certain events of default provisions resulting in the prepayment of the loan or a change in the default rate of interest should also be recorded as an embedded derivative liability but were deemed immaterial for this reporting period due to the triggers being deemed unlikely. Eidos recorded a compound embedded derivative liability of $1.1 million on issuance, which was recorded as a derivative liability in other liabilities on the balance sheet and as a corresponding debt discount.

Eidos calculated the fair values of the derivative liability on issuance and as of December 31, 2019 based on a probability weighted valuation of certain event outcomes and discounted to the present value. The key valuation assumptions used consist of the discount rate of 11.6% and the probability of an underlying event triggering the Success Fee payment and the timing of such events. The derivative liability is being remeasured at each financial reporting period with any changes in fair value being recognized as a component of other income (expense), net. The fair value of the derivative liability was approximately $1.2 million as of December 31, 2019 and was classified as other liabilities on the balance sheet and there was an immaterial change in the fair value of the derivative liability for the year ended December 31, 2019.

The facility fee, fair value of the bifurcated embedded derivative liability on issuance, and other debt issuance costs have been treated as debt discounts on our consolidated balance sheet and together with the final payment charge are being amortized to interest expense throughout the life of the Tranche A loan using the effective interest rate method.

As of December 31, 2019, the net carrying value of the Tranche A loan is $16.1 million. As of December 31, 2019, there are unamortized debt discounts of $2.4 million. Eidos recorded interest expense and amortization of the debt discount in the amount of $0.3 million on the Tranche A loan for the year ended December 31, 2019.

Future minimum payments

The following table presents future payments of principal, interest and final payment charge on the Eidos Tranche A loan as of December 31, 2019:

	Amount (in thousands)
Year Ending December 31:	
2020	$ 1,512
2021	2,961
2022	9,787
2023	8,622
Total future payments	22,882
Less amounts representing interest	(5,382)
Total principal amount of term loan payments	$ 17,500

11. License Agreements

Stanford License Agreement

In April 2016, Eidos entered into a license agreement with the Board of Trustees of the Leland Stanford Junior University ("Stanford University") relating to Eidos' drug discovery and development initiatives. Under this agreement, Eidos has been granted certain worldwide exclusive licenses to make, use and sell products that are covered by licensed patent rights. In March 2017, Eidos paid a license fee of $10,000, which was recorded as research and development expense during the year ended December 31, 2017, as the acquired assets did not have any alternative future use. Eidos may also be required to make future payments of up to approximately $1.0 million to Stanford University upon achievement of specific intellectual property, clinical and regulatory milestone events, and pay royalties of up to low single-digit percentages on future net sales, if any. In addition, Eidos is obligated to pay Stanford University a percentage of non-royalty revenue received by Eidos from its sublicensees, with the amount owed decreasing annually for three years based on when the applicable sublicense agreement is executed. During the years ended December 31, 2019, 2018 and 2017, Eidos recognized research and development expense of $0.2 million, $0.3 million and less than $0.1 million, respectively, in connection with this agreement.

Additionally, under the license agreement with Stanford University, we will pay Stanford University a portion of all nonroyalty sublicensing consideration attributable to the sublicense of the licensed compounds. The license agreement states that if this event occurred in the third year, 10% is payable to Stanford University. During the year ended in December 31, 2019, we recognized $2.5 million as a cost of license revenue upon execution of the Alexion license agreement (see Note 13).

The Regents of the University of California License Agreement

In September 2016, TheRas entered into a license agreement with The Regents of the University of California ("UCSF") relating to TheRas' drug discovery and development initiatives. Under this agreement, TheRas has been granted certain worldwide exclusive licenses to use the licensed compounds (the "UCSF License"). In connection with the UCSF License and subsequent amendments, we paid issuance fees totaling $0.3 million. In addition, under the terms of the UCSF License, we are required to pay to UCSF certain annual license maintenance fees unless we are selling or otherwise exploiting licensed products or services and paying royalties to UCSF on net sales for such licensed products or services. With respect to such royalty obligations, we agreed to pay UCSF low single-digit tiered royalties on annual net sales of licensed products and services, with a minimum royalty requirement of $0.1 million. Our obligation to pay royalties continues on a country-by-country basis until the expiration of all licensed patent rights covering licensed products in such country. In addition, we are obligated to make contingent milestone payments totaling up to $22.4 million upon the achievement of certain clinical or regulatory milestones. In the event that we sublicense the patent rights, UCSF is also entitled to receive a percentage of the sublicensing income received by us. During the years ended December 31, 2019, 2018 and 2017, TheRas recognized research and development expense of $0.4 million, $0.1 million and $0.2 million, respectively, in connection with this agreement.

Leidos Biomedical Research License and Cooperative Research and Development Agreements

In March 2017, TheRas entered into a cooperative research and development agreement ("Leidos CRADA") with Leidos Biomedical Research, Inc. ("Leidos"). In December 2018, TheRas and Leidos entered into a license agreement ("Leidos License," and together with the Leidos CRADA, the "Leidos Agreements") under which TheRas has been granted certain worldwide exclusive licenses to use the licensed compounds. The Leidos Agreements are related to TheRas' drug discovery and development initiatives. During the years ended December 31, 2019, 2018 and 2017, TheRas recognized research and development expenses of $1.9 million, $0.9 million and $0.4 million, respectively, in connection with the Leidos Agreements.

Other License and Collaboration Agreements

In addition to the agreements described above, we have also entered into other license and collaboration agreements with various institutions and business entities on terms similar to those described above, none of which are material individually or in the aggregate.

12. Asset Acquisitions

ML Bio Asset Acquisition

As described in Note 6, as of July 2019, ML Bio was a variable interest entity. Based on the qualitative assessment performed under ASC 805 *Business Combinations*, we concluded that ML Bio was not considered to be a business and accounted for the initial July 2019 investment in ML Bio as an asset acquisition. The assets acquired, liabilities and noncontrolling interest assumed in the transaction were measured based on their fair values. We recognized a loss of $0.4 million in other income (expense), net. The loss was calculated as the sum of consideration paid of $7.0 million and fair value of noncontrolling interest issued of $4.0 million, less fair value of identifiable net assets acquired of $10.6 million.

The fair value of the IPR&D acquired of $1.0 million was charged to research and development expense as it had no alternative future use at the time of the acquisition. BridgeBio may be required to purchase additional shares of preferred stock of up to $24.5 million upon achievement of certain development milestones by ML Bio. The assembled workforce acquired of $0.2 million was amortized during the year ended December 31, 2019.

Retinagenix Asset Acquisition

In June 2019, Retinagenix, Inc. ("Retinagenix") entered into a Unit Purchase and Sale Agreement with the owners of a biopharmaceutical entity to acquire 100% of the outstanding equity of the entity. Retinagenix accounted for the transaction as an asset acquisition as substantially all of the estimated fair value of the gross assets acquired were concentrated in a group of similar identified assets, IPR&D. The assets acquired and liabilities assumed in the transaction were measured based on their fair values.

The fair value of the IPR&D acquired was $0.5 million and was charged to research and development expense as it had no alternative future use at the time of the acquisition. If certain substantive milestones are met in the future, Retinagenix could be required to pay up to $7.0 million in regulatory milestone payments, $65.0 million in sales milestone payments, and pay royalties of up to low single-digit percentages on future net sales. Royalties may increase to up to mid-single-digit percentages in certain circumstances.

Origin Biosciences, Inc. ("Origin") Asset Acquisition

In June 2018, Origin entered into an Asset Purchase Agreement with Alexion Pharma Holding Unlimited Company ("Alexion") to acquire intellectually property rights, including patent rights, know-how, and contracts, related to the ALXN1101 molecule. As consideration, Origin made an upfront cash payment of $1.0 million. There were no material direct transaction costs related to the transaction.

Origin accounted for the transaction as an asset acquisition as substantially all of the estimated fair value of the gross assets acquired was concentrated in a single identified asset, IPR&D, thus satisfying the requirements of the screen test in ASU 2017-01. The assets acquired and liabilities assumed in the transaction were measured based on their fair values. The fair value of the IPR&D acquired was $1.0 million and was charged to research and development expense as it had no alternative future use at the time of the acquisition. If certain substantive milestones are met in the future, Origin could be required to pay up to $18.8 million if Origin receives a priority review voucher from the Food and Drug Administration, $3.0 million in regulatory milestone payments, $17.0 million in sales milestone payments, and pay royalties of up to low double-digit percentages on future net sales, if any.

QED Therapeutics, Inc. ("QED") Asset Acquisition

In January 2018, QED entered into a License Agreement with Novartis International Pharmaceutical, Inc. ("Novartis"), pursuant to which QED acquired certain intellectual property rights, including patents and know-how, related to BBP-831 for the treatment of patients with FGFR-driven diseases. As consideration for the License Agreement, QED made an upfront cash payment of $15.0 million and issued 2,941,176 shares of QED Series A Preferred Stock to Novartis. There were no material direct transaction costs related to the transaction. The fair value of the QED Series A Preferred Stock was valued by a third-party specialist at $0.59 per share or a total fair value of shares issued of $1.7 million.

QED accounted for the transaction as an asset acquisition as substantially all of the estimated fair value of the gross assets acquired was concentrated in a single identified asset, IPR&D, thus satisfying the requirements of the screen test in ASU 2017-01. The assets acquired and liabilities assumed in the transaction were measured based on their fair values. The fair value of the IPR&D acquired was $16.7 million and was charged to research and development expense as it had no alternative future use at the time of the acquisition. If certain substantive milestones are met in the future, QED could be required to pay up to $60.0 million in regulatory milestone payments, $35.0 million in sales milestone payments, and pay royalties of up to low double-digit percentages on future net sales, if any.

Phoenix Tissue Repair, Inc. Asset Acquisition

In July 2017, PTR entered into the Contribution Agreement and Asset Purchase Agreement with Shire Human Genetic Therapies, Inc. and its subsidiary Lotus Tissue Repair, Inc. to acquire the right, title, and interest in certain intellectual property, research program assets, and contracts relating to recombinant human collagen type VII. As consideration, in 2017, PTR made an upfront cash payment of $1.5 million and issued 10,019,900 shares of PTR common stock valued at a nominal fair value at issuance. There were no material direct transaction costs related to the transaction.

PTR accounted for the transaction as an asset acquisition as substantially all of the estimated fair value of the gross assets acquired was concentrated in a single identified asset, IPR&D, thus satisfying the requirements of the screen test in ASU 2017-01. The assets acquired and liabilities assumed in the transaction were measured based on their fair values. The fair value of the IPR&D acquired was $1.5 million and was charged to research and development expense as it had no alternative future use at the time of the acquisition. If certain substantive milestones are met in the future, PTR could be required to pay up to $27.0 million in regulatory milestone payments, $60.0 million in sales milestone payments, and pay royalties of up to low single-digit percentages on future net sales, if any.

During the year ended December 31, 2019, PTR made a milestone payment of $2.0 million in connection with this agreement related to the Phase I initiation milestone being met. This amount was charged to research and development expense as the underlying in-process research and development asset has no alternative future use.

13. License Revenue

Alexion License Agreements

In September 2019, Eidos and an affiliate of Alexion Pharmaceuticals, Inc. ("Alexion") entered into an exclusive license agreement with Alexion to develop, manufacture and commercialize the compound known as AG10 and any of its various chemical forms and any pharmaceutical products containing AG10 in Japan. Under the agreement, Eidos received an upfront nonrefundable payment of $25.0 million.

Additionally, Eidos and Alexion entered into a stock purchase agreement (collectively with the exclusive license agreement, the "Alexion Agreements"), under which Eidos sold to Alexion 556,173 shares of the common stock of Eidos at a price per share of $44.95, for an aggregate purchase price of approximately $25.0 million. The excess of the purchase price over the value of the shares of Eidos' common stock, determined based on the closing price of a share of the common stock of Eidos of $41.91 as reported on The Nasdaq Global Select Market as of the date of execution, was $1.7 million.

Eidos accounted for the exclusive license agreement under ASC 606 and identified the exclusive license as a distinct performance obligation since Alexion can benefit from the license on its own by developing and commercializing the underlying product using its own resources. In addition, Eidos will enter into clinical and commercial supply agreements for the licensed territory. Eidos determined that the optional right to future products under these supply agreements is not considered to represent a material right.

Eidos is also eligible to receive $30.0 million in regulatory milestone payments subject to the achievement of regulatory milestones. Eidos will also receive low double-digit royalty payments based on net sales of AG10 in Japan. The royalty rate is subject to reduction if Alexion is required to obtain intellectual property rights from third parties to develop, manufacture or commercialize AG10 in Japan, or upon the introduction of generic competition into market. Eidos is also in discussions with Alexion on a supply agreement that has not yet been finalized as of the period ending December 31, 2019.

Eidos accounted for the Alexion License Agreement under ASC 606 and identified the exclusive license as a distinct performance obligation since Alexion can benefit from the license on its own by developing and commercializing the underlying product using its own resources. In addition, Eidos will enter into clinical and commercial supply agreements for the licensed territory. Eidos recognized the $25.0 million upfront fee and $1.7 million premium paid for the Eidos' stock for a total upfront payment of $26.7 million in license revenue upon the effective date of the Alexion License Agreement in September 2019. Eidos determined that the license was a right to use Eidos' intellectual property and as of the effective date, Eidos had provided all necessary information to Alexion to benefit from the license and the license term had begun.

Eidos considers the future potential regulatory milestones of up to approximately $30.0 million and the sales-based royalties to be variable consideration. Eidos excluded the regulatory milestones from the transaction price because it determined such payments to be fully constrained under ASC 606 due to the inherent uncertainty in the achievement of such milestone payments and are highly susceptible to factors outside of Eidos' control. As the sales-based royalties are all related to the license of the IP, Eidos will recognize revenue in the period when subsequent sales are made pursuant to the sales-based royalty exception under ASC 606-10-55-65. Eidos will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

License and Exclusivity Agreements with Entities Affiliated with Perceptive Advisors LLC

In October 2019, our subsidiary, QED entered into an exclusive license agreement (the "License Agreement") with a licensee entity in which Perceptive Life Sciences Master Fund, Ltd. ("Perceptive Master Fund") and certain of its affiliated funds hold a majority of the outstanding voting securities. Perceptive Master Fund directly holds shares of our common stock representing a greater than 5% ownership interest. Perceptive Advisors LLC ("Perceptive Advisors," and collectively with Perceptive Master Fund and its affiliated funds, "Perceptive") serves as the investment manager to the Master Fund and may be deemed to beneficially own the securities directly held by Perceptive Master Fund. Mr. Joseph Edelman is the managing member of Perceptive Advisors and may be deemed to beneficially own the securities directly held by Perceptive Master Fund.

Pursuant to the License Agreement, QED granted to the licensee an exclusive, sublicensable license under the licensed patent rights and know-how to develop, manufacture and commercialize infigratinib for any and all human prophylactic and therapeutic uses in all cancer indications (including in combination with other therapies) in certain territories outside the United States. Under the License Agreement, QED received a nonrefundable upfront payment of $10.0 million and was granted certain equity rights in an affiliate of the licensee. Additionally, QED is entitled to receive payments from the licensee totaling an aggregate of up to $132.5 million upon the achievement of specified development and sales milestones and tiered royalties on net sales ranging from the low to mid teens.

In October 2019, our subsidiary, BBP LLC, concurrently entered into an exclusivity agreement with the above-mentioned licensee entity controlled by Perceptive, pursuant to which BBP LLC received equity in the entity representing a 10% ownership interest, valued at approximately $3.8 million at the time of the transaction. The equity interest was issued in consideration for certain rights of first negotiation and rights of first offer granted by BBP LLC to the entity with respect to specified transactions covering intellectual property rights owned or controlled by BBP LLC or its affiliates in certain territories outside the United States. Pursuant to the exclusivity agreement, BBP LLC also received warrant to purchase 10% of the then-fully diluted shares of one of the subsidiary of the above-mentioned licensee entity controlled by Perceptive upon achievement of certain contingent milestones.

We accounted for the license and exclusivity agreement as a single transaction under ASC 606 and identified the exclusive license as a distinct performance obligation since the third party can benefit from the license on its own by developing and commercializing the underlying product using its own resources. In addition, we will enter into clinical and commercial supply agreements for the licensed territory. The Company determined that the optional right to future products under these supply agreements is not considered to represent a material right.

During the year ended December 31, 2019, we recognized $13.8 million in license revenue comprising of $10.0 million in upfront payment received and the fair value of the ordinary shares received amounting to $3.8 million. We determined that the license was a right to use the intellectual property of QED and as of the effective date, we had provided all necessary information to the third party to benefit from the license and the license term. As of December 31, 2019, we also determined the contingent milestone related to our ability to exercise the warrant is not probable. As a result, we did not recognize any fair value of the warrant, which we considered to be immaterial, as revenue or record as an asset.

We consider the future potential development and sales milestones as well as the sales-based royalties to be variable consideration. We excluded the regulatory-based development and sales milestones from the transaction price because we determined such payments to be fully constrained under ASC 606 due to the inherent uncertainty in the achievement of such milestone payments and are highly susceptible to factors outside of our control. As the sales-based royalties are all related to the license of the IP, the Company will recognize revenue in the period when subsequent sales are made pursuant to the sales-based royalty exception under ASC 606-10-55-65. The Company will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

14. Build-to-Suit Operating Lease

In December 2019, we entered into a manufacturing agreement to secure clinical and commercial scale manufacturing capacity for the manufacture of batches of active pharmaceutical ingredients for product candidates of certain subsidiaries of the Company. Unless terminated as allowed within the manufacturing agreement, the agreement will expire five (5) years from when qualified operations begin. Under the terms of the agreement, we are assigned a dedicated manufacturing suite for certain months in each calendar year for a one-time fee of $10.0 million, which will be applied to the buildout, commissioning, qualification, validation, equipping and exclusive use of the dedicated manufacturing suite.

We evaluated our involvement during the construction period and determined the scope of the tenant improvements within dedicated manufacturing suite including the building shells did not qualify as "normal tenant improvements" under ASC Topic 840, *Leases*. Accordingly, for accounting purposes, we will be the deemed owner of the dedicated manufacturing suite during the construction period and considered an embedded operating lease arrangement. We recorded the $10.0 million one-time fee in noncurrent asset. As of December 31, 2019, we paid $2.0 million of the $10.0 million one-time fee and the remaining $8.0 million payable is classified as build-to-suit lease obligation under current liabilities. Upon commencement of construction, we will re-classify such reservation fee under noncurrent asset to construction-in-progress under property and equipment.

15. Related Party Transactions

PellePharm

During the year ended December 31, 2019 and during November through December 2018, we provided nominal services to PellePharm.

16. Stock-Based Compensation

Under each of the legal entity's equity plans, we recorded stock-based compensation in the following expense categories in our consolidated statements of operations for employees and non-employees:

	Year Ended December 31, 2019			
	BridgeBio Equity Plan	Eidos Equity Plan	Other Subsidiaries Equity Plan	Total
	(in thousands)			
Research and development	$ 986	$ 2,313	$ 366	$ 3,665
General and administrative	14,204	3,060	445	17,709
Total stock-based compensation	$ 15,190	$ 5,373	$ 811	$ 21,374

	Year Ended December 31, 2018			
	BridgeBio Equity Plan	Eidos Equity Plan	Other Subsidiaries Equity Plan	Total
	(in thousands)			
Research and development	$ —	$ 1,325	$ 186	$ 1,511
General and administrative	3,183	1,201	172	4,556
Total stock-based compensation	$ 3,183	$ 2,526	$ 358	$ 6,067

	Year Ended December 31, 2017			
	BridgeBio Equity Plan	Eidos Equity Plan	Other Subsidiaries Equity Plan	Total
	(in thousands)			
Research and development	$ —	$ 519	$ 7	$ 526
General and administrative	541	629	145	1,315
Total stock-based compensation	$ 541	$ 1,148	$ 152	$ 1,841

Stock-Based Awards of the Corporation

On June 22, 2019, we adopted the 2019 Stock Option and Incentive Plan (the "2019 Plan"), which became effective on June 25, 2019. The 2019 Plan provides for the grant of stock-based incentive awards, including common stock options and other stock-based awards. We were authorized to issue 11,500,000 shares of common stock for issuance of awards under the 2019 Plan, which may be allocated among stock options, awards of restricted common stock, restricted common units and other stock-based awards.

The 2019 Plan provides that the number of shares reserved and available for issuance will automatically increase each January 1, beginning on January 1, 2020, by 5% of the issued and outstanding number of shares of common stock on the immediately preceding December 31, or such lesser number of shares as determined by the Compensation Committee of the Board of Directors.

On November 13, 2019, the we adopted the 2019 Inducement Equity Plan (the "2019 Inducement Plan"). The 2019 Inducement Plan provides for the grant of stock-based awards to induce highly-qualified prospective officers and employees who are not currently employed by the Corporation or its Subsidiaries to accept employment and to provide them with a proprietary interest in the Company, including common stock options and other stock-based awards. We were authorized to issue 1,000,000 shares of common stock for inducement awards under the 2019 Inducement Plan, which may be allocated among stock options, awards of restricted common stock, restricted common units and other stock-based awards.

The following table summarizes our authorized shares activity under the 2019 Plan and the 2019 Inducement Plans (the "Plans"):

	2019 Plan	2019 Inducement Plan
Balance as of December 31, 2018	—	—
Authorized	11,500,000	1,000,000
Granted — Stock options	(4,397,117)	(253,974)
Granted — Restricted stock units	(181,274)	(180,889)
Granted — Restricted stock awards	(6,819,455)	—
Granted — Common stock	(2,682)	(22,839)
Granted — Market-based restricted stock units	(76,637)	(53,234)
Cancelled — Stock options	23,365	—
Cancelled — Restricted stock	6,867	—
Balance as of December 31, 2019	53,067	489,064

Stock Option Grants of the Corporation

The following table summarizes the Corporation's stock option activity under the Plans for the period through December 31, 2019:

	Options Outstanding	Weighted-Average Exercise Price per Option	Weighted-Average Remaining Contractual Life (years)	Aggregate Intrinsic Value
	(in thousands, except share and per share amounts)			
Outstanding as of December 31, 2018	—	$ —	—	$ —
Granted	4,651,091	$ 20.09		
Exercised	(949)	$ 17.00		
Cancelled	(23,365)	$ 17.00		
Outstanding as of December 31, 2019	4,626,777	$ 20.10	9.6	$ 70,348
Exercisable as of December 31, 2019	514,472	$ 17.89	9.5	$ 8,830

The options granted to employees and non-employees are exercisable at the price of the Corporation's common stock at the respective grant dates. The options granted have a service condition and generally vest over a period of four years.

The aggregate intrinsic value of options outstanding and exercisable as of December 31, 2019 is calculated based on the difference between the exercise price and the current fair value the Corporation's common stock.

During the year ended December 31, 2019, we recognized stock-based compensation expense of $3.9 million related to stock options under the Plans. As of December 31, 2019, there was $32.2 million of total unrecognized compensation cost related to stock options under the Plans. The unrecognized stock-based compensation cost is expected to be recognized over a weighted-average period of 3.4 years.

Restricted Stock Units (RSUs) of the Corporation

During the year ended December 31, 2019, the Board of Directors approved grants of RSUs to senior management and officers subject to continued employment and generally vest over a period of four years.

As of December 31, 2019, there are 362,163 RSUs issued and outstanding with weighted average grant date fair value of $31.98. There were no releases of RSUs during the year ended December 31, 2019.

During the year ended December 31, 2019, we recognized stock-based compensation expense of $0.2 million related to shares of RSUs under the Plans. As of December 31, 2019, there was $11.4 million of total unrecognized compensation cost related to RSUs under the Plans. The unrecognized stock-based compensation cost is expected to be recognized over a weighted-average period of 4.0 years.

Restricted Stock Awards (RSAs) of the Corporation

As disclosed in Note 3, upon the Reorganization, all unvested outstanding management incentive units and common units of BBP LLC were cancelled and converted into shares of the Corporation's RSAs.

The following table summarizes our RSA activity under the Plans for the period through December 31, 2019:

	Unvested Shares of Restricted Stock Outstanding		Weighted-Average Grant Date Fair Value
Balance at December 31, 2018	—		—
BBP LLC units converted into shares of unvested restricted stock of the Corporation	6,819,455	$	3.38
Vested	(1,209,136)	$	2.24
Cancelled	(6,867)	$	7.27
Balance at December 31, 2019	5,603,452	$	3.63

During the year ended December 31, 2019, we recognized stock-based compensation expense of $4.2 million related to RSAs under the Plans. As of December 31, 2019, there was $26.0 million of total unrecognized compensation cost related to RSAs under the Plans. The unrecognized stock-based compensation cost is expected to be recognized over a weighted-average period of 3.5 years. The 5,603,452 unvested RSAs as of December 31, 2019 are included as outstanding shares disclosed in the consolidated balance sheet as of December 31, 2019 as the shares were actually issued upon Reorganization but are subject to forfeiture per the terms of the awards.

Market-Based RSUs of the Corporation

During the year ended December 31, 2019, the Board of Directors approved and granted market-based RSUs. One such market-based RSU award includes a market condition based on the Total Shareholders' Return (TSR) of the Corporation's common stock as compared to the TSR of the Nasdaq Biotechnology Index and the vesting percentage of the award is calculated based on the three-year performance period from vesting commencement date. The other market-based RSU award includes a market condition based on the Corporation's market capitalization reaching $5.0 billion and vests immediately at 100% upon achievement of said market capitalization. The market-based RSUs require continuous employment.

The respective grant date fair values of these awards, which aggregate to $3.8 million for the year December 31, 2019, were determined using a Monte Carlo valuation model and are recognized as compensation expense over the implied service period of the awards.

As of December 31, 2019, there are 129,871 market-based RSUs outstanding with weighted average grant date fair value of $28.98. For the year ended December 31, 2019, we recognized $2.3 million stock-based compensation expense related to market-based RSU awards. As of December 31, 2019, there was $1.5 million of total unrecognized compensation cost related to market-based RSUs under the Plans. There were no such awards prior to 2019.

2019 Employee Stock Purchase Plan

On June 22, 2019, we adopted the 2019 Employee Stock Purchase Plan (the "ESPP") which became effective on June 25, 2019. The ESPP initially reserves and authorizes the issuance of up to a total of 2,000,000 shares of common stock to participating employees. The ESPP provides that the number of shares reserved and available for issuance will automatically increase each January 1, beginning on January 1, 2020, by the lower of: i) 1% of the outstanding number of shares of common stock on the immediately preceding December 31, ii) 2,000,000 shares or iii) such lesser number of shares as determined by the Compensation Committee.

Under the ESPP, eligible employees may purchase shares of BridgeBio common stock through payroll deductions at a price equal to 85% of the lower of the fair market values of the stock as of the beginning or the end of six-month offering periods. An employee's payroll deductions under the ESPP are limited to 15% of the employee's compensation and employees may not purchase more than 3,500 of shares of BridgeBio common stock during any offering period.

During the year ended December 31, 2019, the Company recognized stock-based compensation expense of $0.4 million related to the ESPP. As of December 31, 2019, 1,936,283 shares were reserved for future issuance under the ESPP.

We used the Black-Scholes model to estimate the fair value of stock options and stock purchase rights under ESPP. For the year ended December 31, 2019, we used the following weighted-average assumptions in the Black-Scholes calculations:

	Stock Options	ESPP
Expected term (in years)	5.00-6.08	0.40
Expected volatility	37.4%	43.4%
Risk-free interest rate	1.84%	2.12%
Dividend yield	—	—
Weighted-average fair value of stock-based awards granted	$ 7.81	$ 5.51

Equity-Based Awards of BBP LLC

Up until the reorganization, BBP LLC issued management incentive units and common units (collectively, "BBP LLC equity-based awards"). BBP LLC's Second Amended and Restated Limited Liability Company Agreement, Third Amended and Restated Limited Liability Company Agreement and LLC Agreement provided for the issuance of Management Incentive Units and Common Units to employees and non-employees. During 2019, 2018 and 2017, BBP LLC issued Management Incentive Units and Common Units based on the approval of the board of BBP LLC for each grant date.

Under the terms of the Management Incentive Units' agreements, the vesting schedule is typically 1/60th of the total number of Management Incentive Units, which vest on each monthly anniversary of the vesting commencement date, subject to continued service to BridgeBio. If a Fundamental Transaction takes place, the remaining vesting related to the Management Incentive Units and Common Units will accelerate. Under the terms of the Common Units' agreements, the vesting schedule is typically between two and five years with vesting taking place on each monthly anniversary of the vesting commencement date, subject to continued service to BBP LLC through the applicable vesting date.

No distributions can be made to the holders of Management Incentive Units until the aggregate distributions made to other members (Preferred Unit, Founder Unit and Common Unit members) exceed the Management Incentive Units' participation threshold. BridgeBio has determined that the underlying terms and intended purpose of the Management Incentive Units and Common Units are more akin to an equity-based compensation for employees and non-employees than a performance bonus or profit-sharing arrangement.

As described in Note 3, BBP LLC equity-based awards were cancelled and exchanged for shares of BridgeBio restricted common stock. For the years ended December 31, 2019, 2018 and 2017, equity-based compensation from BBP LLC equity-based awards was $3.4 million, $3.2 million and $0.5 million, respectively.

The following table summarizes authorized BBP LLC equity-based awards activity as if the Management Incentive Units and Common Units were converted to restricted common stock of the Corporation at the earliest period presented:

	Equivalent Shares of the Corporation's Restricted Common Stock
Balance as of January 1, 2017	5,850,264
Granted	4,073,919
Cancelled	(479,114)
Balance as of December 31, 2017	9,445,069
Granted	550,677
Cancelled	(1,263)
Balance as of December 31, 2018	9,994,483
Authorized and granted	2,587,939
Cancelled	(842)
Converted into common stock of the Corporation	(5,762,125)
Converted into unvested restricted common stock of the Corporation	(6,819,455)
Balance as of December 31, 2019	—

The following table summarizes vested BBP LLC equity-based awards activity as if the Management Incentive Units and Common Units were converted to restricted common stock of the Corporation at the earliest period presented:

	Equivalent Shares of the Corporation's Restricted Common Stock	Weighted-Average Grant Date Fair Value
Balance at January 1, 2017	1,495,037	$ 0.31
Vested	1,316,657	$ 0.36
Balance at December 31, 2017	2,811,694	$ 0.34
Vested	1,827,623	$ 0.62
Balance at December 31, 2018	4,639,317	$ 0.45
Vested	1,122,808	$ 2.10
Converted into common stock of the Corporation	(5,762,125)	$ 0.72
Balance at December 31, 2019	—	$ —

The estimated grant-date fair value of each Common Unit and Management Incentive Unit award was calculated using the Black-Scholes option pricing model, based on assumptions as follows:

	Year Ended December 31,		
	2019	2018	2017
Expected term (in years)	1.50	0.75-1.50	1.50
Expected volatility	48.0%-49.0%	40.0%-49.0%	45.0%
Risk-free interest rate	2.34%-2.56%	1.70%-2.56%	1.70%
Dividend yield	—	—	—

The fair value of each Common Unit and Management Incentive Unit award was determined using the methods and assumptions discussed below. Each of these inputs is subjective and generally requires significant judgement and estimation.

Fair value of Management Incentive Units and Common Units —Because there was no public market for BBP LLC's units as BBP LLC was a private company, BBP LLC's board determined the fair value of Common Units and Management Incentive Units by considering a number of objective and subjective factors, including having contemporaneous and retrospective valuations of its equity performed by a third-party valuation specialist, valuations of comparable peer public companies, sales of BBP LLC's redeemable convertible preferred units, operating and financial performance, the lack of liquidity of BBP LLC's units and general and industry-specific economic outlook.

Expected term —The expected term was based on BBP LLC's expectations with regard to an exit strategy such as an IPO or liquidation event.

Expected volatility — BBP LLC was a private company and lacks company-specific historical and implied volatility information. Therefore, it estimated its expected share volatility based on the historical volatility of a set of publicly traded peer companies and expected to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded share price.

Risk-free interest rate —The risk-free interest rate was determined by reference to the United States Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award.

Expected dividend —The dividend yield was assumed to be immaterial based on future distribution expectations throughout the expected term.

Each of the above inputs was subjective and generally required significant judgement and estimation.

Equity Awards of Eidos

Eidos 2016 Equity Incentive Plan

In April 2016, Eidos established its 2016 Equity Incentive Plan (the "Eidos 2016 Plan"), which provides for the granting of equity awards to employees and consultants of Eidos. Awards granted under the Eidos 2016 Plan may be either incentive stock options ("ISOs"), nonqualified stock options ("NSOs") or restricted stock awards. ISOs may be granted only to Eidos employees (including officers and directors who are also employees). NSOs may be granted to Eidos employees and consultants. The exercise price of an ISO and NSO shall not be less than 100% of the estimated fair value of the shares on the date of grant, as determined by the Eidos Board of Directors. The exercise price of an ISO granted to an employee who at the time of grant is a 10% stockholder shall not be less than 110% of the estimated fair value of the shares on the date of grant, as determined by the Eidos Board of Directors. To date, ISOs and NSOs have a term of ten years and generally vest over a four-year period with annual cliff vesting and the balance monthly over 36 months. Upon completion of the Eidos IPO, the remaining shares available for issuance under the Eidos 2016 Plan were retired.

Eidos Amended and Restated 2018 Stock Option and Incentive Plan

In May 2018, the Eidos Board of Directors and stockholders approved the Amended and Restated 2018 Stock Option and Incentive Plan (the "Eidos 2018 Plan"), to replace the Eidos 2016 Plan. The Eidos 2018 Plan became effective upon the Eidos IPO and is administered by the Eidos Board of Directors or an appointed committee, which determines the types of awards to be granted, including the number of shares subject to the awards, the exercise price and the vesting schedule. Under the Eidos 2018 Plan, 598,000 shares of Eidos' common stock have been initially reserved for the issuance of stock options, restricted stock units and other awards to employees, directors and consultants. Options granted under the Eidos 2018 Plan expire no later than 10 years from the date of grant. The exercise price of each option may not be less than 100% of the fair market value of the common stock at the date of grant. Options may be granted to stockholders possessing more than 10% of the total combined voting power of all classes of stocks of Eidos at an exercise price at least 110% of the fair value of the common stock at the date of grant and the options are not exercisable after the expiration of 10 years from the date of grant. Employee stock options generally vest 25% upon one year of continued service to Eidos, with the remainder in monthly increments over three additional years. Upon adoption of the Eidos 2018 Plan, no additional stock awards will be issued under

the Eidos 2016 Plan. Options granted under the Eidos 2016 Plan that were outstanding on the date the Eidos 2018 Plan became effective remain subject to the terms of the Eidos 2016 Plan. In December 2018, the Eidos Board of Directors approved an increase in the number of shares reserved under the Eidos 2018 Plan by 700,000 shares, and this increase was approved by Eidos' stockholders in June 2019. In December 2019, Eidos' board of directors approved an additional increase in the number of shares reserved under the 2018 Plan by 1,500,000 shares. As of December 31, 2019, Eidos has reserved 2,798,000 shares of common stock for issuance under the 2018 Plan, of which the 1,500,000 shares subject to the December 2019 increase remain subject to stockholder approval.

Eidos Employee Stock Purchase Plan

In May 2018, Eidos board of directors and stockholders approved the 2018 Employee Stock Purchase Plan, or the 2018 ESPP, which became effective upon the IPO. The 2018 ESPP is intended to qualify as an employee stock purchase plan under Section 423 of the Internal Revenue Code of 1986, as amended, and is administered by Eidos' board of directors and the Compensation Committee of the board of directors. Under the 2018 ESPP, 143,520 shares of Eidos' common stock have been initially reserved for employee purchases of Eidos' common stock. The 2018 ESPP allows eligible employees to purchase shares of Eidos common stock at a discount through payroll deductions of up to 20% of their eligible compensation. At the end of each offering period, employees are able to purchase shares at 85% of the lower of the fair market value of Eidos' common stock at the beginning of the offering period or at the end of each applicable purchase period. The first purchase period commenced upon the completion of Eidos' IPO and ended on November 30, 2018.

The fair value of the rights granted under the Eidos 2018 ESPP was calculated using the Black-Scholes option-pricing model with the following assumptions:

	Year Ended December 31, 2019	Year Ended December 31, 2018
Expected term in years	0.50	0.48
Expected volatility	63.06%	70.40%
Risk-free interest rate	2.32%	1.50%
Dividend yield	0%	0%

Eidos Stock Options

Activity under the Eidos equity incentive plans is set forth below:

	Options Available for Grant	Options Outstanding	Weighted-Average Exercise Price per Option	Weighted-Average Remaining Contractual Life (years)	Aggregate Intrinsic Value
	(in thousands, except per share and per share data)				
Outstanding as of December 31, 2018	747,057	1,329,762	$ 8.55	9.40	$ 6,928
Additional authorized	1,500,000	—	$ —		
Options granted	(365,573)	365,573	$ 34.51		
Options exercised	—	(306,010)	$ 3.30		
Options cancelled	53,570	(53,570)	$ 7.24		
Outstanding—December 31, 2019	1,935,054	1,335,755	$ 16.91	8.77	$ 54,071
Options exercisable—December 31, 2019		241,289	$ 11.16	8.50	$ 11,155
Options vested and expected to vest—December 31, 2019		1,335,755	$ 16.91	8.77	$ 54,071

Aggregate intrinsic value represents the difference between Eidos' estimated fair value of its common stock and the exercise price of outstanding in–the–money options. The total intrinsic value of options exercised was $12.3 million, $0.9 million and $2.9 million for the years ended December 31, 2019, 2018 and 2017, respectively.

The total fair value of Eidos shares vested during the years ended December 31, 2019, 2018 and 2017 was $5.2 million, $2.5 million and $0.5 million, respectively.

Eidos Stock Options Granted to Non-employees

Stock-based compensation related to stock options granted to non-employees is recognized as the stock options are earned. The fair value of non-employee stock options is estimated using the Black-Scholes valuation model with assumptions generally consistent with those used for employee stock options, with the exception of the expected term, which is the remaining contractual life at each measurement date. During the years ended December 31, 2019, 2018 and 2017, Eidos granted 20,361, 35,880 and 569,252 shares, respectively, to non-employee consultants. Eidos recognized stock-based compensation expense for non-employee awards during the years ended December 31, 2019, 2018 and 2017 of $0.1 million, $1.7 million and $ 0.7 million, respectively.

Eidos Stock Options Valuation

Prior to the completion of Eidos' IPO, the fair value of Eidos shares of common stock underlying its stock options had historically been determined by Eidos board of directors. Because there had been no public market for the Eidos common stock prior to June 2018, Eidos board of directors had determined fair value of the common stock at the time of grant of the option by considering a number of objective and subjective factors including important developments in the Eidos operations, valuations performed by an independent third party, sales of redeemable convertible preferred stock, actual operating results and financial performance, the conditions in the biotechnology industry and the economy in general, the stock price performance and volatility of comparable public companies, and the lack of liquidity of Eidos common stock, among other factors. For stock options granted after the completion of the IPO, Eidos determines the fair value of each share of underlying common stock based on the closing price of Eidos common stock as reported on the date of grant.

The fair value of employee and non-employee director of Eidos stock option awards was estimated at the date of grant using a Black-Scholes option-pricing model with the following assumptions:

	Year Ended December 31, 2019		Year Ended December 31, 2018		Year Ended December 31, 2017	
	Employee	Non-employee	Employee	Non-employee	Employee	Non-employee
Expected term (in years)	6.07	6.09	6.08	9.20	5.83	9.66
Expected volatility	72.4%	73.7%	72.0%	73.9%	68.4%	80.1%
Risk-free interest rate	1.95%	2.49%	2.87%	2.66%	2.27%	2.41%
Dividend yield	—	—	—	—	—	—

The weighted average fair value of stock-based awards granted to employees during the years ended December 31, 2019, 2018 and 2017 was $22.86 per share, $8.46 per share and $4.79 per share, respectively.

Eidos Restricted Stock

In December 2017, Eidos issued 390,546 shares of common stock for no consideration to the founders pursuant to Eidos' Series Seed Preferred Stock Purchase Agreement and license agreement in connection with certain anti-dilution rights held by these parties. If the shares issued under the license agreement represent less than 1% of the shares issued and outstanding of common stock on an as-converted basis, Eidos will issue additional common stock to the founders and Stanford University. Eidos has the right to repurchase the common stock at the fair value per share on the date of repurchase; this repurchase right lapses as the shares vest. The shares cliff vest 25% after one year and vest monthly thereafter over 36 months. As of December 31, 2019 and 2018, 170,866 and 268,504 shares remain subject to repurchase.

Eidos recognizes stock-based compensation expense upon the approval of these awards by the Eidos Board of Directors in September 2017 as vesting provisions are not considered substantive due to the fair value repurchase right. Stock-based compensation expense related to the restricted stock is recognized based on the fair value of the stock on the approval date using the Black-Scholes pricing model. During the years ended December 31, 2019, 2018 and 2017, Eidos recognized expense related to these awards of zero, zero and $0.2 million, respectively.

Eidos Stock-Based Compensation

As of December 31, 2019, there was $13.5 million of total unrecognized compensation cost related to unvested stock-based compensation arrangements under the Eidos 2016 and 2018 Plans. The unrecognized stock-based compensation cost is expected to be recognized over a weighted-average period 2.9 years.

17. Income Taxes

BridgeBio is subject to U.S. federal and state income taxes as a corporation. Prior to the tax-free reorganization, BBP LLC was treated as a pass-through entity for U.S. federal income tax purposes, and as such, was generally not subject to U.S. federal income tax at the entity level. Rather, the tax liability with respect to its taxable income was passed through to its unitholders.

The following table presents the components of net loss before income taxes:

	Year ended December 31,		
	2019	2018	2017
	(in thousands)		
Domestic	$ 288,585	$ 169,451	$ 43,832
Foreign	—	—	—
Total loss before income taxes	$ 288,585	$ 169,451	$ 43,832

There was no income tax expense (domestic and foreign) for the years ended December 31, 2019, 2018 and 2017.

The following table presents a reconciliation of the statutory federal rate and our effective tax rate:

	Year ended December 31,		
	2019	2018	2017
Tax at statutory federal rate	21.0 %	21.0 %	34.0 %
State income taxes, net of federal benefit	—	—	—
Change in valuation allowance	(25.3)	(20.2)	(16.4)
Research and development credits	4.1	1.6	0.8
Change in entity status	1.7	—	—
Nontaxable partnership income	(1.4)	(1.2)	(1.1)
Other	(0.1)	(1.2)	(1.4)
Impact of tax reform	—	—	(15.9)
Effective income tax rate	— %	— %	— %

Significant components of our deferred tax assets and liabilities as of December 31, 2019 and 2018 are as follows:

	2019	2018
	(in thousands)	
Deferred tax assets:		
Net operating loss carry-forwards	$ 94,335	$ 40,896
Amortization	5,196	4,424
Accruals and reserves	1,917	434
Stock-based compensation	1,820	268
Tax credits	18,443	3,728
Equity method investment	7,297	—
Other	210	23
Gross deferred tax assets	129,218	49,773
Less valuation allowance	(128,928)	(49,755)
Deferred tax assets, net of valuation allowance	290	18
Deferred tax liabilities:		
Fixed assets	(290)	(18)
Deferred tax liabilities	(290)	(18)
Net deferred tax assets	$ —	$ —

As of December 31, 2019, we have net operating loss carryforwards available to reduce future taxable income, if any, for federal and California state income tax purposes of approximately $393.4 million and $160.0 million respectively. The federal net operating losses generated prior to 2018 will begin to expire in 2037, losses generated after 2018 will carryover indefinitely. State net operating losses will generally begin to expire in 2037.

As of December 31, 2019, we have federal research and development credit carryforwards of $17.6 million, which will expire beginning in 2037 if not utilized. As of December 31, 2019, we have state research and development tax credit carryforwards of $2.6 million. The state research and development tax credits will expire at various dates.

A valuation allowance is provided for deferred tax assets where the recoverability of the assets is uncertain. The determination to provide a valuation allowance is dependent upon the assessment of whether it is more likely than not that sufficient future taxable income will be generated to utilize the deferred tax assets. Based on the weight of the available evidence, which includes our historical operating losses and forecast of future losses, we provided a full valuation allowance against the deferred tax assets resulting from the tax loss and credits carried forward. The valuation allowance increased by $79.2 million for the year ended December 31, 2019.

Utilization of the net operating loss and credit carryforwards may be subject to a substantial annual limitation due to an ownership change limitation as provided by section 382 of the Internal Revenue Code of 1986, as amended, and similar state provisions. The annual limitation may result in the expiration of net operating losses and credits before utilization. In the event that we had a change of ownership, utilization of the net operating loss and tax credit carryforwards may be restricted.

A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows:

	December 31,	
	2019	2018
	(in thousands)	
Balance at the beginning of the year	$ 1,182	$ 296
Additions (reductions) of prior year positions	2,913	(42)
Additions based on tax positions related to current year	3,509	928
Balance at the end of the year	$ 7,604	$ 1,182

As of December 31, 2019, we have not recorded interest and penalties associated with our unrecognized tax benefits. Our policy is to recognize interest and penalties related to income tax matters in income tax expense.

Our unrecognized gross tax benefits would not reduce the annual effective tax rate if recognized because we have recorded a full valuation allowance on our deferred tax assets. We do not foresee any material changes to the gross unrecognized tax benefit within the next twelve months.

We file federal and various income tax returns. We currently have no federal or state tax examinations in progress. All years are open for examination by federal and state authorities.

In December 2017, the United States government enacted comprehensive tax legislation commonly referred to as the Tax Cuts and Jobs Act (the "Tax Act") and the new legislation contains several key provisions, including a reduction of the federal corporate income tax rate to 21% effective January 1, 2018. We are required to recognize the effect of the tax law changes in the period of enactment, such as remeasuring our United States deferred tax assets and liabilities as well as our valuation allowance against our net United States deferred tax assets. In December 2017, the U.S. Securities and Exchange Commission staff issued Staff Accounting Bulletin No. 118 ("SAB 118"), which allowed us to record provisional amounts during a measurement period not to extend beyond one year of the enactment date. During the fourth quarter of 2018, we completed our accounting for the Tax Act as summarized below.

Due to the change in the statutory tax rate from the Tax Act, we remeasured our federal deferred tax assets as of December 31, 2017 to reflect the reduced rate that will apply in future periods when these deferred taxes are settled or realized. The result was a decrease of $6.8 million to deferred tax assets. No adjustments were made to the provisional estimates recorded.

We determined the one-time transition tax would not be applicable given our facts and circumstances. The one-time transition tax would be based on total post-1986 foreign earnings and profits that were previously deferred from United States income tax. The applicable tax rate is based on the amount of those post-1986 earnings that is held in cash and other specified assets (the "cash position"). We did not have any foreign earnings and profits and thus we would not have any transition tax liability. Our position has not materially changed.

18. Net Loss Per Share

Basic net loss per share is computed by dividing net loss by the weighted- average number of shares of common stock outstanding. Diluted net loss per share is computed by dividing net loss by the weighted-average number of shares of common stock outstanding, plus all additional common shares that would have been outstanding, assuming dilutive potential common shares had been issued for other dilutive securities. For the years ended December 31, 2019, 2018 and 2017, diluted and basic net loss per common share was identical since potential common shares were excluded from the calculation, as their effect was anti-dilutive.

The following common stock equivalents were excluded from the computation of diluted net loss per share, because including them would have been antidilutive:

	As of December 31,		
	2019	2018	2017
Unvested RSAs	5,603,452	5,355,166	6,633,375
Unvested RSUs	362,163	—	—
Unvested market-based RSUs	129,871	—	—
Common stock options issued and outstanding	4,626,777	—	—
	10,722,263	5,355,166	6,633,375

19. Subsequent Events

Subsequent to the year ended December 31, 2019, Eidos has issued an additional 448,755 shares of common stock in “at-the-market” offerings under the 2019 Shelf and received $23.8 million of net proceeds.

SUPPLEMENTARY FINANCIAL DATA (UNAUDITED)
(In thousands, except per share data)

The following table presents certain unaudited consolidated quarterly financial information for the eight quarters in the period ended December 31, 2019. This information has been prepared on the same basis as the audited consolidated financial statements and includes all adjustments (consisting only of normal recurring adjustments) necessary to present fairly the unaudited quarterly results of operations set forth herein

	For the Quarters Ended			
	March 31	June 30 (1)	September 30	December 31
2019				
License revenue	$ —	$ —	$ 26,741	$ 13,819
Total operating expenses	63,752	69,318	81,273	92,457
Loss from operations	(63,752)	(69,318)	(54,532)	(78,638)
Net loss	(69,436)	(74,334)	(60,664)	(84,151)
Net loss attributable to common stockholders of BridgeBio	(61,185)	(65,964)	(59,980)	(73,458)
Net loss per share, basic and diluted	(0.66)	(0.71)	(0.51)	(0.62)

	For the Quarters Ended			
	March 31	June 30	September 30	December 31
2018				
License revenue	$ —	$ —	$ —	$ —
Total operating expenses	41,838	34,783	41,456	65,583
Loss from operations	(41,838)	(34,783)	(41,456)	(65,583)
Net loss	(42,430)	(35,702)	(42,078)	(49,241)
Net loss attributable to common stockholders of BridgeBio	(34,156)	(26,551)	(31,401)	(38,641)
Net loss per share, basic and diluted	(0.66)	(0.45)	(0.52)	(0.52)

(1) Amount for the three months ended June 30, 2019 includes the results of operations of BridgeBio Pharma, Inc. prior to the Reorganization.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the shareholders and the Board of Directors of BridgeBio Pharma, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of BridgeBio Pharma, Inc., its subsidiaries and controlled entities (the "Company") as of December 31, 2019 and 2018, the related consolidated statements of operations, comprehensive loss, redeemable convertible noncontrolling interests and shareholders' equity, and cash flows, for each of the three years in the period ended December 31, 2019, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2019, in conformity accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's 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 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 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 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 financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ **DELOITTE & TOUCHE LLP**

San Francisco, California
March 2, 2020

We have served as the Company's auditor since 2018.

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

Not applicable.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer (our principal executive officer and principal financial officer, respectively), evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2019 and concluded that our disclosure controls and procedures were effective as of that date. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits 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 a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Prior Material Weakness in Internal Control over Financial Reporting

As previously reported in the registration statement on Form S-1 for our IPO and in our subsequent Form 10-Q reports for the periods ending June 30 and September 30, 2019, management and our independent registered public accounting firm identified material weaknesses in internal control over financial reporting during the audit of our consolidated financial statements for the year ended December 31, 2017. A material weakness is a deficiency or combination of deficiencies in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis by the company's internal controls. These material weaknesses that were identified related to the following:

- Insufficient staffing to enable segregation of duties within accounting functions and insufficient written policies and procedures for accounting and financial reporting. These factors contributed to the lack of a formalized process or controls for our management's timely review and approval of journal entries and related financial statement analysis.
- Lack of adequate finance and accounting staff with the appropriate U.S. GAAP technical expertise to identify, evaluate and account for complex and non-routine transactions. As a result, we did not design and maintain formal accounting policies, processes and controls related to complex transactions necessary for an effective financial reporting process.

Management has been actively engaged in remediating the above described material weaknesses. During the year ended December 31, 2019, we began implementing measures designed to improve our internal control over financial reporting to remediate these material weaknesses, including:

- Evaluating the corporate finance and accounting organization and hiring additional qualified accounting and finance personnel including financial consultants to enable the implementation of internal controls over financial reporting and segregating duties among accounting and finance personnel.
- Engaging certified professional accounting consultants to assist with technical accounting and SEC reporting needs, as well as to assist management in the documentation of policies, procedures, and the identification, documentation, and evaluation of our internal controls over financial reporting.
- Evaluating the corporate finance and accounting processes and technologies and implementing certain corporate financial reporting process and technology solutions.
- Formalizing processes and internal control documentation and strengthening supervisory reviews by financial management.

Management has concluded that the actions taken to strengthen our internal controls over financial reporting remediated the two identified material weaknesses as of December 31, 2019. However, 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 applicable policies, processes and documentation requirements may deteriorate.

Changes in Internal Control over Financial Reporting

Other than the changes intended to remediate the material weaknesses noted above, no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the year ended December 31, 2019 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Management's Annual Report on Internal Control over Financial Reporting

This Annual Report on Form 10-K does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of our independent registered public accounting firm due to a transition period established by rules of the SEC for newly public companies.

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 for our 2020 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2019.

We have adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer, controller or persons performing similar functions. A current copy of the code is posted on the Corporate Governance section of our website, which is located at www.bridgebio.com. If we make any substantive amendments to, or grant any waivers from, the code of business conduct and ethics for our principal executive officer, principal financial officer, principal accounting officer, controller or persons performing similar functions, or any officer or director, we will disclose the nature of such amendment or waiver on our website or in a current report on Form 8-K.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item is incorporated by reference from our definitive proxy statement for our 2020 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2019.

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 for our 2020 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2019.

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

The information required by this Item is incorporated by reference from our definitive proxy statement for our 2020 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2019.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this Item is incorporated by reference from our definitive proxy statement for our 2020 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2019.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) The following documents are filed as part of this Annual Report on Form 10-K:

1. Financial Statements:

The following financial statements and schedules of the Registrant are contained in Part II, Item 8, “Financial Statements and Supplementary Data” of this Annual Report on Form 10-K:

	Page
Consolidated Balance Sheets as of December 31, 2019 and 2018	142
Consolidated Statements of Operations for each of the three years in the period ended December 31, 2019	143
Consolidated Statements of Comprehensive Loss for each of the three years in the period ended December 31, 2019	144
Consolidated Statements of Redeemable Convertible Noncontrolling Interests and Stockholders’ Equity for each of the three years in the period ended December 31, 2019	145
Consolidated Statements of Cash Flows for each of the three years in the period ended December 31, 2019	146
Notes to Consolidated Financial Statements	147
Report of Independent Registered Public Accounting Firm	198

2. Financial Statement Schedules:

All schedules have been omitted because of the absence of conditions under which they are required or because the required information, where material, is shown in the financial statements, financial notes or supplementary financial information.

(b) Exhibits required by Item 601 of Regulation S-K:

The exhibits listed in the accompanying Exhibit Index are filed as part of, or incorporated by reference into, this Annual Report on Form 10 K.

ITEM 16. FORM 10-K SUMMARY

None.

Exhibits

Exhibit Number	Exhibit Title	Form	File No.	Exhibit	Filing Date
3.1	Amended and Restated Certificate of Incorporation of the Registrant, as currently in effect.	8-K	001-38959	3.1	July 3, 2019
3.2	Amended and Restated Bylaws of the Registrant, as currently in effect.	8-K	001-38959	3.2	July 3, 2019
4.1	Specimen Common Stock Certificate.	S-1	333-231759	4.1	June 24, 2019
4.2	Fourth Amended and Restated Limited Liability Company Agreement, dated November 20, 2018, by and among BridgeBio Pharma LLC and its members.	S-1	333-231759	4.2	May 24, 2019
4.3	Form of Registration Rights Agreement, among the Registrant and certain of its shareholders, to be in effect immediately prior to completion of this offering.	S-1	333-231759	4.3	June 24, 2019
4.4	Description of Securities.	—	—	—	Filed herewith
10.1	2019 Stock Option and Incentive Plan and forms of award agreements thereunder.	S-1	333-231759	10.1	June 24, 2019
10.2	2019 Employee Stock Purchase Plan.	S-1	333-231759	10.2	June 24, 2019
10.3	Senior Executive Cash Incentive Bonus Plan.	S-1	333-231759	10.3	June 24, 2019
10.4	Form of Indemnification Agreement, between the Registrant and each of its directors.	S-1	333-231759	10.4	June 24, 2019
10.5	Form of Indemnification Agreement, between the Registrant and each of its executive officers.	S-1	333-231759	10.5	June 24, 2019
10.6	Loan and Security Agreement, between BridgeBio Pharma LLC and Hercules Capital, Inc., dated as of June 19, 2018.	S-1	333-231759	10.6	May 24, 2019
10.7	First Amendment to the Loan and Security Agreement, between BridgeBio Pharma LLC and Hercules Capital, Inc., dated as of December 28, 2018.	S-1	333-231759	10.7	May 24, 2019
10.8	Lease Agreement, between BridgeBio Pharma LLC and Michael J. Harbour, dated as of March 23, 2017.	S-1	333-231759	10.8	May 24, 2019
10.9†	Exclusive (Equity) Agreement, by and between Eidos Therapeutics, Inc. and the Board of Trustees of the Leland Stanford Junior University, effective as of April 10, 2016, as amended by Amendment No. 1 effective September 25, 2017.	S-1	333-231759	10.9	May 24, 2019
10.10†	License Agreement, between QED Therapeutics, Inc. and Novartis International Pharmaceutical Ltd., dated as of January 29, 2018.	S-1	333-231759	10.10	May 24, 2019

10.11†	Asset Purchase Agreement, among BridgeBio Pharma LLC, Origin Biosciences, Inc., and Alexion Pharma Holding Unlimited Company, dated as of June 7, 2018.	S-1	333-231759	10.11	May 24, 2019
10.12†	Option Agreement, among PellePharm, Inc., Leo Pharma A/S and Leo Spiny Merger Sub, Inc., dated as of November 19, 2018, as amended on March 13, 2019.	S-1	333-231759	10.12	May 24, 2019
10.13†	Asset Purchase Agreement, among Phoenix Tissue Repair, Inc., Shire Human Genetic Therapies, Inc., and Lotus Tissue Repair, Inc., dated as of July 21, 2017.	S-1	333-231759	10.13	May 24, 2019
10.14†	Exclusive License Agreement, between The Regents of the University of California and TheRas, Inc., dated September 28, 2016, as amended by First Amendment effective January 10, 2017, Second Amendment effective August 10, 2017 and Third Amendment effective September 7, 2018.	S-1	333-231759	10.14	May 24, 2019
10.14A†	Fourth Amendment to the Exclusive License Agreement, between The Regents of the University of California and TheRas, Inc., dated December 16, 2019	—	—	—	Filed herewith
10.15†	Collaboration and License Agreement, between Navire Pharma, Inc. (formerly known as PTP Pharmaceuticals, Inc.) and the Board of Regents of the University of Texas System and The University of Texas M.D. Anderson Cancer Center, dated March 3, 2017, as amended by Amendment No. 1 dated July 10, 2017.	S-1	333-231759	10.15	May 24, 2019
10.16†	Exclusive Patent License Agreement, between The Frederick National Laboratory for Cancer Research, operated by Leidos Biomedical Research, Inc., under sponsorship from the National Cancer Institute, and TheRas, Inc., dated December 14, 2018.	S-1	333-231759	10.16	May 24, 2019
10.17†	Cell Line License Agreement, by and between Life Technologies Corporation and BridgeBio Services, Inc., effective as of November 15, 2018.	S-1	333-231759	10.17	May 24, 2019
10.18	Second Amendment to the Loan and Security Agreement, between BridgeBio Pharma LLC and Hercules Capital Inc., dated as of May 17, 2019.	S-1	333-231759	10.18	May 24, 2019
10.19	Offer Letter, between BridgeBio Services, Inc. and Neil Kumar, dated December 14, 2017.	S-1	333-231759	10.19	June 11, 2019
10.20	Offer Letter, between BridgeBio Services, Inc. and Brian Stephenson, dated October 28, 2018.	S-1	333-231759	10.20	June 11, 2019
10.21	Offer Letter, between Eidos Therapeutics, Inc. and Uma Sinha, dated June 1, 2016, as amended on May 24, 2018.	S-1	333-231759	10.21	June 11, 2019

10.22	Offer Letter, between BridgeBio Services, Inc. and Charles Homcy, dated February 20, 2019.	S-1	333-231759	10.22	June 11, 2019
10.23	Offer Letter, between BridgeBio Services, Inc. and Richard Scheller, dated April 5, 2019.	S-1	333-231759	10.23	June 11, 2019
10.24	Offer Letter, between BridgeBio Services, Inc. and Michael Henderson, dated March 22, 2016, as amended on May 5, 2017.	S-1	333-231759	10.24	June 11, 2019
10.25	Offer Letter, between Eidos Therapeutics, Inc. and Cameron Turtle, dated June 13, 2018.	S-1	333-231759	10.26	June 11, 2019
10.26#	Offer Letter, between BridgeBio Pharma, Inc. and Brian Stolz, dated September 19, 2019	10-Q	000-38959	10.2	November 8, 2019
10.27#	Offer Letter, between and BridgeBio Services, Inc. and Yi Ching Yau, dated September 9, 2019.	10-Q	000-38959	10.3	November 8, 2019
10.28	Consulting Agreement, between Jennifer E. Cook and the Registrant, effective as of October 14, 2019.	—	—	—	Filed herewith
10.29	Loan and Security Agreement, by and between Eidos Therapeutics, Inc., Silicon Valley Bank and Hercules Capital, Inc., dated November 13, 2019.	8-K	000-38959	10.1	November 19, 2019
10.30	Form of Tax Sharing Agreement, between the Registrant and each of its subsidiaries.	S-1	333-231759	10.27	June 24, 2019
10.31	Indemnification Agreement, between BridgeBio Pharma LLC and KKR Genetic Disorder, L.P., dated March 26, 2016.	S-1	333-231759	10.28	June 24, 2019
10.32†	License Agreement, by and between the Registrant and Alexion Pharma International Operations Unlimited Company, dated September 9, 2019	10-Q	000-38959	10.1	November 8, 2019
10.33†	Collaboration Agreement, by and between BridgeBio Gene Therapy, LLC and Catalent Maryland, Inc., formerly Paragon Bioservices, Inc., dated December 31, 2019.	—	—	—	Filed herewith
10.34#	BridgeBio Pharma, Inc. 2019 Inducement Equity Plan.	S-8	333-234803	99.1	November 20, 2019
10.35#	Form of Restricted Stock Award Agreement under BridgeBio Pharma, Inc. 2019 Inducement Equity Plan.	S-8	333-234803	99.2	November 20, 2019
10.36#	Form of Non-Qualified Stock Option Agreement under BridgeBio Pharma, Inc. 2019 Inducement Equity Plan.	S-8	333-234803	99.3	November 20, 2019
10.37#	Form of Restricted Stock Unit Award Agreement under BridgeBio Pharma, Inc. 2019 Inducement Equity Plan.	S-8	333-234803	99.4	November 20, 2019
10.38#	Offer Letter, between BridgeBio Pharma, Inc. and James C. Momtazee, dated February 23, 2020.	—	—	—	Filed herewith
10.39#	Director Compensation Policy	—	—	—	Filed herewith

21	List of Subsidiaries of the Registrant.	—	—	—	Filed herewith
23.1	Consent of Independent Registered Public Accountant Firm.	—	—	—	Filed herewith
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	—	—	—	Filed herewith
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	—	—	—	Filed herewith
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	—	—	—	Filed herewith
32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	—	—	—	Filed herewith
101.INS	XBRL Instance Document.	—	—	—	Filed herewith
101.SCH	XBRL Taxonomy Extension Schema Document.	—	—	—	Filed herewith
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.	—	—	—	Filed herewith
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.	—	—	—	Filed herewith
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.	—	—	—	Filed herewith
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.	—	—	—	Filed herewith

***** This certification will not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent specifically incorporated by reference into such filing.

# Indicates a management contract or any compensatory plan, contract or arrangement.

† Certain confidential portions (indicated by brackets and asterisks) have been omitted from this exhibit in accordance with the rules of the Securities and Exchange Commission.

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.

BridgeBio Pharma, Inc.

Date: March 2, 2020

By: /s/ Neil Kumar

Neil Kumar, Ph.D.
Chief Executive Officer, Director
(Principal Executive Officer)

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Neil Kumar and Brian Stephenson, as their true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for such person and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to the Annual Report on Form 10-K, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he or she could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his substitutes, may lawfully 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 and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Neil Kumar Neil Kumar, Ph.D.	President, Chief Executive Officer and Director (Principal Executive Officer)	March 2, 2020
/s/ Brian Stephenson Brian Stephenson, Ph.D., CFA	Chief Financial Officer (Principal Financial Officer)	March 2, 2020
/s/ Yi Ching Yau Yi Ching Yau	Chief Accounting Officer (Principal Accounting Officer)	March 2, 2020
/s/ Eric Aguiar Eric Aguiar, M.D.	Director	March 2, 2020
/s/ Jennifer E. Cook Jennifer E. Cook	Director	March 2, 2020
/s/ Ronald J. Daniels Ronald J. Daniels	Director	March 2, 2020
/s/ Charles Homcy Charles Homcy, M.D.	Director	March 2, 2020
/s/ James C. Momtazee James C. Momtazee	Director	March 2, 2020

/s/ Ali J. Satvat Ali J. Satvat	Director	March 2, 2020
/s/ Richard H. Scheller Richard H. Scheller, Ph.D.	Director	March 2, 2020

Exhibit 4.4

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

As of December 31, 2019, BridgeBio Pharma, Inc. (the "Company," "we," "us," and "our") had one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended: our Common Stock.

Description of Common Stock

The following description of our Common Stock is a summary and does not purport to be complete. It is subject to and qualified in its entirety by reference to our Amended and Restated Certificate of Incorporation ("Certificate of Incorporation") and our Amended and Restated Bylaws ("Bylaws"), each of which are incorporated by reference as an exhibit to the Annual Report on Form 10-K of which this Exhibit 4.4 is a part, and by applicable law. We encourage you to read our Certificate of Incorporation, our Bylaws and the applicable provisions of the Delaware General Corporation Law for additional information.

Authorized Capital Stock

Our authorized capital stock consists of 500,000,000 shares of common stock, par value $0.001 per share (the "Common Stock"), and 25,000,000 shares of preferred stock, par value $0.001 per share (the "Preferred Stock"), all of which shares of Preferred Stock are undesignated.

Common Stock

The holders of our Common Stock are entitled to one vote for each share held on all matters submitted to a vote of the stockholders. The holders of our Common Stock do not have any cumulative voting rights. Holders of our Common Stock are entitled to receive ratably any dividends declared by our board of directors ("Board") out of funds legally available for that purpose, subject to any preferential dividend rights of any outstanding Preferred Stock. Our Common Stock has no preemptive rights, conversion rights or other subscription rights or redemption or sinking fund provisions.

In the event of our liquidation, dissolution or winding up, holders of our Common Stock will be entitled to share ratably in all assets remaining after payment of all debts and other liabilities and any liquidation preference of any outstanding Preferred Stock. The outstanding shares of our Common Stock are fully paid and nonassessable.

Our Common Stock is listed on The Nasdaq Global Select Market under the symbol "BBIO."

The transfer agent and registrar for our Common Stock is American Stock Transfer & Trust Company, LLC.

Preferred Stock - Limitations on Rights of Holders of Common Stock

Our Board or any authorized committee thereof has the authority, without further action by our stockholders, to issue up to 25,000,000 shares of Preferred Stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting, or the designation of, such series, any or all of which may be greater than the rights of our Common Stock. Any issuance of our Preferred Stock could adversely affect the voting power of holders of our Common Stock and the likelihood that such holders would receive dividend payments and payments upon liquidation. In addition, the issuance of Preferred Stock could have the effect of delaying, deferring or preventing a change of control or other corporate action.

Anti-Takeover Effects of Our Certificate of Incorporation and Our Bylaws

Our Certificate of Incorporation and Bylaws include a number of provisions that may have the effect of delaying, deferring or discouraging another party from acquiring control of us and encouraging persons considering unsolicited tender offers or other unilateral takeover proposals to negotiate with our Board rather than pursue non-negotiated takeover attempts. These provisions include the items described below.

Board Composition and Filling Vacancies.

Our Certificate of Incorporation provides for the division of our Board into three classes serving staggered three-year terms, with one class being elected each year. Our Certificate of Incorporation also provides that directors may be removed only for cause by the affirmative vote of the holders of at least 75% of the shares then entitled to vote at an annual election of directors. Furthermore, any vacancy on our Board, however occurring, including a vacancy resulting from an increase in the size of our Board, may be filled by the affirmative vote of a majority of our directors then in office even if less than a quorum.

No Written Consent of Stockholders.

Our Certificate of Incorporation provides that all stockholder actions are required to be taken by a vote of the stockholders at an annual or special meeting, and that stockholders may not take any action by written consent in lieu of a meeting. This limit may lengthen the amount of time required to take stockholder actions and would prevent the amendment of our Bylaws or removal of directors by our stockholder without holding a meeting of stockholders.

Meetings of Stockholders.

Our Bylaws provide that only a majority of the members of our Board then in office may call special meetings of stockholders and only those matters set forth in the notice of the special meeting may be considered or acted upon at a special meeting of stockholders. Our Bylaws limit the business that may be conducted at an annual meeting of stockholders to those matters properly brought before the meeting.

Advance Notice Requirements.

Our Bylaws establish advance notice procedures with regard to stockholder proposals relating to the nomination of candidates for election as directors or new business to be brought before meetings of our stockholders. These procedures provide that notice of stockholder proposals must be timely given in writing to our corporate secretary prior to the meeting at which the action is to be taken. Generally, to be timely, notice must be received at our principal executive offices not less than 90 days or more than 120 days prior to the first anniversary date of the annual meeting for the preceding year. The notice must contain certain information specified in our Bylaws.

Amendment to Certificate of Incorporation and Bylaws.

As required by the Delaware General Corporation Law, any amendment of our Certificate of Incorporation must first be approved by a majority of our Board, and if required by law or our Certificate of Incorporation, must thereafter be approved by a majority of the outstanding shares entitled to vote on the amendment, and a majority of the outstanding shares of each class entitled to vote thereon as a class, except that the amendment of the provisions relating to stockholder action, directors, limitation of liability and the amendment of our Certificate of Incorporation must be approved by not less than 75% of the outstanding shares entitled to vote on the amendment, and not less than 75% of the outstanding shares of each class entitled to vote thereon as a class. Our Bylaws may be amended by the affirmative vote of a majority vote of the directors then in office, subject to any limitations set forth in the Bylaws; and may also be amended by the affirmative vote of at least 75% of the outstanding shares entitled to vote on the amendment, or, if the Board recommends that the stockholders approve the amendment, by the affirmative vote of the majority of the outstanding shares entitled to vote on the amendment, in each case voting together as a single class.

Exclusive Jurisdiction of Delaware for State Law Claims.

Unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for any state law claim for (i) any derivative action or proceeding brought on behalf of the Company, (ii) any action asserting a claim of breach of a fiduciary duty owed by any director, officer, employee or agent of the Company to the Company or the Company's stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law or the Certificate of Incorporation or Bylaws, (iv) any action to interpret, apply, enforce or determine the validity of our Certificate of Incorporation or Bylaws, or (v) any action asserting a claim against the Company governed by the internal affairs doctrine (the "Delaware Forum Provision"); provided, however, that this Delaware Forum Provision does not apply to any actions arising under the Securities Act or the Exchange Act. The Delaware Forum Provision may impose additional litigation costs on stockholders in pursuing such claims, particularly if the stockholders do not reside in or near the State of Delaware. Additionally, the Delaware Forum Provision may limit our stockholders' ability to bring a claim in a judicial forum that they find favorable for disputes with us or our directors, officers, employees or agents, which may discourage the filing of such lawsuits. The Court of Chancery of the State of Delaware may also reach different judgment or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders.

Undesignated Preferred Stock.

Our Certificate of Incorporation provides for authorized shares of Preferred Stock. The existence of authorized but unissued shares of Preferred Stock may enable our Board to render more difficult or to discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise. For example, if in the due exercise of its fiduciary obligations, our Board were to determine that a takeover proposal is not in the best interests of us or our stockholders, our Board could cause shares of Preferred Stock to be issued without stockholder approval in one or more private offerings or other transactions that might dilute the voting or other rights of the proposed acquirer or insurgent stockholder or stockholder group. In this regard, our Certificate of Incorporation grants our Board broad power to establish the rights and preferences of authorized and unissued shares of Preferred Stock. The issuance of shares of Preferred Stock could decrease the amount of earnings and assets available for distribution to holders of shares of Common Stock. The issuance may also adversely affect the rights and powers, including voting rights, of these holders and may have the effect of delaying, deterring or preventing a change in control of us.

Section 203 of the Delaware General Corporation Law

We are subject to the provisions of Section 203 of the Delaware General Corporation Law, or Section 203. In general, Section 203 prohibits a publicly-held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a three-year period following the time that this stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner. A "business combination" includes, among other things, a merger, asset or stock sale or other transaction resulting in a financial benefit to the interested stockholder. An "interested stockholder" is a person who, together with affiliates and associates, owns, or did own within three years prior to the determination of interested stockholder status, 15% or more of the corporation's voting stock.

Under Section 203, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions: before the stockholder became interested, the Board approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder; upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, shares owned by persons who are directors and also officers, and employee stock plans, in some instances; or at or after the time the stockholder became interested, the business combination was approved by the Board of the corporation and authorized at an annual or special meeting of the stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

A Delaware corporation may “opt out” of these provisions with an express provision in its original certificate of incorporation or an express provision in its certificate of incorporation or bylaws resulting from a stockholders’ amendment approved by at least a majority of the outstanding voting shares. We have not opted out of these provisions. As a result, mergers or other takeover or change in control attempts of us may be discouraged or prevented.

[***] Certain confidential portions (indicated by brackets and asterisks) have been omitted from this exhibit in accordance with the rules of the Securities and Exchange Commission.

FOURTH AMENDMENT

to the

Exclusive License Agreement

Effective September 28, 2016

Between

THE REGENTS OF THE UNIVERSITY OF CALIFORNIA

And

THERAS, INC.

Effective December 16, 2019, (the "Fourth Amendment Effective Date") THE REGENTS OF THE UNIVERSITY OF CALIFORNIA ("THE REGENTS"), a California corporation, having its statewide administrative offices at 1111 Franklin Street, 12th Floor, Oakland, California 94607-5200 and acting through its Office of Technology Management, University of California San Francisco ("UCSF"), 600 16th Street, Suite S-272, San Francisco, CA 94143 and TheRas, Inc., a Delaware corporation, having a principal place of business at 421 Kipling Street, Palo Alto, CA 94301 ("LICENSEE"), agree as follows:

1. BACKGROUND

1.1 THE REGENTS and LICENSEE are parties to a License Agreement effective September 28, 2016 with UC Agreement Control No. 2017-03-0138 ("Original Agreement") for "Covalent Modification on CAAX- box Cysteine of K-Ras 4B Using Tethering Compounds" as described in UC Case No. [***], a first subsequent amendment with an effective date of January 10, 2017 (the "First Amendment"), a subsequent amendment with an effective date of August 10, 2017 (the "Second Amendment"), and a subsequent amendment with an effective date of September 7th, 2018 (the "Third Amendment").

1.2 THE REGENTS and LICENSEE wish to amend the Original Agreement to add additional patent rights, listed below, to the Original Agreement.

UC Case No.	TheRas Ref. No.	Application No.	Case Title
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]

and additional edits as reflected below.

2. AMENDMENTS

2.1 Background Paragraph A is hereby deleted and replaced with the following:

"A. Certain inventions, generally characterized as "Covalent Modification on CAAX-box Cysteine of K-Ras 4B Using Tethering Compounds" (UC Case Nos. [***] and Leidos Biomedical No. [***]) (collectively "Original Invention"), made in the course of research at UCSF and Leidos Biomedical Research, Inc. ("Leidos") by Drs. Frank P. McCormick, Stephan C. Gysin, Adam R. Renslo, and David Turner at UCSF and by Drs. Anna E. Maciag and Oleg Chertov of Leidos (collectively, the "Original Inventors") and are claimed in Patent Rights as defined below.

Certain inventions generally characterized as "Phenylacetamide- and triazole-based covalent inhibitors targeting H95 in Kras" as described in UC Case No. [***] and Leidos Biomedical No. [***] (collectively the "Second Invention"), made in the course of research at UCSF by Drs. Frank P. McCormick, Adam R. Renslo, and Elizabeth D. Vo at UCSF and by Drs. Anna E. Maciag, David Turner, and Marcin Dyba of Leidos Biomedical Research, Inc. ("Leidos") (collectively, the "Second Inventor List") and are claimed in Patent Rights a defined below.

The Original Invention and the Second Invention are collectively referred to as the "Initial Invention Set".

[***] Certain confidential portions (indicated by brackets and asterisks) have been omitted from this exhibit in accordance with the rules of the Securities and Exchange Commission.

(zzTempText)

Certain inventions generally characterized as “Sulfonamide-based modulators of KRAS4b with enhanced biochemical and biological activity over analogous amides” as described in UC Case No [***] (the “Third Invention”), were made in the course of research at UCSF by Dr. Adam R Renslo at UCSF, at Leidos by Drs. Anna E. Maciag, David M. Turner, Christopher J. Brassard, Vandana Kumari, and Marcin Dyba, and at Licensee by Drs. Matthew Alexander James Duncton, Eddy Low, Anjali Pandey, Swapan Kuma, Samanta, Athisayamani Jeyaraj Duraiswamy, Holly V. Adcock, Daniel Hamza, and Stuart T. Onions (“Third Inventor List”) and are claimed in Patent Rights as defined below.

Certain inventions generally characterized as “K-Ras Modulators with an Acrylamide Moiety” as described in UC Case No [***] (the “Fourth Invention”) were made in the course of research at UCSF by Drs. Adam R, Renslo and David Turner, at Leidos by Drs. David Turner, Anna E. Maciag, Christopher J. Bassard, at Vandana Kumari, and at Licensee by Drs. Anjali Pandey, Matthew Alexander James Duncton, and Swapan Kumar Samanta (“Fourth Inventor List”) and are claimed in Patent Rights as defined below.

Certain inventions generally characterized as “K-Ras Modulators with a Direct-Linked Sulfonamide Moiety” as described in UC Case No [***] (the “Fifth Invention”) were made in the course of research at UCSF by Drs. Adam R. Renslo and David Turner, at Leidos by Dr. David Turner, and at Licensee by Drs. Anjali Pandey and Swapan Kumar Samanta (“Fifth Inventor List”) and are claimed in Patent Rights as defined below.

The Third Invention, Fourth Invention, and Fifth Invention are collectively referred to as the “Subsequent Invention Set”.

The Initial Invention Set and the Subsequent Invention Set are collectively referred to as the “Invention”. The Original Inventors, the Second Inventor List, the Third Inventor List, the Fourth Inventor List, and the Fifth Inventor List are collectively referred to as the “Inventors”.

2.2 Paragraph 1.11 is hereby deleted and replaced with the following:

“1.11 Patent Rights” means the Valid Claims of the following:

(a) to the extent assigned to or otherwise obtained by The Regents and/or Leidos, the following United States patents and patent applications, herein as defined as “Initial Patent Rights”:

[***] Certain confidential portions (indicated by brackets and asterisks) have been omitted from this exhibit in accordance with the rules of the Securities and Exchange Commission.

(zzTempText)

UC Case Number	TheRas Ref. No.	Application Number	Filing or Issue Date
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]

Initial Patent Rights shall further include the Valid Claims of, to the extent assigned to or otherwise obtained by The Regents and/or Leidos, the corresponding foreign patents and patent applications and any reissues, extensions, substitutions, continuations, divisions, and continuation-in-part applications (but only those Valid Claims in the continuation-in-part applications that are entirely supported in the specification and entitled to the priority date of the parent application). Further, The Regents agrees that it will not file or prosecute additional patent applications, outside the scope of the Patent Rights, based on the invention disclosure existing as of the Effective Date of the Original Agreement that is identified as UC Case No. [***] and Leidos Biomedical No. [***] or existing as of the Second Amendment Effective Date that is identified as UC Case No. [***] and Leidos Biomedical No. [***]. For the avoidance of doubt, this definition of Patent Rights excludes any rights in and to Option Inventions, except as provided under Article 4."

(b) to the extent assigned to or otherwise obtained by The Regents, the following United States patents and patent applications, herein defined as the "Subsequent Patent Rights":

UC Case Number	TheRas Case No.	Application Number	Jurisdiction	Filing Date
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]

[***] Certain confidential portions (indicated by brackets and asterisks) have been omitted from this exhibit in accordance with the rules of the Securities and Exchange Commission.

(zzTempText)

UC Case Number	TheRas Case No.	Application Number	Jurisdiction	Filing Date
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]

Subsequent Patent Rights shall further include the Valid Claims of, to the extent assigned to or otherwise obtained by The Regents, the corresponding foreign patents and patent applications and any reissues, extensions, substitutions, continuations, divisions, and continuation-in-part applications (but only those Valid Claims in the continuation-in-part applications that are entirely supported in the specification and entitled to the priority date of the parent application). For the avoidance of doubt, Subsequent Patent Rights shall further include provisional or nonprovisional applications filed within the Paris convention year with claims to additional compounds or sub-genera that fall within the scope of the genus described in the Subsequent Patent Rights existing as of the Fourth Amendment Effective Date, provided that (1) such applications are conceived and reduced to practice by Dr. Adam Renslo (including together with inventors at Leidos and/or Licensee), (2) such applications are assigned to or otherwise obtained by only The Regents, Leidos, and Licensee, and (3) within sixty (60) days of the filing of such patent applications, the parties amend in writing the table in this Section 2.2(b).

For the avoidance of doubt, Patent Rights shall include both the Initial Patent Rights and the Subsequent Patent Rights. For the avoidance of doubt, this definition of Patent Rights excludes any rights in and to Option Inventions, except as provided under Article 4."

[***] Certain confidential portions (indicated by brackets and asterisks) have been omitted from this exhibit in accordance with the rules of the Securities and Exchange Commission.

(zzTempText)

2.3 The following is hereby added to the end of Paragraph 3.3

"3.3.1 If The Regents (as represented by the actual knowledge of the licensing professional responsible for administration of this Agreement) becomes aware of, or if a third party becomes aware of and notifies such licensing professional of, an application or use for Licensed Products within the licensed Field of Use and there is reasonable scientific, and clinical basis for such application of use, but for which such uses have not been developed and are not, at such time, being developed by Licensee, then The Regents, through the Office of Technology Transfer, may give written notice to Licensee thereof.

3.3.2 Within [***] of such notice, Licensee shall give The Regents written notice stating whether Licensee agrees to develop and commercialize Licensed Products for such application ("New Licensed Products"). Such notice shall be accompanied by a plan for the development of New Licensed Products, including specific diligence requirements (the "New Licensed Product Development Plan"). If Licensee has not notified The Regents, in accordance with the foregoing, that Licensee agrees to develop and commercialize such New Licensed Products within such [***] period, then Licensee shall be deemed to not so agree.

3.3.3 If Licensee agrees, as set forth in Paragraph 3.3.2, to develop and commercialize such New Licensed Products, then Licensee shall (i) use Commercially Reasonable Efforts, as defined below, to proceed with the development, manufacture and commercialization of such New Licensed Products and use Commercially Reasonable Efforts to market the same in accordance with the Development Plan and in quantities sufficient to meet market demand; and (ii) Licensee shall submit a written progress report setting forth in detail the status of such development, manufacture and commercialization every six (6) months to The Regents, which may be a consolidated progress report combining the New Licensed Products and the Licensed Products.

3.3.3.1 "Commercially Reasonable Efforts" means, with respect to (i) achieving any objective by the Licensee, using diligent, good faith efforts to accomplish such objective as [***]; and (ii) with respect to any objective relating to the development or commercialization of any Licensed Product by the Licensee means those efforts and resources that would be used by Licensee with regard to the diligent development, manufacture and commercialization of pharmaceutical products [***].

[***] Certain confidential portions (indicated by brackets and asterisks) have been omitted from this exhibit in accordance with the rules of the Securities and Exchange Commission.

(zzTempText)

3.3.4 If Licensee does not agree, as set forth in Paragraph 3.3.2, to develop and commercialize such New Licensed Products, or if Licensee fails to comply with Paragraph 3.3.3 in its pursuit of the development and commercialization thereof in accordance with the Development Plan, then The Regents shall have the right to seek one or more third parties for the development and commercialization of such New Licensed Products and refer such third party to Licensee so that such third party may request a sublicense allowing for development and commercialization of such New Licensed Products. If the third party requests a sublicense, then Licensee shall use commercially reasonable efforts to negotiate with such third party the terms and conditions for such sublicense.

3.3.5 If Licensee does not grant a sublicense to the third party within a reasonable time after such request (and, in any event, within [***] after such request) or refuses to grant such sublicense under reasonable terms, then Licensee shall promptly, or, in the event of such refusal, within [***] after such refusal, submit to The Regents a written report specifying the license terms proposed by the third party ("Third Party Terms") and a written justification for the Licensee's refusal or failure to grant such sublicense. If The Regents may dispute as to whether Third Party Terms are reasonable under the circumstances. If such a dispute arises, The Regents and Licensee will resolve such dispute promptly by negotiations between for The Regents the Executive Director of The University of California, San Francisco's Office of Technology Management and the Chief Executive Officer of Licensee. If The Regents and Licensee fail to reach a resolution, upon the request of The Regents, The Regents and Licensee will discuss in good faith the possibility of arbitration. If it is finally determined that the Third Party Terms are reasonable, then Licensee shall (a) grant such sublicense to such third party on such terms; or (b) use Commercially Reasonable Efforts to develop such New Licensed Product in accordance with Paragraph [3], either by itself or through its affiliates or through its then current sublicensee.

2.4 Paragraph 7.1 is hereby deleted and replaced with the following:

"7.1 The Licensee will also pay to The Regents a license maintenance fee as follows for UC Case No. [***]:

7.1.1 [***] on [***].

7.1.2 [***] beginning on the [***] and continuing annually on each subsequent anniversary of the Effective Date of the Original Agreement

[***] Certain confidential portions (indicated by brackets and asterisks) have been omitted from this exhibit in accordance with the rules of the Securities and Exchange Commission.

(zzTempText)

7.1.3 Notwithstanding the payment obligations set forth in Section 7.1.1 and 7.1.2, license maintenance fees set forth in Paragraphs 7.1.1 and 7.1.2 are not due on any anniversary of the Effective Date of the Original Agreement if on that date, the Licensee is Selling or otherwise exploiting Licensed Products or Licensed Services covered by Patent Rights under UC Case No. [***] and is paying an Earned Royalty to The Regents on the Net Sales of such Licensed Product or Licensed Service.

7.2 The Licensee will also pay to The Regents a license maintenance fee as follows for UC Case No. [***]:

7.2.1 [***] on [***].

7.2.2 [***] beginning on the [***] and continuing annually on each subsequent anniversary of the Second Amendment Effective Date.

7.2.3 Notwithstanding the payment obligations set forth in Section 7.2.1 and 7.2.2, license maintenance fees set forth in Paragraphs 7.2.1 and 7.2.2 are not due on any anniversary of the Second Amendment Effective Date if on that date, the Licensee is Selling or otherwise exploiting Licensed Products or Licensed Services covered by Patent Rights under UC Case No. [***] and is paying an Earned Royalty to The Regents on the Net Sales of such Licensed Product or Licensed Service.

7.3 The Licensee will also pay to The Regents a license maintenance fee as follows for UC Case No. [***]:

7.3.1 [***] on [***].

7.3.2 [***] beginning on the [***] and continuing annually on each subsequent anniversary of the Third Amendment Effective Date.

7.3.3 Notwithstanding the payment obligations set forth in Section 7.3.1 and 7.3.2, license maintenance fees set forth in Paragraphs 7.3.1 and 7.3.2 are not due on any anniversary of the Third Amendment Effective Date if on that date, the Licensee is Selling or otherwise exploiting Licensed Products or Licensed Services covered by Patent Rights under UC Case No. [***] and is paying an Earned Royalty to The Regents on the Net Sales of such Licensed Product or Licensed Service.

[***] Certain confidential portions (indicated by brackets and asterisks) have been omitted from this exhibit in accordance with the rules of the Securities and Exchange Commission.

(zzTempText)

7.4 The Licensee will also pay to The Regents a license maintenance fee as follows for UC Case No. [***]:

7.4.1 [***] on b[***].

7.4.2 [***] beginning on the [***] and continuing annually on each subsequent anniversary of the Fourth Amendment Effective Date.

7.4.3 Notwithstanding the payment obligations set forth in Section 7.4.1 and 7.4.2, license maintenance fees set forth in Paragraphs 7.4.1 and 7.4.2 are not due on any anniversary of the Fourth Amendment Effective Date if on that date, the Licensee is Selling or otherwise exploiting Licensed Products or Licensed Services covered by Patent Rights under UC Case No. [***] and is paying an Earned Royalty to The Regents on the Net Sales of such Licensed Product or Licensed Service.

7.5 The Licensee will also pay to The Regents a license maintenance fee as follows for UC Case No. [***]:

7.5.1 [***] on [***].

7.5.2 [***] beginning on the [***] and continuing annually on each subsequent anniversary of the Fourth Amendment Effective Date.

7.5.3 Notwithstanding the payment obligations set forth in Section 7.5.1 and 7.5.2, license maintenance fees set forth in Paragraphs 7.5.1 and 7.5.2 are not due on any anniversary of the Fourth Amendment Effective Date if on that date, the Licensee is Selling or otherwise exploiting Licensed Products or Licensed Services covered by Patent Rights under UC Case No. [***] and is paying an Earned Royalty to The Regents on the Net Sales of such Licensed Product or Licensed Service.

7.6 The license maintenance fees set forth above in Paragraphs 7.1, 7.2, 7.3, 7.4, and 7.5 are non-refundable and are not an advance or otherwise creditable against any royalties or other payments required to be paid under the terms of this Agreement.

2.5 Paragraph 9.1.4 is hereby deleted and replaced in its entirety with the following:

“9.1.4 Licensee shall indicate to The Regents in royalty reports which Patent Rights correspond to the royalty payments for each Licensed Product.”

[***] Certain confidential portions (indicated by brackets and asterisks) have been omitted from this exhibit in accordance with the rules of the Securities and Exchange Commission.

(zzTempText)

2.6 Paragraph 13.3 is hereby deleted and replaced with the following:

"13.3 The Licensee will:

13.3.1 [***]

13.3.2 [***]

13.3.3 With respect to one Licensed Product:

[***]

The Regents recognizes that there are uncertainties associated with the development of therapeutic products and the regulatory process required by the FDA (and Foreign regulatory authorities that are equivalent to the FDA), and that it may be necessary from time to time to amend one or more of the milestones under Paragraphs 13.3.3.2 through 13.3.3.7. Accordingly, if Licensee is unable to meet one or more of such specified milestones and Licensee demonstrates to The Regents, based on the Regents' reasonable, objective, good faith assessment of Licensee's demonstration and supporting documentation, that Licensee has used and is using Licensee's diligent efforts (with supporting documentation) to meet such milestone and to [***], then upon submission in writing by Licensee to The Regents of the aforementioned diligent efforts and a plan to overcome such regulatory hurdles, The Regents will extend the deadline for each such milestone under Paragraphs 13.3.3.2 through 13.3.3.7 for a [***] provided Licensee also has paid to The Regents a fee, for each such extension, [***]. An extension of one milestone in Paragraph 13.3.3 will extend all remaining milestones in Paragraph 13.3.3 by the same extension time period, an extension of one milestone in Paragraph 13.3.4 will extend all remaining milestones in Paragraph 13.3.4, and an extension of one milestone in Paragraph 13.3.5 will extend all remaining milestones in Paragraph 13.3.5. For the avoidance of doubt, as of the Fourth Amendment Effective Date, Licensee has used one out of three one-year extensions.

and

13.3.5 use commercially reasonable efforts to fill the market demand for Licensed Products and Licensed Services following commencement of marketing at any time.

2.7 The following is hereby added to the end of Paragraph 14.4.1:

"If applicable, the report shall also include Licensee's progress in developing any New Patent Products elected for commercial development by Licensee pursuant to Paragraph 3.3 of this Agreement."

[***] Certain confidential portions (indicated by brackets and asterisks) have been omitted from this exhibit in accordance with the rules of the Securities and Exchange Commission.

(zzTempText)

2.8 Paragraph 25.1.4 is hereby deleted and replaced with the following:

"in the case of notices, if sent by email, on the date the recipient acknowledges having received that email by either an email sent to the sender or by a notice delivered by another method in accordance with this section 25.1, provided that, automated replies and "read receipts" shall not be considered acknowledgement of receipt and any provision of notice of breach or termination shall be send using certified mail or global express carrier.

In the case of Licensee:
TheRas, Inc.
421 Kipling Street
Palo Alto, CA 94301
Attention: Neil Kumar
Email: [***]

In the case of The Regents:

For notices:
University of California, San Francisco
Innovation Ventures, Office of Technology Management, Box 2142
600 16th Street, Suite S272
San Francisco, CA 94143
(for Fed-Ex use postal code 94158)
Attention: Director, Technology Management
Referring to: UC Case Nos. [***]
Email: [***]

For remittance of payments:
Innovation Alliances and Services
Attn: Accounts Receivable University of California
Office of the President
1111 Franklin Street, 5th Floor
Oakland, CA 94607-5200
Referring to: UC Case Nos. [***]

3. FEES

3.1 Amendment Issue Fee: the Licensee will pay to The Regents an amendment license issue fee of [***] within [***] of the Fourth Amendment Effective Date. This fee is non-refundable, non-cancelable and is not an advance or otherwise creditable against any royalties or other payments required to be paid under the terms of this Fourth Amendment or Original Agreement.

[***] Certain confidential portions (indicated by brackets and asterisks) have been omitted from this exhibit in accordance with the rules of the Securities and Exchange Commission.

(zzTempText)

4. MISCELLANEOUS

4.1 All other terms and conditions of the Original Agreement will remain in full force and effect.

4.2 This Fourth Amendment may be executed in one or more counterparts, each of which together shall constitute one and the same Agreement. For purposes of executing this Agreement, a facsimile (including a PDF image delivered via email) copy of this Agreement, including the signature pages, will be deemed an original. The parties agree that neither party will have any rights to challenge the use or authenticity of a counterpart of this Agreement based solely on that its signature, or the signature of the other party, on such counterpart is not an original signature.

IN WITNESS WHEREOF, the parties hereto have executed these presents by their duly authorized officers or representatives as of the dates below:

THE REGENTS OF THE UNIVERSITY OF CALIFORNIA

By	/s/ Gonzalo Barrera-Hernandez, Ph.D.
Name	Gonzalo Barrera-Hernandez, Ph.D.
Title	Associate Director, Innovation Ventures, UCSF
Date	December 16, 2019

THERAS, INC.

By	/s/ Eric Gomez
Name	Eric Gomez
Title	Vice President
Date	December 12, 2019

ACTIVE/101829023.3

[***] Certain confidential portions (indicated by brackets and asterisks) have been omitted from this exhibit in accordance with the rules of the Securities and Exchange Commission.

(zzTempText)

CONSULTING AGREEMENT

Effective October 14, 2019 (the "Effective Date"), Jennifer Cook Consulting ("Consultant") and BridgeBio Services, Inc., a Delaware corporation, agree as follows:

As used herein, the "Company" shall refer to BridgeBio Pharma, Inc. and its subsidiaries, including without limitation BridgeBio Services, Inc.; provided, that Consultant will be directly engaged by BridgeBio Services, Inc.

1. Services; Payment; No Violation of Rights or Obligations. Consultant agrees to undertake and complete the Services (as defined in Exhibit A) in accordance with and on the schedule specified in Exhibit A. As the only consideration due Consultant regarding the subject matter of this Agreement, Company will pay Consultant in accordance with Exhibit A. Unless otherwise specifically agreed upon by Company in writing (and notwithstanding any other provision of this Agreement), all activity relating to Services will be performed by and only by Consultant or by employees of Consultant who have been approved in writing in advance by Company with respect to each such employee. Consultant agrees that it will not (and will not permit others to) (a) violate any agreement with or rights of any third party, or (b) except as expressly authorized by Company in writing hereafter, use or disclose at any time Consultant's own or any third party's confidential information or intellectual property, whether in connection with the Services or otherwise for or on behalf of Company.

2. Ownership Rights; Proprietary Information; Publicity.

a. Company shall own all right, title and interest (including all intellectual property rights of any sort throughout the world) relating to any and all inventions, works of authorship, designs, know-how, ideas and information made or conceived or reduced to practice, in whole or in part, by or for or on behalf of Consultant during the term of this Agreement that relate to the subject matter of or arise out of or in connection with the Services or any Proprietary Information (as defined below) (collectively, "Inventions") and Consultant will promptly disclose and provide all Inventions to Company. For purposes of the copyright laws of the United States, all Inventions will constitute works made for hire, except to the extent such Inventions cannot by law be works made for hire. Consultant hereby assigns to Company Consultant's right, title and interest in and to such Inventions. Consultant shall assist Company, at Company's expense, to further evidence, record and perfect such assignment, and to perfect, obtain, maintain, enforce and defend any rights assigned. Consultant hereby irrevocably designates and appoints Company as its agents and attorneys-in-fact, coupled with an interest, to act for and on Consultant's behalf to execute and file any document and to do all other lawfully permitted acts to further the foregoing with the same legal force and effect as if executed by Consultant and all other creators or owners of the applicable Invention. Consultant will neither make any use of any funds, space, personnel, facilities, equipment or other resources of any Institution or other third party in performing the Services hereunder nor take any other action that would result in any third party owning or having a right in any Inventions.

b. Consultant will not disclose to Company or induce the Company to use any confidential information or material belonging to any other party.

c. Consultant agrees that all Inventions and all other business, technical and financial information (including, without limitation, the identity of and information relating to customers or employees) developed, learned or obtained by or on behalf of Consultant during the period that Consultant is to be providing the Services that relate to Company or the business or demonstrably anticipated business of Company or in connection with the Services or that are received by or for Company in confidence, constitute "Proprietary Information." During the term of this Agreement and thereafter, Consultant shall hold in confidence and not disclose or, except in performing the Services, use any Proprietary Information. However, Consultant shall not be obligated under this paragraph with respect to information Consultant can document is or becomes readily publicly available without restriction through no fault of Consultant. Upon termination or as otherwise requested by Company, Consultant will promptly provide to Company all items and copies containing or embodying Proprietary Information (including electronic files), except that Consultant may keep its personal copies of its compensation records and this Agreement. Consultant may disclose the Proprietary Information of Company to the extent required by a law, regulation, or an order of a court of competent jurisdiction, provided that Consultant promptly provides Company with prior written notice in order to permit Company to prevent such disclosure and/or to seek confidential treatment of such information. Proprietary Information that is disclosed pursuant to such legally required disclosure shall remain otherwise subject to the confidentiality and non-use provisions set forth herein. Consultant also recognizes and agrees that Consultant has no expectation of privacy with respect to Company's telecommunications, networking or information processing systems (including, without limitation, stored computer files, email messages and voice messages) and that Consultant's activity, and any files or messages, on or using any of those systems may be monitored at any time without notice.

d. As additional protection for Proprietary Information, Consultant agrees that during the period over which it is to be providing the Services and for one (1) year thereafter, Consultant will not directly or indirectly encourage or solicit any employee or consultant of Company to leave Company for any reason.

e. To the extent allowed by law, Section 2(a) and any license granted Company hereunder includes all rights of paternity, integrity, disclosure and withdrawal and any other rights that may be known as or referred to as "moral rights," "artist's rights," "droit moral," or the like (collectively "Moral Rights"). To the extent any of the foregoing is ineffective under applicable law, Consultant hereby provides any and all ratifications and consents necessary to accomplish the purposes of the foregoing to the extent possible and agrees not to assert any Moral Rights with respect thereto. Consultant will confirm any such ratifications and consents from time to time as requested by Company. If any other person is in any way involved in any Services, Consultant will obtain the foregoing ratifications, consents and authorizations from such person for Company's exclusive benefit.

f. If any part of the Services or Inventions or information provided hereunder is based on, incorporates, or is an improvement or derivative of, or cannot be reasonably and fully made, used, sold, offered for sale, imported, copied, displayed, performed, reproduced, distributed, used to create derivative works or and otherwise exploited without using or violating

technology or intellectual property rights owned by or licensed to Consultant (or any person involved in the Services) and not assigned hereunder, Consultant hereby grants Company and its successors a perpetual, irrevocable, worldwide royalty-free, non-exclusive, sublicensable (through multiple tiers) right and license to exploit and exercise all such technology and intellectual property rights in support of Company's exercise or exploitation of the Services, Inventions, other work or information performed or provided hereunder, or any assigned rights (including any modifications, improvements and derivatives of any of them).

g. Consultant agrees not to file any patent, copyright, trademark or other application or registration based on Company's Proprietary Information, and not to seek to make or protect improvements thereon, without Company's prior written approval.

3. Warranties and Other Obligations. Consultant represents, warrants and covenants that: (i) the Services will be performed in a professional and workmanlike manner and that none of such Services nor any part of this Agreement is or will be inconsistent with any obligation Consultant may have to others; (ii) all work under this Agreement shall be Consultant's original work and none of the Services or Inventions nor any development, use, production, distribution or exploitation thereof will infringe, misappropriate or violate any intellectual property or other right of any person or entity (including, without limitation, Consultant); (iii) Consultant has the full right to allow it to provide Company with the assignments and rights provided for herein (and has written enforceable agreements with all persons necessary to give it the rights to do the foregoing and otherwise fully perform this Agreement); (iv) Consultant shall comply with all applicable laws and Company safety rules in the course of performing the Services; (v) if Consultant's work requires a license, Consultant has obtained that license and the license is in full force and effect; and (vii) Consultant acknowledges that Company may be obligated to report fees paid to Consultant under this Agreement in accordance with applicable Laws that require reporting of payments or transfers of value provided to health care providers, including, but not limited to, the Physician Payments Sunshine Law, 42 U.S.C. § 13207h, and applicable state sunshine reporting Laws.

4. Limitation of Liability.

a. Total Liability. The total cumulative liability of Consultant to the Company with respect to services performed or to be performed pursuant to this Agreement, whether in contract, indemnity, contribution, or (including negligence, whether active, passive, or any other kind) or otherwise, shall not exceed the gross compensation received by Consultant under this Agreement; provided, however, that such liability shall be further limited in the following respects:

(i) Consultant shall not be liable to the Company for any third party's special, consequential, incidental or penal losses or damages; and

(ii) Consultant shall not be liable to the Company for losses, damages or claims which are either (A) discovered by the Company more than one year from the completion of the portion of the scope of Services which are involved, or (B) as to which the Company fails to notify Consultant within 30 days from the date of discovery.

b. Hold Harmless. Except to the extent that Consultant may be liable to Company under Section 4(a) above and to the extent permitted by law, the Company agrees to indemnify and hold harmless Consultant against all loss, damage, liability, claim or suit (including expenses and attorneys' fees), resulting from injury to any person or damage to any property arising out of or related to the performance of the Services under this Agreement, whether in contract, indemnity, tort (including negligence, whether active, passive, or any other kind) or otherwise (collectively, "Losses"); provided, however, that such obligation to indemnify and hold harmless shall not apply to any Losses to the extent arising out of or related to (i) Consultant's material breach of any of Consultant's obligations under this Agreement; (ii) Consultant's negligence or willful misconduct in connection with the Services or (iii) Consultant's material violation of any law, rule or regulation related to the Services.

5. Termination. If either party breaches a material provision of this Agreement, the other party may terminate this Agreement upon ten (10) days' notice, unless the breach is cured within the notice period. Company also may terminate this Agreement at any time, with or without cause, upon thirty (30) days' notice, but, if (and only if) such termination is without cause, Company shall upon such termination pay Consultant all unpaid, undisputed amounts due for the Services completed prior to notice of such termination. Sections 2 (subject to the limitations set forth in Section 2(d)) through 9 of this Agreement and any remedies for breach of this Agreement shall survive any termination or expiration. Company may communicate the obligations contained in this Agreement to any other (or potential) client or employer of Consultant.

6. Relationship of the Parties; Independent Contractor; No Employee Benefits. Notwithstanding any provision hereof, Consultant is an independent contractor and is not an employee, agent, partner or joint venturer of Company and shall not bind nor attempt to bind Company in any way . Consultant shall accept any directions issued by Company pertaining to the goals to be attained and the results to be achieved by Consultant, but Consultant shall be solely responsible for the manner and hours in which the Services are performed under this Agreement. Consultant shall not be eligible to participate in any of Company's employee benefit plans, fringe benefit programs, group insurance arrangements or similar programs. Company shall not provide workers' compensation, disability insurance, Social Security or unemployment compensation coverage or any other statutory benefit to Consultant. Consultant shall comply at Consultant's expense with all applicable provisions of workers' compensation laws, unemployment compensation laws, federal Social Security law, the Fair Labor Standards Act, federal, state and local income tax laws, and all other applicable federal, state and local laws, regulations and codes relating to terms and conditions of employment required to be fulfilled by employers or independent contractors. Consultant will ensure that its approved employees, contractors and others involved in the Services, if any, are bound in writing to the foregoing, and to all of Consultant's obligations under any provision of this Agreement, for Company's benefit and Consultant will be responsible for any noncompliance by them. Consultant agrees to indemnify Company from any and all claims, damages, liability, settlement, attorneys' fees and expenses, as incurred, on account of the foregoing or any breach of this Agreement or any other action or inaction by or for or on behalf of Consultant.

7. Assignment. This Agreement and the services contemplated hereunder are personal to Consultant and Consultant shall not have the right or ability to assign, transfer or subcontract any rights or obligations under this Agreement without the written consent of Company. Any attempt to do so shall be void. Company may fully assign and transfer this Agreement in whole or part. This Agreement shall be binding upon the parties and their respective successors and permitted assigns.

8. Notice. All notices under this Agreement shall be in writing and shall be deemed given when personally delivered, or three (3) days after being sent by prepaid certified or registered U.S. mail to the address of the party to be noticed as set forth herein or to such other address as such party last provided to the other by written notice.

9. Miscellaneous. Any breach of Section 2 or 3 will cause irreparable harm to Company for which damages would not be an adequate remedy, and therefore, Company will be entitled to injunctive relief with respect thereto in addition to any other remedies. The failure of either party to enforce its rights under this Agreement at any time for any period shall not be construed as a waiver of such rights. No changes or modifications or waivers to this Agreement will be effective unless in writing and signed by both parties. In the event that any provision of this Agreement shall be determined to be illegal or unenforceable, that provision will be limited or eliminated to the minimum extent necessary so that this Agreement shall otherwise remain in full force and effect and enforceable. This Agreement shall be governed by and construed in accordance with the laws of the State of California without regard to the conflicts of laws provisions thereof. In any action or proceeding to enforce rights under this Agreement, the prevailing party will be entitled to recover costs and attorneys' fees. Headings herein are for convenience of reference only and shall in no way affect interpretation of the Agreement. This Agreement, together with the Exhibits hereto constitutes the entire agreement between the parties as to the subject matter hereof, and supersedes any previous oral or written communications, representations, understandings, or agreements between them as to such subject matter. The parties may execute this Agreement in counterparts, each of which is deemed an original, but all of which together constitute one and the same agreement. Electronic signatures hereon are legal, valid and enforceable as originals.

10. Defend Trade Secrets Act of 2016; Other Notices. Consultant understands that pursuant to the federal Defend Trade Secrets Act of 2016, Consultant shall not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret that (A) is made (i) in confidence to a federal, state, or local government official, either directly or indirectly, or to an attorney; and (ii) solely for the purpose of reporting or investigating a suspected violation of law; or (B) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal. Consultant further understands that nothing contained in this Agreement limits Consultant's ability to (A) communicate with any federal, state or local governmental agency or commission, including to provide documents or other information, without notice to the Company, or (B) share compensation information concerning Consultant or others, except that this does not permit Consultant to disclose compensation information concerning others that Consultant obtains because Consultant's job responsibilities require or allow access to such information.

[Remainder of Page Intentionally Left Blank]

BRIDGEBIO SERVICES, INC.

By: /s/ Neil Kumar

Name: Neil Kumar

Title: CEO

JENNIFER COOK CONSULTING

By: /s/ Jennifer E. Cook

Name: Jennifer E. Cook

Title: Owner and Principal

Address:

EXHIBIT A

SERVICES

This Agreement shall have a two (2) year term from the Effective Date. Consultant will render to the Company the following services (the "Services"):

- provide expert consulting services to the Company regarding matters relating to commercial activities as Senior Advisor (the "Field of Interest"); and

- collaborate and provide advice and assistance to Company as is mutually agreed by the parties.

FEES/EXPENSES

- **Cash**: The Company shall pay Consultant a consulting fee at the annual rate of $200,000.00, payable in accordance with the Company's standard payroll schedule.

- **Options**: Subject to approval by the Board of Directors or the Compensation Committee of the Company, by such date that is no later than the next regularly scheduled meeting thereof following the Effective Date, Consultant shall be granted an option worth $200,000.00 to purchase a number of shares of the Company's common stock equal to $200,000.00 divided by the Black-Scholes value of an option to purchase one share of Company common stock on the date of grant (the "Option"), at an exercise price per share equal to the fair market value of a share of the Company's common stock (being the closing price of a share of Company common stock as reported on the Nasdaq Global Select Market (or any successor exchange upon which the Company's common stock is traded) on the date that Consultant's Option is granted). Fifty percent (50%) of the Option will vest on the one (1)-year anniversary of the Effective Date, and the remaining 50% of the Option will vest on the two (2)-year anniversary of the Effective Date, subject to Consultant's continuous service under this Agreement through both such dates. The Option shall be subject to the terms and conditions of the 2019 Stock Option and Incentive Plan, as amended from time to time (the "Plan") and the stock option agreement thereunder, which Consultant shall be required to sign as a condition to receiving Consultant's Option and which shall reflect the relevant terms set forth in this Agreement.

- **Restricted Stock Units**: Subject to approval by the Board of Directors or the Compensation Committee of the Company, by such date that is no later than the next regularly scheduled meeting thereof following the Effective Date, Consultant shall be granted $200,000.00 worth of restricted stock units, with the number of restricted stock units to be determined by dividing $200,000.00 by the closing price of a share of Company common stock as reported on the Nasdaq Global Select Market (or any successor exchange upon which the Company's common stock is traded) on the Effective Date (the "RSUs"). Each RSU entitles you to one share of Company common stock if and when the RSU vests. Fifty percent (50%) of the RSUs will vest on the one (1)-year anniversary of the Effective

Date and the remaining 50% of the RSUs will vest on the two (2)-year anniversary of the Effective Date, subject to Consultant's continuous service under this Agreement through both such dates. The RSUs will be subject to the terms and conditions applicable to awards granted under the Plan and the applicable RSU award agreement, which Consultant will be required to sign as a condition to receiving the RSUs.

- The Company will reimburse Consultant for all reasonable travel and out-of-pocket expenses incurred by Consultant in performing the Services pursuant to this Agreement, provided that Consultant receives written consent from the Company's Chief Executive Officer prior to incurring such expenses and submits receipts for such expenses to the Company in accordance with Company policy. Consultant shall submit to Company all statements for expenses incurred and services performed on a monthly basis in a form prescribed by the Company. Payment of such invoices shall be due within thirty (30) days of the Company's receipt thereof.

Exhibit 10.33

[***] Certain confidential portions (indicated by brackets and asterisks) have been omitted from this exhibit in accordance with the rules of the Securities and Exchange Commission.

COLLABORATION AGREEMENT

by and between

BRIDGEBIO GENE THERAPY, LLC

and

CATALENT MARYLAND, INC.

Dated as of December 31, 2019

TABLE OF CONTENTS

		Page
ARTICLE I DEFINITIVE AGREEMENTS		2
1.1	General	2
1.2	BridgeBio Manufacturing and Supply Agreement	2
1.3	Additional Manufacturing and Supply Agreements	3
ARTICLE II ROLES AND RESPONSIBILITIES OF THE PARTIES		3
3	General	3
3	Catalent	3
2.3	BridgeBio	4
2.4	No Obligation to Perform	4
ARTICLE III DEDICATED CLEAN ROOM SUITE; BWI FACILITY		5
3.1	The Dedicated Clean Room Suite.	5
3.2	The BWI Facility	6
ARTICLE IV STEERING COMMITTEE		6
6	Joint Steering Committee	6
4.2	Decision-Making	7
4.3	Periodic Status Updates	8
ARTICLE V REGULATORY MATTERS		9
5.1	Ownership of Regulatory Materials	9
5.2	Regulatory Filings and Regulatory Approvals	9
5.3	Communications	10
5.4	Reserved.	10
5.5	Regulatory Authority Communications Received	10
5.6	Environmental Audit of BWI Facility	11
ARTICLE VI LIMITATIONS AND CERTAIN RIGHTS		11
6.1	Limitations	11
6.2	Continuity of Operations	11
ARTICLE VII FORCE MAJEURE		12
7.1	Force Majeure Events	12
7.2	Examples	12
7.3	Process	12
ARTICLE VIII CONFIDENTIALITY		13
8.1	Sharing of Confidential Information	13
8.2	Confidential Disclosure Agreement	13
8.3	Confidential Information	13
8.4	Exceptions to Confidential Information	14
8.5	Confidentiality Obligations	14
8.6	Permitted Disclosure and Use	15
8.7	Notification	16
8.8	Publicity	16
8.9	Use of Names	16
8.10	Defend Trade Secrets Act Notice	16

8.11	Survival	16
ARTICLE IX FINANCIAL PROVISIONS		17
9.1	Clean Room Reservation Fee	17
9.2	Clean Room Use Fee.	17
9.3	BridgeBio-Requested Equipment	17
9.4	Withholding Tax Matters	18
9.5	Audit	18
ARTICLE X INTELLECTUAL PROPERTY		19
10.1	General	19
10.2	License to Catalent	19
10.3	License to BridgeBio	19
10.4	Project Intellectual Property	20
10.5	Patent Filings; Cooperation	20
ARTICLE XI REPRESENTATIONS AND WARRANTIES		20
11.1	BridgeBio and Catalent Mutual Representations and Warranties	20
11.2	Mutual Covenants; No Debarment	21
11.3	Additional Representations, Warranties and Covenants by Catalent	22
11.4	Additional Representations, Warranties and Covenants of BridgeBio	22
11.5	No Other Representations or Warranties	23
11.6	Catalent Indemnity	23
11.7	BridgeBio Indemnity	24
11.8	Indemnification Procedures	24
11.9	Insurance	25
ARTICLE XII TERMINATION AND SURVIVAL		25
12.1	Term and Termination	25
12.2	Effect of Termination	26
ARTICLE XIII DISPUTE RESOLUTION		29
13.1	Disputes	29
13.2	Dispute Resolution	29
13.3	Patent and Trademark Dispute Resolution	30
13.4	Injunctive Relief	30
ARTICLE XIV MISCELLANEOUS		30
14.1	Assignment; Binding Effect	30
14.2	Expenses	30
14.3	Notices	31
14.4	Severability	32
14.5	Entire Agreement	32
14.6	Waiver	32
14.7	Governing Law; Jurisdiction; Venue	32
14.8	Headings	32
14.9	Counterparts	32
14.10	Construction	33
14.11	Interpretation	33
14.12	Relationship of the Parties	33

Attachments

A Definitions
B Minimum Annual Threshold and Forecasting
C Dedicated Clean Room Suite Floor Plan
D Base Equipment Package

Schedules

2.2 Summary of Key Milestones for Dedicated Clean Room Suite
3.1(b) Readiness Determination Check List

COLLABORATION AGREEMENT

THIS COLLABORATION AGREEMENT (this "**Agreement**"), dated as of the 31st day of December, 2019 (the "**Effective Date**"), is entered into by and among **BRIDGEBIO GENE THERAPY, LLC**, a limited liability corporation organized and existing under the Laws of Delaware and having a place of business at 421 Kipling Street, Palo Alto, California 94301, ("**BridgeBio**") and **CATALENT MARYLAND, INC.** (formerly Paragon Bioservices, Inc.), a corporation organized and existing under the Laws of Delaware and having a place of business at 801 West Baltimore Street, Suite 302, Baltimore, Maryland 21201 ("**Catalent**"). BridgeBio and Catalent are sometimes referred to herein, individually, as a "**Party**" and, collectively, as the "**Parties**." All capitalized terms used herein, including in the Exhibits and Schedules hereto, shall have the meanings specified in **Exhibit A** attached hereto or elsewhere in this Agreement, as applicable, unless otherwise specified.

RECITALS

WHEREAS, BridgeBio and its majority- and wholly-owned subsidiaries including ASPA Therapeutics, Inc. ("**ASPA**"), Adrenas Therapeutics, Inc. ("**Adrenas**"), and Audition Therapeutics, Inc. ("**Audition**") (BridgeBio and its subsidiaries are collectively referred to herein as the "**BridgeBio Entities**" and each subsidiary is referred to herein as **"BridgeBio Entity"**) are gene therapy companies that are currently developing Adeno-associated virus ("**AAV**")-delivered therapeutics for the treatment of genetic diseases. BridgeBio (on behalf of itself and the other BridgeBio Entities) is interested in securing clinical and commercial scale manufacturing capacity for the Manufacture of Batches of Bulk Drug Substance of which the BridgeBio Entities or BridgeBio's designated Strategic Partners may later contract with Catalent for clinical and/or commercial supply (each such Batch of Bulk Drug Substance being a "**BridgeBio Product**" and collectively the "**BridgeBio Products**");

WHEREAS, Catalent has process development, manufacturing, and related services experience and expertise, and operates facilities for the development and manufacturing of biopharmaceuticals, including but not limited to a clinical and commercial scale biomanufacturing facility located at 7555 Harmans Road, Baltimore, Maryland (the "**BWI Facility**");

WHEREAS, the Parties wish to enter into a business transaction involving the commitment by Catalent to BridgeBio of dedicated biomanufacturing space and the execution by both Parties of various agreements governing collaboration, development, clinical and/or commercial supply of and with respect to BridgeBio Products (hereinafter the "**Proposed Transaction**");

WHEREAS, the Proposed Transaction contemplates that during the Term the BridgeBio Entities and Catalent will enter into manufacturing and supply agreements for clinical and commercial supply manufacturing of one or more BridgeBio Products (each such agreement being referred to herein as the "**BridgeBio Manufacturing and Supply Agreement**");

WHEREAS, on August 22, 2019, ASPA and Catalent entered into an Interim Services Agreement ("**ISA**") in order to commence with the reservation, planning, and design of the clean room suite to be dedicated to BridgeBio, initiate the exchange of information regarding the Manufacturing Process of the BridgeBio Products, and order long lead-time equipment (hereinafter the "**Transition Services**");

WHEREAS, on November 23, 2019, ASPA and Catalent executed the First Amendment to the Interim Services Agreement to extend the term thereof;

WHEREAS, to consummate the Proposed Transaction, the Parties intend to execute (i) this Agreement, which, among other things, will set forth the terms and conditions of the overall relationship between the Parties and the dedication of [***] at the BWI Facility for BridgeBio for a [***] period during each calendar year for the Term of this Agreement (collectively, the "**Dedicated Clean Room Collaboration**"), and (ii) one or more BridgeBio Manufacturing and Supply Agreements; and

WHEREAS, this Agreement provides for certain rights, obligations, terms and conditions among the Parties with respect to the Dedicated Clean Room Collaboration.

NOW, THEREFORE, in consideration of the foregoing and the representations, warranties, covenants, agreements and provisions set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, and intending to be legally bound hereby, the Parties agree as follows:

ARTICLE I
DEFINITIVE AGREEMENTS

1.1 General. This Agreement, together with the BridgeBio Manufacturing and Supply Agreement (including the Quality Agreements) and any Additional Manufacturing and Supply Agreements are collectively referred to herein as the "**Definitive Agreements**" and set forth the material terms related to the roles, allocations of responsibilities, rights, obligations, terms and conditions for each of the Parties' involvement in the Dedicated Clean Room Collaboration.

1.2 BridgeBio Manufacturing and Supply Agreements. During the Term, one or more BridgeBio Entities and Catalent will enter into one or more agreements for development services and clinical supply Manufacture and Delivery of one or more BridgeBio Products under which scopes of work for development services and/or clinical supply for each BridgeBio Products will be issued (each agreement being a "**Development Services and Clinical Supply Agreement**" and each scope of work being a "**Scope of Work**"). Catalent shall enter into Development Services and Clinical Supply Agreements with ASPA, Adrenas and Audition for the development services and/or clinical supply for products relating to the treatment, prevention or diagnosis of Canavan Disease, Congenital Adrenal Hyperplasia, and TMC-1-dependent genetic hearing loss (the "**Existing Programs**"). The Parties shall negotiate in good faith on commercially reasonable terms a Development Services and Clinical Supply Agreement for at least one (1) Existing Program within [***] of the Effective Date. Further, it is anticipated that one or more of the

[***] Certain confidential portions (indicated by brackets and asterisks) have been omitted from this exhibit in accordance with the rules of the Securities and Exchange Commission.

BridgeBio Entities and Catalent will enter into one or more agreements for the commercial supply of each BridgeBio Product for which BridgeBio submits for Regulatory Approval (each a "**Commercial Supply Agreement**"). The Development Services and Clinical Supply Agreements and Commercial Supply Agreements are each a BridgeBio Manufacturing and Supply Agreement. It is the intention of the Parties that each of the BridgeBio Entities and Catalent will enter into a separate BridgeBio Manufacturing and Supply Agreement that is unique to the BridgeBio Products being Developed by that BridgeBio Entity.

1.3 Additional Manufacturing and Supply Agreements. In addition to the BridgeBio Manufacturing and Supply Agreement for clinical supply of BridgeBio Products, the Parties anticipate that additional supply agreements may be negotiated in good faith as part of the Dedicated Clean Room Collaboration for BridgeBio's Strategic Partners (each such agreement being an "**Additional Manufacturing and Supply Agreement**").

ARTICLE II
ROLES AND RESPONSIBILITIES OF THE PARTIES

2.1 General. The roles and responsibilities of each Party with respect to activities under the Dedicated Clean Room Collaboration are as provided herein. The Parties understand and agree that there are significant interdependencies by and between each Party in carrying out their respective responsibilities under this Agreement. This Article II is intended to give an overview of the respective roles and responsibilities of the Parties and to provide the appropriate context for those roles and responsibilities.

2.2 Catalent. Catalent shall, by itself or through subcontractors, be responsible for the following:

(a) Constructing the Dedicated Clean Room Suite and the Associated Infrastructure, each of which is defined below, in a manner that (i) accommodates the use of the BridgeBio Technology for the Manufacture of the BridgeBio Products in compliance with cGMP requirements and the principles in their respective Quality Agreements, and (ii) achieves the timeline attached hereto as Schedule 2.2 or such other date(s) as BridgeBio and Catalent may agree on in writing;

(b) Completing the qualification and other activities related to the Dedicated Clean Room Suite and the BWI Facility (including the installation of all equipment for use in the Dedicated Clean Room Suite);

(c) Ensuring that all equipment used in the Dedicated Clean Room Suite are suitable for the Manufacture of BridgeBio Products in accordance with the related Definitive Agreements;

(d) Conducting all of its activities under the Dedicated Clean Room Collaboration in good scientific manner, in compliance with all material respects of this Agreement, all requirements of applicable Laws and Regulatory Acts and any other requirements, and as applicable, of cGMPs;

(e) Remaining in compliance with and maintaining the necessary regulatory filings in accordance with applicable Laws and Regulatory Acts with respect to the BWI Facility and Dedicated Clean Room Suite; and

(f) Using commercially reasonable efforts to achieve the objectives of the Dedicated Clean Room Collaboration efficiently and expeditiously.

2.3 BridgeBio. BridgeBio shall, by itself or through subcontractors, be responsible for the following:

(a) Providing reasonable support to Catalent in planning the Dedicated Clean Room Suite in preparation for the Manufacture of the BridgeBio Products;

(b) Using commercially reasonable efforts to achieve the objectives of the Dedicated Clean Room Collaboration efficiently and expeditiously;

(c) Consulting with Catalent in the planning, specification, and procurement of BridgeBio-Requested Equipment to be deployed in the Dedicated Clean Room Suite for the Manufacture of BridgeBio Products;

(d) To the extent within the control of BridgeBio, support the timely transfer of BridgeBio Technology associated with the BridgeBio Products, including but not limited to timely transferring of the Manufacturing Process, batch production records, standard operating procedures, raw materials, and assays and analytical methods, if applicable;

(e) Timely performance of necessary audits and inspections of the Dedicated Clean Room Suite and installed BridgeBio-Requested Equipment to confirm readiness for the Manufacture of the BridgeBio Products; and

(f) Promptly making all required payments set forth in this Agreement, consisting of the following, if applicable: Clean Room Reservation Fee, Clean Room Use Fee, BridgeBio-Requested Equipment Cost, and BridgeBio-Requested Equipment Use Fee.

2.4 No Obligation to Perform. Neither Catalent nor its Affiliates shall be obliged to Manufacture any BridgeBio Product for sale in any countries that are targeted by the comprehensive sanctions, restrictions or embargoes administered by the United Nations, European Union, United Kingdom, or the United States if it is prevented from doing so, or would be required to obtain or apply for special permission to do so, due to any restriction (such as an embargo) imposed on it by any Governmental Authority, including those imposed by the U.S. Department of the Treasury's Office of Foreign Assets Control.

ARTICLE III
DEDICATED CLEAN ROOM SUITE; BWI FACILITY

3.1 The Dedicated Clean Room Suite.

(a) As part of the Dedicated Clean Room Collaboration, Catalent shall dedicate clean room space at the BWI Facility, designated as [***] (the "**Dedicated Clean Room Suite**"), for the purpose of exclusively Manufacturing BridgeBio Products for [***] (each [***] period being a "**Dedicated Manufacturing Period**"), beginning and ending at the same time each year during the Term of this Agreement. The Parties agree that the Dedicated Manufacturing Period will commence on [***] and conclude on [***]. The commencement and conclusion of the Dedicated Manufacturing Period may be modified based upon the written agreement of the Parties. The approximate outline of the floor plan and location of the Dedicated Clean Room Suite within the BWI Facility is set forth in **Exhibit C** attached hereto. As part of its obligation to perform Manufacturing of BridgeBio Products in the Dedicated Clean Room Suite, Catalent shall provide the necessary supporting cGMP infrastructure required for clean room operations, including QC, warehousing, buffer preparation, master cell bank storage ("**Associated Infrastructure**").

(b) The Dedicated Manufacturing Period shall first commence upon the determination by the JSC that the Dedicated Clean Room Suite and Associated Infrastructure have been fully qualified and validated for cGMP Manufacturing of the BridgeBio Products (such determination being a "**Readiness Determination**.") Notwithstanding the forgoing, if the JSC approves the commencement of Manufacturing in the Dedicated Clean Room Suite prior to the Readiness Determination, the start date of the Manufacturing shall be deemed the Readiness Determination. In the event that BridgeBio desires to exclusively secure the Dedicated Clean Room Suite for an entirety of the remaining Term, it shall provide Catalent with a notice of its intent at least [***] prior to the time it would like to secure the space and the Parties agree to negotiate in good faith the exclusive access of BridgeBio to the Dedicated Clean Room Suite for the remaining term, subject to its availability and any additional term of fees that will be charged to BridgeBio. The Readiness Determination shall consider cGMP readiness of the Dedicated Clean Room Suite and Associated Infrastructure, as provided for in Schedule 3.1(b), as well as compliance with the applicable regulatory and quality assurance requirements for cGMP Manufacturing. Upon the Readiness Determination, BridgeBio shall start paying [***] use fee (payable as set forth in Section 9.2(a)) for the ongoing operational and maintenance costs associated with the Dedicated Clean Room Suite (as are necessary to maintain cGMP operations), which shall include, but are not limited to, costs associated with maintenance and repairs, equipment calibration and metrology, environmental monitoring, cleaning, solid and liquid waste disposal, warehousing, raw material and product storage, personal protective equipment, shipping and receiving, and utilities (such fee being the "**Clean Room Use Fee**").

(c) As part of the Dedicated Clean Room Collaboration and more fully set forth in **Exhibit B** attached hereto, the Parties have agreed to the following operational provisions for the use of the Dedicated Clean Room Suite during the Term: (i) minimum [***] ordering obligations for the Manufacture of clinical and/or commercial supply of BridgeBio Products in the Dedicated Clean Room Suite following the Readiness Determination, (ii) the establishment of procedures for the initial forecasting and rolling forecasts of the BridgeBio Entities' ordering of clinical and/or commercial supply Manufacturing of the BridgeBio Products in the Dedicated Clean Room Suite, and (iii) any other services to be performed by Catalent for BridgeBio to which the Parties mutually agree.

[***] Certain confidential portions (indicated by brackets and asterisks) have been omitted from this exhibit in accordance with the rules of the Securities and Exchange Commission.

3.2 The BWI Facility.

(a) Catalent shall maintain full and exclusive rights over the operation of the BWI Facility and, as contemplated in this Agreement during the Dedicated Manufacturing Period, shall use the Dedicated Clean Room Suite for the benefit of BridgeBio for the Manufacture of the BridgeBio Products. Except that as provided for in Section 9.2(b), Catalent may use the Dedicated Clean Room Suite or clean rooms within the Dedicated Clean Room Suite for Manufacturing for other Catalent customers during the Dedicated Manufacturing Period solely upon BridgeBio's prior written approval, provided that Catalent timely returns the Dedicated Clean Room Suite, or clean rooms within the Dedicated Clean Room Suite, such that the compliance with applicable Law or Manufacture of the BridgeBio Products will not be delayed or otherwise adversely affected.

(b) [***] is responsible for all costs associated with the readiness and on-going operation of the BWI Facility (and its systems) and the Dedicated Clean Room Suite. If BridgeBio makes specific requests regarding the construction, layout, commissioning, qualification and/or validation of the Dedicated Clean Room Suite or the equipment installed in the Dedicated Clean Room Suite that are unique to the Manufacture of BridgeBio Products, Catalent agrees to reasonably consider such requests [***]. If [***] Catalent will implement the requested changes.

ARTICLE IV
STEERING COMMITTEE

4.1 Joint Steering Committee. The Parties have established a Joint Steering Committee (the "**Joint Steering Committee**," or "**JSC**") comprised of representatives of the Parties. The JSC has and will continue to oversee and coordinate all aspects of (x) the Dedicated Clean Room Collaboration, and (y) the Definitive Agreements. The JSC will periodically meet in person, by videoconference or teleconference. Among the activities for oversight by the JSC are the following:

(a) Review, coordinate and discuss the overall plans for (i) completing and maintaining the Dedicated Clean Room Suite, (ii) the use of the Dedicated Clean Room Suite for the Manufacture of BridgeBio Products, and (iii) forecasting, ordering and delivery of Products;

(b) Review plans and timelines, and any amendments thereto, for the layout and process flows in the Dedicated Clean Room Suite;

(c) Review matters related to potential regulatory approvals of the BWI Facility and any post-regulatory approval commitments for the BWI Facility related to the Manufacture of BridgeBio Products;

(d) Planning and scheduling the Manufacturing of BridgeBio Products in the Dedicated Clean Room Suite on a quarterly and annual basis;

[***] Certain confidential portions (indicated by brackets and asterisks) have been omitted from this exhibit in accordance with the rules of the Securities and Exchange Commission.

(e) Review Catalent's risk assessments relating to operations, employees, technology, suppliers, inventory policy, emergency plans related to the Dedicated Clean Room Suite;

(f) Undertake annually, if not more frequently, review the BridgeBio Product Manufacturing costs and Procurement Costs and develop and implement plans to reduce the BridgeBio Product Manufacturing costs and Procurement Costs and, if such cost reductions or savings are actually realized, establish a process for the sharing of such cost reductions and savings;

(g) Review the BridgeBio Entities' proposed product pipeline and any potential Strategic Partners under consideration, and discuss potential conflicts with Catalent's then-existing obligations to Third Parties;

(h) Undertake such other matters as expressly indicated by this Agreement; and

(i) Undertake such other matters as may be mutually agreed in writing by the Parties.

The JSC shall not have the power to take any action to interpret, amend or modify the Definitive Agreements, or waive compliance therewith. The Parties acknowledge and agree to establish sub-committees of the JSC and/or additional operational committees, as appropriate and as mutually agreed upon, that may be delegated or otherwise assigned the governance or operational responsibilities set forth above and that are more narrowly focused on issues relating to a particular BridgeBio Products or group of BridgeBio Products, such as a joint manufacturing committee.

4.2 Decision-Making.

(a) The decisions of the JSC with respect to matters subject to its decision-making authority shall be made as set forth in this Section 4.2 and shall be final. Subject to and after giving effect to the provisions of Section 4.2(b), all decisions of the JSC will be made by unanimous vote or written consent, with BridgeBio and Catalent each having, collectively among its respective members, one (1) vote in all decisions, such decision to be documented in the meeting minutes. The JSC shall use commercially reasonable efforts to resolve the matters within its roles and functions or otherwise referred to it with due regard to the Dedicated Clean Room Collaboration and Definitive Agreements. If the JSC cannot reach consensus on a matter within [***] (or such longer period of time as mutually agreed by the Parties) after such matter has been presented to the JSC, then such matter shall be handled in the following manner. Any disputed matter that cannot be resolved by the JSC shall be first referred to the executive officers designated by each Party. Such executive officers shall use commercially reasonable efforts to reach mutually acceptable resolutions on all such disputed matters. If such executive officers are unable to resolve any disputed matter within [***] (or such longer period of time as mutually agreed by the Parties) after the dispute is first referred to them, the matter shall be resolved as provided in Section 4.2(b).

[***] Certain confidential portions (indicated by brackets and asterisks) have been omitted from this exhibit in accordance with the rules of the Securities and Exchange Commission.

(b) If any matter within the decision-making authority of the JSC remains unresolved following attempted resolution under Section 4.2(a), the following shall apply:

(i) Subject to and after giving effect to the provisions of Section 4.2(b)(iv), if the dispute relates to clinical, commercial supply or regulatory matters regarding any BridgeBio Product, BridgeBio shall have final decision-making authority with respect to such matters. In the event any such matter requires an immediate or prompt decision and the JSC is not able to reach agreement, BridgeBio, by written notice to Catalent, may inform it of the need to accelerate a decision on that matter and that it is electing to exercise its decision-making authority on a shortened time frame than that set forth in Section 4.2(a).

(ii) Subject to and after giving effect to the provisions of Section 4.2(b)(iv), if the dispute relates to construction, commission, qualification and validation of the BWI Facility and the Dedicated Clean Room Suite, Catalent shall have final decision-making authority with respect to such matters, provided that Catalent's final decision-making authority does not include the Readiness Determination. In the event any such matter requires an immediate or prompt decision and the JSC is not able to reach agreement, Catalent, by written notice to BridgeBio, may inform it of the need to accelerate a decision on that matter and that it is electing to exercise its decision-making authority on a shortened time frame than that set forth in Section 4.2(a).

(iii) Subject to and after giving effect to the provisions of Section 4.2(b)(i), (ii) and (iv), any remaining unresolved dispute regarding a matter within the decision-making authority of the JSC shall be resolved in accordance with Article XIII, and none of the Parties shall have any final decision-making authority with respect to such dispute.

(iv) Notwithstanding the foregoing provisions of this Section 4.2(b): (A) either Party's exercise of a right to finally resolve a dispute hereunder shall not excuse the other Party from any of its obligations specifically enumerated under the Definitive Agreements; and (B) neither Party shall exercise such a right in a manner that violates any rights or obligations specifically addressed in any Definitive Agreements. In addition, in resolving a dispute hereunder each Party shall act in good faith.

4.3 Periodic Status Updates. Each Party shall provide the JSC with reports detailing the activities it conducts under the Dedicated Clean Room Collaboration on a periodic basis to be reviewed and, if appropriate, acted upon by the JSC. Such reports shall be provided at least five (5) Business Days prior to the JSC meeting at which the report is scheduled to be discussed.

ARTICLE V
REGULATORY MATTERS

5.1 Ownership of Regulatory Materials. Any and all Regulatory Materials, including Regulatory Approvals, arising under the Dedicated Clean Room Collaboration in respect to BridgeBio Products and the Manufacture thereof, including labeling and packaging and any Drug Master Files and Chemistry, Manufacturing and Control ("**CMC")** (or equivalent) sections of any such Regulatory Materials shall be in the name of the applicable BridgeBio Entity, and such BridgeBio Entity shall own all right, title and interest in and to all such Regulatory Materials; provided, however, that Regulatory Materials, including Regulatory Approvals, solely relating to establishment license approvals for the BWI Facility and the Dedicated Clean Room Suite shall be in the name of Catalent, and Catalent shall own all right, title and interest in and to only such Regulatory Materials, subject to and after giving effect to the BridgeBio Entity's right to use such establishment license approvals in connection with its Development, Manufacturing and Commercialization activities for the Manufacture of BridgeBio Product.

5.2 Regulatory Filings and Regulatory Approvals.

(a) **BridgeBio General Responsibilities**. The applicable BridgeBio Entity shall be solely responsible for the preparation of all Regulatory Materials owned by such BridgeBio Entity, and all costs related thereto, including as may be necessary or desirable for obtaining and maintaining Regulatory Approvals owned by such BridgeBio Entity. BridgeBio and other BridgeBio Entities shall not identify Catalent in any Regulatory Materials without Catalent's prior written consent. Such consent shall not be unreasonably withheld, conditioned, or delayed.

(b) **Manufacturing Approvals and BWI Facility Related Sections**. Catalent shall be responsible for the preparation of all Regulatory Materials solely relating to establishment license approvals for the BWI Facility and the Dedicated Clean Room Suite for the Manufacture of BridgeBio Products under the Dedicated Clean Room Collaboration and Definitive Agreements. Catalent also shall prepare and provide to the BridgeBio Entities the Regulatory Materials relating to such establishment license approvals in a timely manner in order for the BridgeBio Entities to comment and agree on and to use in compiling, supporting and maintaining each BridgeBio Entity's regulatory filings for its BridgeBio Products. Catalent shall provide such Regulatory Materials with the content and in the format required by a Regulatory Authorities as well as such content and format requested by the BridgeBio Entities. Without limiting the foregoing and as provided for in a Scope of Work under a BridgeBio Manufacturing and Supply Agreement, Catalent will provide BridgeBio with available data and documentation necessary to support a BridgeBio Entity's submission to any Regulatory Authority, and provide responses to questions raised by a Regulatory Authority with respect to Manufacturing BridgeBio Products that are necessary for Regulatory Approval of the BWI Facility as a clinical or commercial supply manufacturing (as applicable under the respective BridgeBio Manufacturing and Supply Agreement), testing, and packaging site for the applicable BridgeBio Products. To the extent that a Regulatory Approval of a BridgeBio Entity's Products in jurisdictions other than the U.S. or EU impose additional requirements on Catalent, Catalent agrees to comply with such requirements, at such BridgeBio Entity's cost and expense, provided that compliance with the additional requirements does not materially disrupt Catalent's operation of the BWI Facility.

5.3 Communications. The BridgeBio Entities shall be primarily responsible for communicating with any Regulatory Authority having jurisdiction anywhere in the world regarding BridgeBio Products under the Dedicated Clean Room Collaboration; provided, that BridgeBio shall keep the JSC reasonably and timely informed of all such relevant communications regarding such BridgeBio Product or their components; and Catalent shall, at no cost to the BridgeBio Entity, where requested by the BridgeBio Entity to do so, assist the BridgeBio Entity in communications as they pertain to the Manufacture of BridgeBio Product, including but not limited to provision of documentation and other evidence, preparation for and participation in any inspection and conduct of any other activities necessary to facilitate the communications between the BridgeBio Entity and the Regulatory Authority. Catalent shall be responsible for communicating with any Regulatory Authority having jurisdiction over the BWI Facility used in the Manufacture of BridgeBio Product under the Dedicated Clean Room Collaboration; provided, that Catalent shall, as promptly as practicable but in no event later than the time frames agreed on in the Quality Agreement, notify the applicable BridgeBio Entity in the event that Catalent communicates, or intends to communicate, either on its own initiative in accordance with this Agreement or as a result of such a Regulatory Authority initiating contact with Catalent that may affect or involve operations associated with the Manufacture of a BridgeBio Product, and promptly provide the BridgeBio Entity with a copy of all such communications.

5.4 Reserved.

5.5 Regulatory Authority Communications Received.

(a) **General**. Catalent shall inform the applicable BridgeBio Entity as promptly as practicable but in no event later than within the time frames agreed in the Quality Agreement of notification of any action by, or notification or other information which it receives (directly or indirectly) from, any Regulatory Authority with respect to a BridgeBio Product or the BWI Facility which: (i) raises any material concerns regarding the safety or efficacy of a BridgeBio Product; (ii) relates to expedited and periodic reports of adverse events with respect to a BridgeBio Product; (iii) are Regulatory Warning Notices; and/or (iv) which may have an adverse impact on Regulatory Approval, Development, Manufacturing or Commercialization of a BridgeBio Product.

(b) **Cooperation**. The Parties shall reasonably cooperate with and assist each other in complying with regulatory obligations, including by each Party providing to the Parties such information and documentation which is in such Party's possession as may be reasonably necessary for a Party to prepare a response to an inquiry from a Regulatory Authority with respect to BridgeBio Products or the BWI Facility under the Dedicated Clean Room Collaboration.

(c) **Disclosures**. In addition to its obligations under this Agreement, Catalent shall promptly disclose to the applicable BridgeBio Entities the following regulatory information: all material notices or demands received from Regulatory Authorities in connection with a BridgeBio Product or the BWI Facility under the Dedicated Clean Room Collaboration, including any notice, audit notice, notice of initiation by Regulatory Authorities of investigations, inspections, detentions, seizures or injunctions, a notice of violation letter (i.e., an untitled letter), warning letter, service of process or other inquiry, including that which may affect the overall compliance status of any party participating in the Manufacturing of a BridgeBio Product under the Dedicated Clean Room Collaboration.

5.6 Environmental Audit of BWI Facility.

Catalent agrees that BridgeBio (the "**Auditing Party**") shall have the right upon reasonable notice and during normal business hours, at the Auditing Party's expense, once every year during the Term of this Agreement to conduct, or to nominate a Third Party (subject to the execution of confidentiality and indemnity agreements reasonably acceptable to Catalent and the Auditing Party) to conduct on the Auditing Party's behalf, an environmental audit of Catalent's operations at the BWI Facility under this Agreement to monitor Catalent's compliance with applicable environmental Laws and Regulatory Acts, and with applicable environmental health safety guidelines; provided, however, the Auditing Party or any such Third Party may not perform any invasive testing of the BWI Facility without Catalent's prior written consent, which shall not be unreasonably withheld, conditioned or delayed, and the Auditing Party or any such Third Party will provide Catalent the opportunity to accompany Auditing Party or any such Third Party in the event of any such invasive testing of the BWI Facility.

ARTICLE VI
LIMITATIONS AND CERTAIN RIGHTS

6.1 Limitations.

(a) **No Unauthorized Use**. Each Party covenants that it will not use or practice any Patents, Know-How or Confidential Information licensed, sublicensed, disclosed or otherwise made available to it under the Definitive Agreements except for the purposes expressly permitted in an applicable license grant to such Party that is explicitly set forth in the Definitive Agreements. Except as explicitly set forth in the Definitive Agreements, no Party grants any license, express or implied, under any Patents, Know-How, Regulatory Materials, Confidential Information or any other intellectual property rights, whether by implication, estoppel or otherwise.

(b) **Limited Access**. Catalent hereby covenants to and agrees with BridgeBio that it and its Affiliates shall limit access to the materials, processes, methods and Confidential Information utilized in the Manufacturing of BridgeBio Products to such employees of Catalent or its Affiliates on a need to know/access basis, where each such employees are bound by confidentiality and intellectual property provisions at least as protective of BridgeBio Entities or Strategic Partners as those set forth in this Agreement.

6.2 Continuity of Operations.

(a) Through the Term, Catalent shall keep up to date a clearly organized, written record of all standard operating procedures and other Know-How utilized by or on behalf of Catalent to fulfill its obligations and perform under the Definitive Agreements, including: (i) as it relates to the operation and maintenance of the BWI Facility in connection with Manufacturing BridgeBio Products under the Dedicated Clean Room Collaboration; and (ii) the utilization (or not) of any BridgeBio Technology (including, for example, the Know-How of any Third-Party (such as a redundant contract development and manufacturing organization)) made available to Catalent by or on behalf of BridgeBio.

[***] Certain confidential portions (indicated by brackets and asterisks) have been omitted from this exhibit in accordance with the rules of the Securities and Exchange Commission.

(b) For the sole purpose of the Dedicated Clean Room Collaboration, Catalent hereby grants to the BridgeBio Entities a non-exclusive, fully paid up, perpetual, irrevocable right and license to use for the Licensed Purpose (i) standard operating procedures, other Know-How and Confidential Information of Catalent, as well as (ii) the Regulatory Materials and Regulatory Approvals (together with a right of reference in all such approvals and materials) in the name of, owned by or otherwise held by or behalf of Catalent or its Affiliates relating to the BWI Facility's establishment license and other licenses for the maintenance and operation of the BWI Facility (the "**Licensed Subject Matter**"). The BridgeBio Entities agree not to use such license for any purpose other than verifying the completeness of the licensed subject matter, unless and until this Agreement is terminated due to material breach by Catalent under any Definitive Agreement or bankruptcy of Catalent in which case the BridgeBio Entities may use such license for the purposes of Development, Manufacture, and Commercializing of a BridgeBio Product that was the subject of a BridgeBio Manufacturing and Supply Agreement or an Additional Supply Agreement.

ARTICLE VII
FORCE MAJEURE

7.1 Force Majeure Events. No Party shall be in default under this Agreement because of any failure to perform if the failure arises from causes beyond the control and without the fault or negligence of such Party ("Force Majeure Event"), unless:

(a) The supplies, services or other subject matter impacted by the Force Majeure Event were obtainable from other sources; and

(b) The Party experiencing a Force Majeure Event preventing it from performing its obligations or duties under this Agreement failed to obtain such supplies, services or other subject matter therefrom.

7.2 Examples. Examples of these Force Majeure Events are: (1) acts of God or of the public enemy, (2) acts of any Governmental Authority in either its sovereign or contractual capacity, (3) fires, (4) floods, (5) epidemics, (6) quarantine restrictions, (7) strikes (exclusive of labor disputes), (8) freight embargoes, and (9) unusually severe weather. A Force Majeure Event does not include (i) a party's financial inability to perform, or general business or economic conditions affecting the industry as a whole, or (ii) an act, omission or circumstance arising from the negligence or willful misconduct of the party claiming that a Force Majeure event has occurred.

7.3 Process.

(a) The Party experiencing a Force Majeure Event preventing it from performing its obligations or duties under this Agreement shall promptly notify the other Party of the occurrence and particulars of such Force Majeure Event and shall provide the other Party, from time to time, with its best estimate of the duration of such Force Majeure Event and with notice of the resolution or cessation thereof. The Party so affected shall use commercially reasonable efforts to avoid or promptly remove such causes of nonperformance.

(b) Upon resolution or cessation of the Force Majeure Event, the affected Party shall promptly notify the other Party thereof, and performance of any suspended obligation or duty under this Agreement shall promptly recommence.

(c) This Article VII will not operate to excuse payment by either Party of any amounts due to another Party under this Agreement

ARTICLE VIII
CONFIDENTIALITY

8.1 Sharing of Confidential Information. The BridgeBio Entities may from time to time share and exchange Confidential Information with Catalent and Catalent may share Confidential Information from any one of the BridgeBio Entities with any of the other BridgeBio Entities and/or BridgeBio Pharma, Inc. (the parent entity of BridgeBio).

8.2 Confidential Disclosure Agreement. Catalent and each of ASPA and Adrenas entered into GMP Manufacturing Services Agreements (each a "**GMP Agreement**") with an effective date of [***]. The confidentiality obligations set forth in the GMP Agreements remain in full force and effect and, in the event of a conflict between the confidentiality obligations provided in the GMP Agreements and this Agreement, the terms in this Agreement will control solely with respect to the Dedicated Clean Room Collaboration.

8.3 Confidential Information. As used in this Agreement and the other Definitive Agreements, the term "Confidential Information" means the following:

(a) all information furnished by or on behalf of a disclosing party, its Affiliates or any of its or their respective Representatives (the "**Disclosing Party**"), to the other Party, its Affiliates or any of its or their respective Representatives (the "**Receiving Party**"), whether furnished before, on or after the Effective Date and furnished in any form, including written, verbal, visual, electronic or in any other media or manner and information acquired by observation or otherwise during any site visit at the other Party's facility. Confidential Information includes all proprietary technologies, know-how, trade secrets, discoveries, inventions and any other intellectual property (whether or not patented), analyses, compilations, business or technical information and other materials prepared by either Party, their respective Affiliates, or any of its or their respective Representatives, containing or based in whole or in part on any information furnished by the Disclosing Party, its Affiliates or any of its or their respective Representatives; and

(b) any information concerning this Agreement or the other Definitive Agreements; and

[***] Certain confidential portions (indicated by brackets and asterisks) have been omitted from this exhibit in accordance with the rules of the Securities and Exchange Commission.

(c) includes but is not limited to that which relates to business plans, strategic plans or business methods that derive economic value from not being generally known to other persons or easily ascertainable by other persons, business policies, research, product plans, BridgeBio Products or components thereof, product pricing or product strategy, services, service pricing or service strategy, manufacturing information, actual or proposed alliance partners, actual or proposed vendors, vendor offerings and pricing, actual or proposed customers, customer usage and customer purchasing potential, employee and consulting relationship information, actual or proposed markets, sales and marketing materials, plans and methods, specifications, shop-practices, software, developments, inventions (whether or not patented), product names or marks, trade secrets, technologies, discoveries, and any other intellectual property (whether or not registered), processes, designs, drawings, engineering, hardware configuration information or finance, accounting or financial plans and forecasts, compilations, formulas, devices, methods, prototypes, techniques, procedures, protocols, programs, records, and databases.

8.4 Exceptions to Confidential Information. Confidential Information shall not include any information or materials to the extent the Receiving Party can reasonably demonstrate through its contemporaneous written records that such information or materials are or have been:

(a) part of public domain at the time of its creation or receipt by the Receiving Party or which thereafter becomes part of the public domain other than as a result of a breach of this Agreement or the obligations of confidentiality under this Agreement; or

(b) is approved in writing by the Disclosing Party for release; or

(c) independently developed by the Receiving Party or its Affiliates or Representatives without use of or reference to the Confidential Information of the Disclosing Party; or

(d) received from a Third Party who, to the knowledge of the Receiving Party, is not under any obligation of confidentiality towards the Disclosing Party with respect to such information.

The Receiving Party has the burden of proving any of the above exceptions. The Disclosing Party has the right to inspect the Receiving Party's documentary evidence upon which the Receiving Party bases its claim that Confidential Information is within any of the above exceptions.

8.5 Confidentiality Obligations. Each Party shall keep all Confidential Information received from or on behalf of another Party with the same degree of care with which it maintains the confidentiality of its own Confidential Information, but in all cases no less than a reasonable degree of care. Each Party, in their position as a Receiving Party hereunder, shall, during the Term and for [***] thereafter:

(a) not use the Disclosing Party's Confidential Information other than as strictly necessary to exercise its rights and perform its obligations under this Agreement; and

[***] Certain confidential portions (indicated by brackets and asterisks) have been omitted from this exhibit in accordance with the rules of the Securities and Exchange Commission.

(b) maintain the Disclosing Party's Confidential Information in strict confidence and, subject to Section 8.6, not disclose the Disclosing Party's Confidential Information to any Person without the Disclosing Party's prior written consent, provided, however, the Receiving Party may disclose the Confidential Information to its Representatives who:

(i) have a need to know the Confidential Information for purposes of the Receiving Party's performance, or exercise of its rights concerning the Confidential Information, under this Agreement, it being understood that, except as provided for in Section 8.6, in no event shall Catalent share any Confidential Information of BridgeBio with other customers of Catalent (excluding BridgeBio Entities) or use such information for the benefit of other customers of Catalent (excluding BridgeBio Entities);

(ii) have been apprised of this restriction; and

(iii) are themselves bound by written nondisclosure agreements or ethical obligations of confidentiality at least as restrictive as those set forth in this Section 8.5, provided further that the Receiving Party shall be responsible for ensuring its Representatives' compliance with, and shall be liable for any breach by its Representatives of the confidentiality and non-disclosure obligations set forth herein.

8.6 Permitted Disclosure and Use. Notwithstanding Section 8.5, a Party may disclose Confidential Information belonging to another Party if and only to the extent such disclosure is reasonably necessary to:

(a) comply with applicable Laws, Regulatory Acts, rules, regulations, government requirements or court orders, provided that the Receiving Party shall promptly notify the Disclosing Party of its notice of any such requirements, and provide the Disclosing Party a reasonable opportunity to seek a protective order or other appropriate remedy or waive its rights under this Article VIII; and disclose only the portion of Confidential Information that it is legally required to furnish;

(b) secure any Regulatory Approvals for the BridgeBio Products, provided that the Disclosing Party will take all reasonable steps to limit disclosure of the Confidential Information outside such Regulatory Authority and to otherwise maintain the confidentiality of the Confidential Information; or

(c) solely with respect to Confidential Information consisting of this Agreement and, if executed, the other Definitive Agreements and the financial aspects of such agreements, for the presentation of or reporting to (i) financial agencies or institutions, (ii) actual or potential investors or brokers, or (iii) potential Third Party acquirors (including their respective officers, directors, employees and representatives) of all or substantially all of the relevant Party's assets or lines of business; and maintaining compliance with the Definitive Agreements executed in connection with this Section 8.6(c)(i), (ii) and (iii); provided that any such disclosure is provided pursuant to a confidentiality agreement containing similar or more restrictive terms than in this Agreement.

8.7 Notification. A Receiving Party shall notify a Disclosing Party promptly upon discovery of any unauthorized use or disclosure of a Disclosing Party's Confidential Information and will cooperate with a Disclosing Party in any reasonably requested fashion to assist a Disclosing Party to regain possession of such Confidential Information and to prevent its further unauthorized use or disclosure.

8.8 Publicity. The Parties agree that any public announcement of the execution of this Agreement will be in the form of a mutual press release to be agreed upon by the Parties. Except as otherwise provided in this Section 8.8, each Party shall maintain the confidentiality of all provisions of this Agreement, and without the prior written consent of the other Party, which consent shall not be unreasonably withheld, no Party nor its respective Affiliates shall make any press release or other public announcement of the provisions of this Agreement to any Third Party, except for: (i) disclosures required by stock exchange regulation or any listing agreement with a national securities exchange, in which case a Disclosing Party shall provide the other Parties with at least [***] notice unless otherwise not practicable, but in any event no later than the time a disclosure required by such stock exchange regulation or listing agreement is made; and (ii) disclosures as may be required by applicable Laws and Regulatory Acts, including but not limited to those required by the Securities Exchange Commission and the FDA, in which case a Disclosing Party shall provide the other Parties with prompt advance notice of such disclosure and cooperate with the other Party to seek a protective order or other appropriate remedy, including a request for confidential treatment in the case of a filing with the Securities and Exchange Commission. A Party may publicly disclose without regard to the preceding requirements of this Section 8.8 any information that was previously publicly disclosed pursuant to this Section 8.8.

8.9 Use of Names. Except as otherwise set forth in this Agreement, no Party shall use the name of another Party in relation to the Dedicated Clean Room Collaboration in any public announcement, press release or other public document without the written consent of such other Party.

8.10 Defend Trade Secrets Act Notice. The Receiving Party acknowledges, and shall inform its Representatives of, the following notice required by the Defend Trade Secrets Act: An individual will not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret that is made in confidence to a federal, state, or local government official or to an attorney solely for the purpose of reporting or investigating a suspected violation of law. Similarly, an individual will not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret that is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal. An individual who files a lawsuit for retaliation by an employer for reporting a suspected violation of law may disclose the trade secret to that individual's attorney and use the trade secret information in the court proceeding, if the individual files any document containing the trade secret under seal; and does not disclose the trade secret, except pursuant to court order.

8.11 Survival. The obligations and prohibitions contained in this Article VIII as they apply to Confidential Information shall survive the expiration or termination of this Agreement for a [***].

[***] Certain confidential portions (indicated by brackets and asterisks) have been omitted from this exhibit in accordance with the rules of the Securities and Exchange Commission.

ARTICLE IX
FINANCIAL PROVISIONS

9.1 Clean Room Reservation Fee. BridgeBio shall pay Catalent a Clean Room Reservation Fee of **[***]** for the Dedicated Clean Room Suite according to the terms herein as follows: (i) [***] which has already been paid to Catalent pursuant to the ISA, (ii) [***] shall be paid within [***] from the Effective Date of this Agreement, (iii) [***] shall be paid within [***] following the date of the [***], and (iv) [***] shall be paid within [***] following the date of the [***].

9.2 Clean Room Use Fee.

(a) As set forth in Article III, upon the start of the first BMP following the Readiness Determination and during the Dedicated Clean Room Period (defined below), BridgeBio shall pay to Catalent an annual Clean Room Use Fee equal to **[***]**, payable in advance with [***] payable prior to the [***] and [***] payable prior to the [***], and prorated for the first year and the last year based on the date of the Readiness Determination. If an extension to the Dedicated Clean Room Period is exercised by BridgeBio, the Clean Room Use Fee shall be subject to reasonable adjustments by Catalent during the Extended Dedicated Clean Room Period. Payments of the Clean Room Use Fee shall be made within [***] upon receipt of an invoice from Catalent (the "**Clean Room Use Fee Invoice**").

(b) If the Dedicated Clean Room Suite is not being fully utilized for the Manufacture of BridgeBio Products based on the BridgeBio Entities' binding forecasts of its supply needs during a Dedicated Manufacturing Period, Catalent may use the Dedicated Clean Room Suite or rooms within the Dedicated Clean Room Suite for Manufacturing on behalf of other Catalent customers by providing notice to BridgeBio at least [***] prior to the date of its intended use (a "**Catalent Use Request**") and such Catalent Use Notice shall describe the schedule during which the room will be used and the nature of the Manufacturing activities that will be performed, subject to any confidentiality requirements between Catalent and its customers. As provided for in **Exhibit B,** Catalent shall provide a credit to BridgeBio against the Clean Room Use Fee on a proportional basis for each month of use of the suite or the clean rooms therein by Catalent for other Catalent customers (the "**Catalent Use Credit**").

9.3 BridgeBio-Requested Equipment. If BridgeBio has equipment needs beyond the Base Equipment Package that have been discussed and approved by the JSC or otherwise authorized in a writing duly executed by an officer of BridgeBio, Catalent will procure such equipment in consultation with BridgeBio (the "**BridgeBio-Requested Equipment**") and BridgeBio will pay (i) the actual procurement cost of the BridgeBio-Requested Equipment (the "**BridgeBio-Requested Equipment Cost**"), (ii) as approved by the JSC, a reimbursement to Catalent of up to [***] of the BridgeBio-Requested Equipment Cost for Catalent's internal and external costs for installing, commissioning, qualifying, and validating the BridgeBio-Requested Equipment, and (iii) an annual equipment use fee to cover the maintenance, metrology/calibration, storage, and any other costs associated with the BridgeBio-Requested Equipment (the "**BridgeBio-Requested Equipment Use Fee**"). Upon receipt of an invoice from Catalent for the procurement

[***] Certain confidential portions (indicated by brackets and asterisks) have been omitted from this exhibit in accordance with the rules of the Securities and Exchange Commission.

of the BridgeBio-Requested Equipment Cost, along with supporting documentation from the equipment vendor, BridgeBio shall pay to Catalent the invoiced amount within [***] of receipt. [***] shall own all right, title, and interest in and to any and all such BridgeBio-Requested Equipment and such equipment shall be used in the performance of Development and Manufacturing services solely for [***] unless otherwise mutually agreed by the Parties. [***] shall be responsible for the use, maintenance, repair and storage of the BridgeBio-Requested Equipment; [***] shall be responsible for the cost of the maintenance, and repair of the BridgeBio-Requested Equipment which shall be included in the BridgeBio-Requested Equipment Use Fee. BridgeBio shall be consulted for all non-routine maintenance and repairs involving BridgeBio-Requested Equipment. In addition to the BridgeBio-Requested Equipment Cost and at BridgeBio's cost, Catalent will procure and maintain spare parts and equipment necessary to ensure the BridgeBio-Requested Equipment is fully operational during the Term of the Agreement. Furthermore, Catalent shall maintain the BridgeBio-Requested Equipment in a validated state during the Term of this Agreement. If at any time during a calendar year, Catalent uses the BridgeBio-Requested Equipment for other Catalent customers, Catalent shall [***]. However, notwithstanding the foregoing, any costs for non-routine maintenance or repairs which are the result of Catalent's use of such equipment for other Catalent customers shall not be charged to BridgeBio. Disposition of BridgeBio-Requested Equipment upon expiration or termination of this Agreement shall be pursuant to Section 12.2. [***] may request to purchase from [***] any BridgeBio-Requested Equipment and terms of sale will be as mutually agreed to in writing by the Parties.

9.4 Withholding Tax Matters. Only if applicable during the Term, a Party making a payment to another Party under the Dedicated Clean Room Collaboration will have the right to withhold taxes in the event that authorities in any country requires tax withholding on amounts paid hereunder to such other Party. Any such withheld taxes shall be paid by such paying Party to the proper taxing authority on behalf of such other Party. The paying Party will secure and send to such other Party proof evidencing payment of such taxes withheld and paid by the paying Party for the benefit of such other Party. The paying Party will, upon request of the other Party, assist that Party in claiming exemption from (or reduction in the amount of) such deductions or withholdings under any applicable income tax treaty by providing such documentation as may be reasonably required by such other Party to claim such exemption.

9.5 Audit. During the Term of this Agreement and for a period of [***] after its termination, expiration or cancellation, but no more than once each [***] and only once within the [***] period after termination, expiration or cancellation, BridgeBio shall, upon [***] prior written notice, have the right to have an independent Third Party auditor, mutually acceptable to both Parties, examine the relevant books and records of Catalent for the previous [***] to confirm the costs related to (i) Procurement Costs, (ii) BridgeBio-Requested Equipment, (iii) the BridgeBio-Requested Equipment Use Fees, and (iv) CRUF Credits were made in accordance with and consistent with the requirements of this Agreement. Any such auditor shall be subject to confidentiality obligations no less stringent than those contained in this Agreement, and Catalent shall not be obligated to disclose its Confidential Information to the auditor except to the extent such disclosure is necessary to verify the accuracy of costs described above. The audits shall be

conducted during reasonable business hours and a copy of any such audit report shall be provided to Catalent at the same time it is provided to BridgeBio. The cost of all audits conducted pursuant to this Section 9.4 shall be borne [***] unless the auditors find an overcharge by Catalent for such fees in an amount equal to the greater of (x) [***] and (y) [***] charged by Catalent for such items, in which case [***] of the audit shall be borne [***].

ARTICLE X
INTELLECTUAL PROPERTY

10.1 General. As part of the Dedicated Clean Room Collaboration, this Article X provides the general terms regarding Intellectual Property and attendant rights of the Parties thereto. The BridgeBio Manufacturing and Supply Agreement will also have terms and conditions pertaining to the parties' rights and responsibilities as to Intellectual Property. In the event of a conflict between the terms and conditions in this Agreement as to Intellectual Property associated with a BridgeBio Product and the terms and conditions in the BridgeBio Manufacturing and Supply Agreement, the conflicting terms and conditions in the applicable BridgeBio Manufacturing and Supply Agreement shall control. In the event of a conflict between the terms and conditions in this Agreement as to Intellectual Property associated with the Dedicated Clean Room Suite and the terms and conditions in the BridgeBio Manufacturing and Supply Agreement, the conflicting terms and conditions in this Agreement shall control.

10.2 License to Catalent. BridgeBio retains all right, title, and interest in and to any BridgeBio Intellectual Property. During the Term, BridgeBio hereby grants to Catalent a fully paid, non-exclusive license under any and all BridgeBio Intellectual Property and BridgeBio Arising IP that is necessary for the sole and limited purpose of Catalent's performance of its obligations under this Agreement (limited to BridgeBio Products), including, without limitation, the Dedicated Clean Room Collaboration.

10.3 License to BridgeBio. Except as expressly set forth herein, Catalent retains all right, title, and interest in and to any Catalent Intellectual Property. Any Intellectual Property arising under the Dedicated Clean Room Collaboration that relates generally to the Development or Manufacture of substances or drug products, including any process, protocol, technology, Know-How or the like that applies generally to the conduct by Catalent of laboratory and manufacturing operations and activities, except to the extent any of the same constitutes BridgeBio Intellectual Property or BridgeBio Arising IP, or incorporates or utilizes BridgeBio Confidential Information, BridgeBio Arising IP, BridgeBio Intellectual Property, BridgeBio's proprietary materials, or are directly related to the BridgeBio Product and/or directly related to those aspects of the Manufacturing Process that are specific to the BridgeBio Product, shall be "Catalent Arising IP," and Catalent shall own all right, title and interest therein. Catalent hereby grants to BridgeBio [***]

[***] Certain confidential portions (indicated by brackets and asterisks) have been omitted from this exhibit in accordance with the rules of the Securities and Exchange Commission.

10.4 Project Intellectual Property. All Intellectual Property created or developed by (i) BridgeBio or (ii) solely or jointly by or on behalf of Catalent in the course of participating in the Dedicated Clean Room Collaboration that incorporates or utilizes BridgeBio Confidential Information, BridgeBio's proprietary materials, or BridgeBio Intellectual Property or are directly related to a BridgeBio Product and/or directly related to those aspects of the Manufacturing Process that are specific to a BridgeBio Product or are an express deliverable to BridgeBio, shall be "**BridgeBio Arising IP**" and the exclusive property of BridgeBio. As such BridgeBio Arising IP is created or developed, Catalent shall provide written notice to BridgeBio of any such BridgeBio Arising IP and is recognized as such by Catalent, as soon as possible but no later than [***] after conception or observation of the same by Catalent. Catalent hereby assigns to BridgeBio all right, title, and interest in and to all such BridgeBio Arising IP, free and clear of all liens, claims, and encumbrances, and shall take any actions, including but not limited to the execution of documents, reasonably requested by BridgeBio and at BridgeBio's expense, to effect the purposes of the foregoing. Notwithstanding the foregoing, for clarity, to the extent Intellectual Property is created or developed under another Definitive Agreement, the terms and conditions of such Definitive Agreement shall control.

10.5 Patent Filings; Cooperation. The Parties agree to reasonably cooperate in the preparation, filing, prosecution and maintenance of all Patents disclosing or claiming the BridgeBio Arising IP or the Catalent Arising IP (collectively, the "**Arising IP Patents**"), including obtaining and executing necessary powers of attorney and assignments by the named inventors, providing relevant technical reports to the filing Party concerning Inventions disclosed in such Arising IP Patents, obtaining execution of such other documents which are needed in the filing and prosecution of such Arising IP Patents. The Parties shall cooperate reasonably in the prosecution of all Arising IP Patents.

ARTICLE XI
REPRESENTATIONS AND WARRANTIES

11.1 BridgeBio and Catalent Mutual Representations and Warranties. BridgeBio and Catalent each hereby represent, warrant and covenant to one another as follows, as of the Effective Date:

(a) **Corporate/Company Existence and Power**. It is a company or corporation duly organized, validly existing, and in good standing under the Laws of the jurisdiction in which it is incorporated, and has full company or corporate power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as contemplated in this Agreement, including the right to grant the licenses granted by it hereunder (except as provided in Section 11.1(d)).

(b) **Authority and Binding Agreement**.

(i) It has the company or corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder,

[***] Certain confidential portions (indicated by brackets and asterisks) have been omitted from this exhibit in accordance with the rules of the Securities and Exchange Commission.

(ii) It has taken all necessary company or corporate action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder, and

(iii) This Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, and binding obligation of such Party that is enforceable against it in accordance with its terms, except as enforcement may be affected by bankruptcy, insolvency or other similar Laws and by general principles of equity.

(c) **No Conflicts**. The execution, delivery and performance of this Agreement by it does not (i) conflict with any agreement, instrument or understanding, oral or written, to which it is a party and by which it may be bound or (ii) violate any Laws of any Governmental Authority having jurisdiction over it.

(d) **All Consents and Approvals Obtained**. Except with respect to Regulatory Approvals for the Development, Manufacturing or Commercialization of a BridgeBio Product, (i) all necessary consents, approvals and authorizations of, and (ii) all notices to, and filings by such Party with, all Governmental Authorities and other Persons required to be obtained or provided by such Party as of the Effective Date in connection with the execution, delivery and performance of this Agreement have been obtained and provided, except for those approvals, if any, not required at the time of execution of this Agreement.

(e) **Compliance with Law**. The Parties shall perform all of their respective obligations under this Agreement in full compliance with all applicable Laws.

(f) **Banned Transactions or Dealings**. No transactions or dealings under this Agreement shall be conducted with or for a Person that is designated as the target of any sanctions, restrictions or embargoes administered by the United Nations, European Union, United Kingdom or the United States of America.

11.2 Mutual Covenants; No Debarment. No Party shall use in any capacity, in connection with the Dedicated Clean Room Collaboration or its Development, Manufacture or Commercialization of a BridgeBio Product hereunder, any Person who has been debarred pursuant to Section 306 of the FD&C Act (or similar Law outside of the U.S.), who is the subject of a conviction described in such section, and each Party shall inform the other Party in writing immediately if it or any Person who is performing services for such Party hereunder is debarred or is the subject of a conviction described in Section 306 (or similar Law outside of the U.S.), or if any action, suit, claim, investigation or legal administrative proceeding is pending or, to such Party's knowledge, is threatened, relating to the debarment of such Party or any Person used in any capacity by such Party.

11.3 Additional Representations, Warranties and Covenants by Catalent. Catalent represents, warrants and covenants to BridgeBio as follows:

(a) As of the Effective Date, to the best of Catalent's knowledge, the use of Catalent Technology in the performance of activities contemplated for the Dedicated Clean Room Collaboration as of the Effective Date shall not infringe any Intellectual Property of Third Parties. Catalent covenants to BridgeBio that it shall promptly notify the applicable BridgeBio Entities in writing should it become aware of any claims asserting such infringement, which could reasonably be expected to affect a BridgeBio Entity's ability to perform under the Definitive Agreements.

(b) (i) As of the Effective Date, there is no claim, action, suit, proceeding or governmental investigation ("**Action**") of any nature filed, made, taken or threatened against or by Catalent; and (ii) to the best of Catalent's knowledge as of the Effective Date, after reasonable inquiry and investigation, no event has occurred or circumstances exist that may give rise to, or serve as a basis for, any such Action which could reasonably be expected to affect Catalent's or a BridgeBio Entity's ability to perform the Definitive Agreements.

(c) Catalent, to the best of its knowledge, has complied, is now complying, and will comply, with all applicable Law and Regulatory Acts relative to its use and improvement of the BWI Facility that could adversely affect its ability to Manufacture BridgeBio Products and all terms of the BWI Lease. The BWI Lease means that specific lease agreement entered into by and between Harmons Road Associates, LLC ("**Landlord**") and Paragon, dated December 20, 2017. Catalent will notify BridgeBio of any material breach or alleged breach of the BWI Lease by Catalent or Landlord that could adversely affect its ability to Manufacture BridgeBio Products.

(d) Catalent has obtained, or will obtain prior to Manufacturing the first BridgeBio Product in the Dedicated Clean Room Suite, and will maintain during the Term of this Agreement any required licenses, permits and authorizations necessary to perform the Manufacturing at the BWI Facility for each BridgeBio Entity pursuant to a BridgeBio Manufacturing and Supply Agreement.

(e) To Catalent's knowledge, no legal or regulatory requirement imposed on Catalent by a Regulatory Authority will prevent Catalent from performing its obligations under this Agreement, or otherwise complying with its obligations under this Agreement.

[***]

11.4 Additional Representations, Warranties and Covenants of BridgeBio. BridgeBio hereby represents, warrants and covenants to Catalent that, as of the Effective Date, that to the best of BridgeBio's knowledge, the use of BridgeBio Technology in the performance of activities contemplated for the Dedicated Clean Room Collaboration as of the Effective Date shall not infringe any Intellectual Property of Third Parties.

[***] Certain confidential portions (indicated by brackets and asterisks) have been omitted from this exhibit in accordance with the rules of the Securities and Exchange Commission.

11.5 No Other Representations or Warranties. EXCEPT AS EXPRESSLY STATED IN THIS ARTICLE XI OR ANY OF THE DEFINITIVE AGREEMENTS, NO REPRESENTATIONS OR WARRANTIES WHATSOEVER, WHETHER EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED REPRESENTATION OR WARRANTY WITH RESPECT TO (I) MERCHANTABILITY, NON-INFRINGEMENT, SUITABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE, (II) THE LIKELIHOOD OF SUCCESS OF ANY APPLICATION FOR MARKETING AUTHORIZATION RELATING TO ANY BRIDGEBIO PRODUCT CURRENTLY IN DEVELOPMENT OR FOR WHICH MARKETING AUTHORIZATION HAS NOT YET BEEN GRANTED EITHER IN THE U.S. OR IN ANY OTHER COUNTRY, OR (III) THE PROBABLE SUCCESS OR PROFITABILITY OF ANY BRIDGEBIO PRODUCT AFTER THE EFFECTIVE DATE ARE MADE OR GIVEN BY OR ON BEHALF OF A PARTY AND, EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, ALL REPRESENTATIONS AND WARRANTIES, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE, ARE HEREBY EXPRESSLY EXCLUDED.

11.6 Catalent Indemnity. Catalent shall defend, indemnify and hold harmless BridgeBio and its Affiliates (each, a "**BridgeBio Indemnitee**") from and against any and all liabilities, losses, costs and expenses (collectively, "**Loss**") suffered or incurred by them in connection with any claim brought by a Third Party that arises or is alleged to arise from or in connection with:

(a) Any material breach of representation or warranty or covenant made by Catalent under this Agreement or any material breach of Catalent's obligations under this Agreement;

(b) Catalent's use of the Dedicated Clean Room Suite for other Catalent customers;

(c) any gross negligence or willful misconduct of Catalent, its Affiliates or any of their respective Representatives with respect to the performance of this Agreement; and

(d) infringement of any Third-Party Intellectual Property arising from the use of the Catalent Technology pursuant to any of this Agreement;

except to the extent in each case that the Loss in question resulted from the gross negligence or willful misconduct of, or material breach of this Agreement by, a BridgeBio Indemnitee or any of its or their Representatives.

11.7 BridgeBio Indemnity. BridgeBio shall defend, indemnify and hold harmless Catalent and its respective Affiliates (each, a "**Catalent Indemnitee**") from and against any and all Loss suffered or incurred by them in connection with any claim brought by a Third Party that arises or is alleged to arise from or in connection with:

(a) any material breach of representation or warranty or covenant made by BridgeBio under this Agreement or any material breach of BridgeBio's obligations under this Agreement;

(b) any gross negligence or willful misconduct of BridgeBio, its Affiliates or any of their respective Representatives with respect to the performance of this Agreement; and

(c) infringement of any Third-Party Intellectual Property arising from the use of the BridgeBio Technology pursuant to any of this Agreement, in a manner Covered by BridgeBio Patents;

except to the extent in each case that the Loss in question (i) resulted from the gross negligence or willful misconduct of, or material breach of this Agreement by, a Catalent Indemnitee or any of its or their Representatives, or (ii) resulted from any activities for which Catalent is obligated to indemnify a BridgeBio Indemnitee pursuant to Section 11.6.

11.8 Indemnification Procedures. The Person or Persons claiming indemnity under this Article XI (the "**Indemnified Party**") shall give written notice to the Party from whom indemnity is being sought (the "**Indemnifying Party**") promptly after learning of such claim. The Indemnified Party shall provide the Indemnifying Party with reasonable assistance, at the Indemnifying Party's expense, in connection with the defense of the claim for which indemnity is being sought. The Indemnifying Party shall have the right, but not the obligation, to assume and conduct the defense of the claim with counsel of its choice; provided, the Indemnified Party may participate in and monitor such defense with counsel of its own choosing at its sole expense. The Indemnifying Party shall not settle any claim without (a) first consulting with the Indemnified Party, and (b) obtaining the prior written consent of the Indemnified Party, not to be unreasonably withheld or delayed, unless the settlement involves only the payment of money, provided that such settlement does not adversely affect the Indemnified Party's rights under this Agreement or impose any obligations on the Indemnified Party in addition to those set forth herein. The Indemnified Party shall not settle or compromise any such claim without (x) first consulting with the Indemnifying Party, and (y) obtaining the prior written consent of the Indemnifying Party. If the Indemnifying Party does not assume and conduct the defense of the claim as provided above, (i) the Indemnified Party may, using counsel of its choice, defend against such claim in any manner the Indemnified Party may deem reasonably appropriate, and (ii) the Indemnifying Party shall remain responsible to indemnify the Indemnified Party as provided in this Article XI, provided, that in such instance such indemnity shall also include the reasonable legal fees and reasonable Out-of-Pocket Costs incurred by the Indemnified Party in connection with so defending itself in the absence of a defense being provided by the Indemnifying Party.

11.9 Insurance. Upon the Effective Date as to Catalent, and within [***] of the Effective Date with respect to BridgeBio, through the remainder of the Term of this Agreement, each Party, and, to the extent applicable, its approved subcontractors, shall obtain and maintain (or have obtained and maintained on its behalf) with insurers having A.M. Best ratings of A-VII or higher at all times as of and after the date of this Agreement, at its own cost and expense: (i) general liability insurance with a per occurrence limit of [***] or equivalent and an annual aggregate limit of [***] or equivalent; and (ii) Workers' Compensation as required by all applicable laws and Employer's Liability coverage with a limit of not less than [***]. If any such policy is replaced, each Party agrees to purchase tail coverage or ensure that the new policy has a retroactive date that is consistent with the start of any work under a scope of work and that such Party will continue to be covered on the replacement policy. Each Party may self-insure all or any portion of the required insurance as long as, together with its Affiliates, its US GAAP net worth is greater than [***] or equivalent, or its annual EBITDA (earnings before interest, taxes, depreciation and amortization) is greater than [***] or equivalent. Waivers of subrogation and additional insured status obligations will operate the same whether insurance is carried through third parties or self-insured. Upon the other Party's written request from time to time, each Party shall promptly furnish to the other Party a certificate of insurance or other evidence of the required insurance. Without limiting the foregoing, each Party shall obtain and maintain Special Form (formerly known as All Risk) insurance coverage which includes business interruption. For the avoidance of doubt, BridgeBio may satisfy its insurance requirements set forth in this Section 11.9 if an Affiliate of BridgeBio obtains and maintains insurance that covers BridgeBio as provided for herein.

ARTICLE XII
TERMINATION AND SURVIVAL

12.1 Term and Termination.

(a) The term of this Agreement shall begin on the Effective Date and continue until the earlier of (i) the latest expiration or termination of the (x) the BridgeBio Manufacturing and Supply Agreement or (y) any Additional Manufacturing and Supply Agreement, (ii) [***] from the Readiness Determination (the "**Dedicated Clean Room Period**"), or (iii) termination in accordance with this Section 12.1 (the period from the Effective Date to termination being the "**Term**"). Subject to the mutual agreement of the Parties, the Agreement may be extended for an additional [***] (provided that BridgeBio provides notice of its desire to such extension at least [***] before the end of the Dedicated Clean Room Period) (the "**Extended Dedicated Clean Room Period**"). The Parties may otherwise extend the Term by mutual written agreement.

(b) BridgeBio shall have the right to terminate this Agreement by giving written notice to Catalent in the event of any of the following:

(i) For convenience; or

[***] Certain confidential portions (indicated by brackets and asterisks) have been omitted from this exhibit in accordance with the rules of the Securities and Exchange Commission.

(ii) If any of the BridgeBio Products undergoes a market withdrawal, or otherwise is determined by BridgeBio or a Regulatory Authority to have material safety, efficacy, or Manufacturing risks which could impact the Commercialization of the BridgeBio Product and such risks would reasonably be expected to similarly impact all other BridgeBio Products that are the subject of a Manufacturing and Supply Agreement, in each case leading to the cessation or termination of Development, Manufacture, or Commercialization of, or seeking Regulatory Approval for, the BridgeBio Product; or

(iii) If BridgeBio has, in good faith, exhausted all reasonable remedies to resolve a patent dispute and a court or other competent authority issues a final decision that BridgeBio Technology infringes a valid and enforceable Patent held by a Third Party or grants an injunction that renders BridgeBio unable to sell a BridgeBio Product.

[***]

(c) Either Party hereto shall have the right to terminate this Agreement by giving the other Party written notice in the event of any of the following:

(i) The bankruptcy or insolvency of the other Party; or

(ii) If the other Party is in material breach of one of the Definitive Agreements, provided that if the breach is capable of cure (1) the non-breaching Party shall first provide [***] prior written notice and an opportunity to cure to the breaching Party and (2) in the event the breach is not cured within such [***] period, the breaching Party has not diligently pursued an acceptable cure and provided a reasonable plan of proposed actions and schedule for completing such cure outside the [***] period that the non-breaching Party agrees, in its sole discretion, is reasonably likely to allow for cure in a sufficient and timely enough manner; or

(iii) The other Party is suspended or debarred by FDA or the United States government.

12.2 Effect of Termination.

(a) If this Agreement is terminated by BridgeBio pursuant to Sections 12.1(b)(i) or (iii) or by Catalent pursuant to Section 12.112.1(c), the economic consequences will be solely as follows (except, in the case of termination for breach, to the extent additional remedies are available under applicable Law): Catalent shall be entitled to the Clean Room Reservation Fee. In addition, Catalent shall also be paid all other amounts owed by BridgeBio under the terms of this Agreement as of the date of termination including, but not limited to, any outstanding or owed Clean Room Use Fees, BridgeBio-Requested Equipment Costs, and BridgeBio-Requested Equipment Use Fees. BridgeBio shall pay to Catalent all of the outstanding unpaid and undisputed invoices within [***] of the date of termination.

(b) If this Agreement is terminated by BridgeBio pursuant to Section 12.1(b)(ii), the economic consequences will be solely as follows: Catalent shall provide to BridgeBio a refund of a portion of the Clean Room Reservation Fee based upon the following sliding scale: [***] of the Clean Room Reservation Fee for each full calendar year remaining in the Dedicated Clean Room Period (*e.g.*, if the product fails within [***] after the Readiness Determination and BridgeBio terminates the Agreement, Catalent will refund [***] of the Clean Room Reservation Fee). If the termination date is prior to the Readiness Determination (and prior to BridgeBio's final payment of the Clean Room Use Fee pursuant to Section 9.1), Catalent shall provide to BridgeBio a refund of [***] of the Clean Room Reservation Fee paid as of the date of termination. BridgeBio also shall pay to Catalent all amounts outstanding and owed as of the date of termination including, but not limited to, Clean Room Use Fees, BridgeBio-Requested Equipment Costs, and BridgeBio-Requested Equipment Use Fees. BridgeBio shall pay to Catalent all of the outstanding unpaid and undisputed invoices within [***] of the date of termination.

(c) If this Agreement is terminated by BridgeBio pursuant to Section 12.1(b)(iv) or 12.1(b)(v), the economic consequences will be solely as follows: Catalent shall provide to BridgeBio a refund of a portion of the Clean Room Reservation Fee based upon the following sliding scale: [***] of the Clean Room Reservation Fee for each full calendar year remaining in the Dedicated Clean Room Period. BridgeBio shall pay to Catalent all amounts outstanding and owed as of the date of termination including, but not limited to, Clean Room Use Fees, BridgeBio-Requested Equipment Costs, and BridgeBio-Requested Equipment Use Fees. BridgeBio shall pay to Catalent all of the outstanding unpaid and undisputed invoices within [***] of the date of termination.

(d) If this Agreement is terminated by BridgeBio at any time during the Dedicated Clean Room Period pursuant to Sections 12.1(c), the economic consequences will be solely as follows (except to the extent additional remedies are available under applicable Law): Catalent shall provide BridgeBio [***]. BridgeBio shall pay to Catalent all amounts outstanding and owed as of the date of termination including, but not limited to, Clean Room Use Fees, BridgeBio-Requested Equipment Costs, and BridgeBio-Requested Equipment Use Fees. BridgeBio shall pay to Catalent all of the outstanding unpaid and undisputed invoices within [***] of the date of termination.

(e) Unless otherwise agreed by the Parties, a termination of this Agreement shall result in the termination of all other Definitive Agreements. To the extent that BridgeBio, a BridgeBio Entity or a Strategic Partner desire to extend such other Definitive Agreements beyond the termination of this Agreement, Catalent agrees to negotiate in good faith the extension of such agreements; provided, however, Catalent shall have no obligation to provide the Dedicated Clean Room Suite for use in the Manufacture of BridgeBio Products. For the avoidance of doubt, following termination of this Agreement, the Parties may, but are not obligated to, negotiate one or more separate agreements for the manufacture and supply of BridgeBio Products.

(f) [***], CATALENT'S LIABILITY TO BRIDGEBIO FOR ANY AND ALL INJURIES, CLAIMS, LOSSES, EXPENSES, OR DAMAGES, WHATSOEVER, ARISING OUT OF OR IN ANY WAY RELATED TO THE ACTIVITIES OF THIS AGREEMENT, FROM ANY CAUSE OR CAUSES INCLUDING, BUT NOT LIMITED TO, BREACH OF CONTRACT, NEGLIGENCE, ERRORS, OMISSIONS OR STRICT LIABILITY, SHALL NOT EXCEED THAT AMOUNT EQUIVALENT TO [***]. [***], IN NO EVENT WILL EITHER PARTY BE LIABLE TO OTHER PARTY FOR ANY INDIRECT, SPECIAL, CONSEQUENTIAL, PUNITIVE OR EXEMPLARY DAMAGES (INCLUDING, BUT NOT LIMITED TO, DAMAGES BASED UPON LOST PROFITS, RELIANCE OR EXPECTATION, BUSINESS INTERRUPTION, LOST BUSINESS, OR LOST SAVINGS) FOR ANY ACTS OR FAILURE TO ACT UNDER THIS AGREEMENT, INCLUDING ANY TERMINATION OF THIS AGREEMENT IN ACCORDANCE WITH ITS TERMS, EVEN IF THE PARTY HAS BEEN ADVISED OF THE POSSIBLE EXISTENCE OF SUCH DAMAGES. FOR CLARITY, THE PARTIES ACKNOWLEDGE AND AGREE THAT ANY AMOUNTS PAID TO THIRD PARTIES FOR THIRD PARTY CLAIMS ARE NOT SUBJECT TO THE LIMITATION IN THE PREVIOUS SENTENCE. The limitations of liability reflect the allocation of risk between the Parties. The limitations specified in this Section 12.2 will survive and apply even if any limited remedy specified in this Agreement is found to have failed of its essential purpose.

(g) Upon (a) termination or during the notice period regarding termination of this Agreement, (b) on expiry of this Agreement, or (c) at any time upon a BridgeBio Entity's or Strategic Partner's written request, Catalent shall provide reasonable assistance to the applicable BridgeBio Entity or Strategic Partner with respect to the transfer to another manufacturer (including, the applicable BridgeBio Entity or Strategic Partner) of the then-current Manufacturing Process (and any Manufacturing Process Developed for such BridgeBio Entity or Strategic Partner) for the BridgeBio Product under the applicable Definitive Agreement. Catalent agrees to provide copies of all necessary and relevant documents, manufacturing instructions, batch records, specifications and any other relevant documentation, and without limiting the license set forth in Section 10.3, all relevant Manufacturing know-how, and licenses under Catalent Intellectual Property and Catalent Arising IP related to the BridgeBio Product necessary to enable the applicable BridgeBio Entity or Strategic Partner or its designee to Manufacture BridgeBio Product in accordance with the specifications and the applicable cGMP requirements. Pursuant to this Section 12.2(f), the BridgeBio Entity or Strategic Partner who will receive the above-mention documentation shall be subject to confidentiality obligations no less stringent than those contained in this Agreement. To the extent that such transfer of technology involves Catalent Confidential Information, Catalent Intellectual Property and/or Catalent Arising IP, the Third Party receiving such information or intellectual property shall agree that its use of same is solely for the purposes of Manufacturing the BridgeBio Products that were the subject of the respective BridgeBio Manufacturing and Supply Agreement. Except for a material breach of this Agreement by Catalent, Catalent may charge to BridgeBio and BridgeBio agrees to pay (or obligate a BridgeBio Entity or Strategic Partner to pay) all reasonable and customary technology transfer fees and expenses for such efforts. [***] In all circumstances, Catalent will use at least commercially reasonable efforts to meet the timeline requested by the applicable BridgeBio Entity or Strategic Partner.

[***] Certain confidential portions (indicated by brackets and asterisks) have been omitted from this exhibit in accordance with the rules of the Securities and Exchange Commission.

(h) In the event of termination or expiration of this Agreement, in addition to any rights or obligations that by their terms are intended to survive the Term of this Agreement, the following provisions shall survive such termination: Article V, Article VI, Article VIII, Article X, Section 11.5, Section 11.6, Section 11.7, Section 11.8, Section 12.2, Article XIII, and Article XIV. Termination or expiration of this Agreement and the other Definitive Agreements for any reason will not relieve the Parties of any liability accruing prior thereto and will be without prejudice to the rights and remedies of any Party with respect to any antecedent breach of the provisions of this Agreement or the other Definitive Agreements.

(i) Each Party acknowledges that, in the event of termination and unless otherwise agreed to by BridgeBio, Catalent shall promptly return or destroy, as directed by BridgeBio, any master or working cell banks and BridgeBio Materials as well as BridgeBio Technology and BridgeBio-Requested Equipment, and each Party shall promptly return to the other Party or destroy (as such other Party may direct) all data and documents in any form comprising or containing any Confidential Information of the other Party, except that each Party may retain: (a) one copy of the other Party's Confidential Information in secure legal archives for evidentiary purposes only and (b) a copy of computer records or files containing such Confidential Information that have been created pursuant to automatic archiving or back-up procedures that cannot reasonably be deleted (collectively, "**Retained Copies**"), provided, however, that any such Retained Copies will be kept confidential by the Receiving Party in accordance with the terms and provisions of this Agreement for as long as the Receiving Party is in possession of the Retained Copies. In addition, upon request, Catalent shall provide a written certification to BridgeBio that (i) Catalent and its subcontractors have satisfied their confidentiality and recording obligations in all respects and (ii) all BridgeBio Know-How and copies thereof on any media in possession of Catalent, any of its employees or contractors have been destroyed or returned to BridgeBio, such certification to be signed by a duly authorized officer of Catalent.

ARTICLE XIII
DISPUTE RESOLUTION

13.1 Disputes. The Parties recognize that, from time to time, disputes may arise as to certain matters which relate to a Party's rights and/or obligations in connection with this Agreement. It is the objective of the Parties to establish procedures to facilitate the resolution of disputes arising under this Agreement in an expedient manner by mutual cooperation and without resort to litigation. To accomplish this objective, the Parties agree to follow the procedures set forth in this Article XIII to resolve any controversy or claim arising out of, relating to or in connection with this Agreement.

13.2 Dispute Resolution. Any dispute that arises between the Parties in connection with this Agreement shall first be presented to the senior executives of the Parties for consideration and resolution. If such executives cannot reach a resolution of the dispute within a reasonable time, then such dispute shall be resolved by binding alternative dispute resolution in accordance with the International Institute for Conflict Prevention and Resolution's Rules for Administrated Arbitration. Arbitration shall be conducted in New York, New York, in the English language.

[***] Certain confidential portions (indicated by brackets and asterisks) have been omitted from this exhibit in accordance with the rules of the Securities and Exchange Commission.

13.3 Patent and Trademark Dispute Resolution. Any dispute, controversy or claim relating to the scope, validity, enforceability or infringement of any Patent rights covering the Manufacture, use or sale of any product or technology or of any trademark rights relating to any product or technology shall be submitted to a patent office or court of competent jurisdiction in which such Patent or trademark rights were granted or arose.

13.4 Injunctive Relief. Nothing herein may prevent a Party from seeking a preliminary injunction or temporary restraining order, in any court of competent jurisdiction, so as to prevent any Confidential Information from being disclosed in violation of an applicable confidentiality agreement entered into by the Parties or to prevent the threat of imminent harm.

ARTICLE XIV
MISCELLANEOUS

14.1 Assignment; Binding Effect.

(a) This Agreement shall not be assignable by any Party hereto without the prior written consent of each of the other Parties, provided, however, that BridgeBio may assign this Agreement in whole or in part without the advance written consent of Catalent to (i) its Affiliates or [***]

(b) BridgeBio may assign its rights and obligations under this Agreement in part on a Product-by-Product and Definitive Agreement-by-Definitive Agreement basis, [***]

(c) Further, upon written request by BridgeBio, [***]

(d) Any assignment of this Agreement not made in accordance with this Section 14.1 is prohibited hereunder and shall be null and void.

14.2 Expenses. Except as expressly specified herein, each Party shall bear its own expenses with respect to this Agreement and the other Definitive Agreements.

[***] Certain confidential portions (indicated by brackets and asterisks) have been omitted from this exhibit in accordance with the rules of the Securities and Exchange Commission.

14.3 Notices. All notices, requests, claims, demands and other communications hereunder shall be in writing and shall be deemed to have been duly given (a) when received if delivered personally, (b) when transmitted by e-mail (with confirmation of successful transmission and with a duplicate copy directed pursuant to the methods set forth in (c) or (d) below), (c) upon receipt, if sent by registered or certified mail (postage prepaid, return receipt requested) and (d) the day after it is sent, if sent for next-day delivery to a domestic address by overnight mail or courier, to the Parties at the following addresses:

If to BridgeBio

BridgeBio Gene Therapy, LLC
Attn: Eric David, President & CEO
421 Kipling St.
Palo Alto, CA 94301
Telephone:
Email: emd@bridgebio.com

with a copy to:

BridgeBio Gene Therapy, LLC
Attn: Justin To, VP Operations
421 Kipling St.
Palo Alto, CA 94301
Telephone:
Email: jt@bridgebio.com

If to Catalent

Catalent Maryland, Inc.
Attn: President – Gene Therapy
801 West Baltimore Street, Suite 302
Baltimore, Maryland 21201
Telephone: 410-975-4050
Email: Peter.Buzy@catalent.com

with a copy to:

Catalent Pharma Solutions, LLC
14 Schoolhouse Road
Somerset, NJ 08873 USA
Attn: General Counsel (Legal Department)
E-Mail: GenCouns@catalent.com
Facsimile: +1 (732) 537-6491

Mr. Andrew L. Strong
Pillsbury Winthrop Shaw Pittman, LLP
909 Fannin, Suite 2000
Houston, Texas 7701
Email: andrew.strong@pillsburylaw.com

provided, however, that if any Party shall have designated a different address by notice to the others, then to the last address so designated.

14.4 Severability. If any term, provision, covenant or restriction of this Agreement is held by a court of competent jurisdiction or other authority to be invalid, void, unenforceable or against its regulatory policy such determination shall not affect the enforceability of any others or of the remainder of this Agreement; and in connection with such term, provision, covenant or restriction of this Agreement which is held invalid, void, unenforceable or against regulatory policy, the Parties shall negotiate in good faith with a view to the substitution therefor of a suitable and equitable solution in order to carry out, so far as may be valid and enforceable, the intent and purpose of such invalid term, provision, covenant or restriction and, absent any agreement by the Parties, such court of competent jurisdiction or other authority shall substitute therefore such term, provision, covenant or restriction as is legal, valid and enforceable but otherwise similar to the invalid term, provision, covenant or restriction.

14.5 Entire Agreement. This Agreement may not be amended, supplemented or otherwise modified except by an instrument in writing signed by the Parties hereto. The Definitive Agreements contain the entire agreement of the Parties hereto with respect to the Dedicated Clean Room Collaboration, superseding all negotiations, prior discussions and preliminary agreements made prior to the date hereof.

14.6 Waiver. The failure of any Party to enforce any condition or part of this Agreement at any time shall not be construed as a waiver of that condition or part, nor shall it forfeit any rights to future enforcement thereof. No waiver of any provision of this Agreement will be valid unless made in writing and signed by the Party to which such performance is due.

14.7 Governing Law; Jurisdiction; Venue. This Agreement (including any claim or controversy arising out of or relating to this Agreement) shall be governed by the Laws of the State of Delaware without regard to conflict of law principles that would result in the application of any Law other than the Laws of the State of Delaware. The Parties hereto agree that a final judgment in any such action shall be conclusive and, notwithstanding anything to the contrary, may be enforced in other jurisdictions by suit on the judgment or in any other manner provided by Law. The United Nations Convention on Contracts for the International Sale of Goods shall not apply to this Agreement.

14.8 Headings. The headings of the Articles, Sections, Subsections, Schedules and Exhibits of this Agreement are inserted for convenience only and shall not be deemed to constitute a part hereof.

14.9 Counterparts. This Agreement may be signed in any number of counterparts, each and every one of which shall be considered one and the same agreement and shall become effective when a counterpart hereof shall have been signed by each of the Parties and delivered to each of the other Parties, notwithstanding variations in format or file designation which may result from the electronic transmission, storage and printing of copies of this Agreement from separate computers or printers. Facsimile signatures and signatures transmitted via PDF shall be treated as original signatures.

[***] Certain confidential portions (indicated by brackets and asterisks) have been omitted from this exhibit in accordance with the rules of the Securities and Exchange Commission.

14.10 Construction. The language in all parts of this Agreement shall be construed, in all cases, according to its fair meaning. The Parties acknowledge that each Party and its counsel have reviewed and revised this Agreement and that any rule of construction to the effect that any ambiguities are to be resolved against a drafting Party shall not be employed in the interpretation of this Agreement.

14.11 Interpretation.

(a) When a reference is made in this Agreement to an Article, Section, Exhibit, Schedule, Recital or Preamble, such reference is to an Article, Section, Exhibit, Schedule, Recital or Preamble of or to this Agreement unless otherwise indicated.

(b) The words "hereof," "herein," "hereto" and "hereunder" and words of similar import, when used in this Agreement, shall refer to this Agreement as a whole, including the Exhibits and Schedules, and not to any particular provision of this Agreement.

(c) The terms defined in the singular have a comparable meaning when used in the plural, and vice versa.

(d) Words of one gender include the other gender.

(e) References to a Person are also to its successors and permitted assigns.

(f) The term "Dollars" and "$" means United States Dollars.

(g) The word "including" means "including without limitation" and the words "include" and "includes" have corresponding meanings.

(h) References herein to an agreement, law or regulation include such agreement, law or regulation as amended, restated, supplemented, or otherwise modified from time to time unless otherwise specified.

14.12 Relationship of the Parties. This Agreement and the Dedicated Clean Room Collaboration are not intended by the Parties to constitute or create a joint venture, pooling arrangement, partnership, or formal business organization of any kind, and the rights and obligations of the Parties shall be only those expressly set forth herein and therein. No Party will have any right, power or authority, nor will they represent themselves as having any authority to assume, create or incur any expense, liability or obligation, express or implied, on behalf of another Party, or otherwise act as an agent for another Party for any purpose.

* * * * * * * * * * *

[***] Certain confidential portions (indicated by brackets and asterisks) have been omitted from this exhibit in accordance with the rules of the Securities and Exchange Commission.

IN WITNESS WHEREOF, the Parties hereto have caused this Collaboration Agreement to be executed by their respective duly authorized officers as of the date first above written.

BRIDGEBIO GENE THERAPY LLC

By: /s/ Eric David

Name: Eric David

Title: CEO – Gene Therapy

CATALENT MARYLAND, INC.

By: /s/ Peter Buzy

Name: Peter Buzy

Title: President – Gene Therapy

EXHIBIT A

DEFINITIONS

This **Exhibit A** to this Collaboration Agreement provides agreed upon definitions applicable to the Parties for purposes of this Agreement. All capitalized terms used in this Agreement shall have the meanings ascribed thereto in this **Exhibit A**.

1.1 Definitions.

"**Affiliate(s)**" means, (i) with respect to any Third Party, any other corporation, firm, partnership or other entity that directly or indirectly through one or more intermediaries, controls, is controlled by or is under common control with such entity; (ii) and with respect to BridgeBio, it means BridgeBio Pharma, Inc. and any corporation, firm, partnership or other entity controlled by BridgeBio Pharma, Inc.; and (iii) with respect to Catalent, it means Catalent Pharma Solutions, Inc. and any corporation, firm, partnership or other entity controlled by Catalent Pharma Solutions, Inc. For purposes of this definition, the term "**control**" means the ownership of more than fifty percent (50%) of the securities or other ownership interests representing the equity voting stock or general partnership or membership interest of such entity or the power to direct or cause the direction of the management or policies of such entity, whether through the ownership of voting securities, by contract, or otherwise.

"**BridgeBio Drug Product**" means a finished dosage form that contains a BridgeBio Product, generally, but not necessarily, in association with one or more other ingredients.

"**BridgeBio Intellectual Property"** means BridgeBio Patents and BridgeBio Technology owned or Controlled by BridgeBio prior to the Effective Date, or otherwise arising outside the performance of this Agreement.

"**BridgeBio Know-How**" means any present and future Know-How, including any and all BridgeBio Technology, owned or Controlled by BridgeBio that is necessary for or is useful to the Development, Manufacture or Commercialization of BridgeBio Products. For purposes of this definition, BridgeBio shall not be deemed to Control any Know-How that is licensed or disclosed by Catalent to BridgeBio pursuant to this Agreement.

"**BridgeBio Materials**" means any or all of the master cell bank, working cell bank and/or research cell bank vials, the Cell Line, and the DNA plasmids, as provided by or made available to Catalent by or on behalf of BridgeBio or its predecessor in interest, or as Developed by Catalent for purposes of Manufacturing BridgeBio Products, as the same may be amplified, processed, or improved by Catalent in accordance with this Agreement, as well as all information provided by or on behalf of BridgeBio concurrently therewith that specifically relates thereto.

"**BridgeBio Patents**" means any Patent that is owned or Controlled by BridgeBio as of the Effective Date or comes under the ownership or Control of BridgeBio during the Term and Covers the Development, Manufacture, use or Commercialization of BridgeBio Products. For purposes of this definition, BridgeBio shall not be deemed to Control any Patent that is licensed by Catalent to BridgeBio pursuant to this Agreement.

"**BridgeBio-Requested Equipment**" means the equipment requested by BridgeBio for the Manufacture of the BridgeBio Products as set forth in Section 9.3 that is in addition to the Base Equipment Package.

"**BridgeBio Technology**" means the Technology of BridgeBio developed or obtained by or on behalf of BridgeBio or a BridgeBio Entity related to one or more BridgeBio Products, or the Manufacture of any of the foregoing prior to the Effective Date or arising outside the performance of this Agreement. BridgeBio Technology specifically includes any BridgeBio Know-How and BridgeBio Materials.

"**Base Equipment Package**" means the standard equipment package to be used in the Manufacture of BridgeBio Products in a single clean room suite. Subject to final approval by the JSC, the equipment comprising the Base Equipment Package is listed in and attached hereto as **Exhibit D**.

"**Batch**" is defined as a specific quantity of bulk drug substance that is intended to have uniform character and quality within specified limits and is produced according to a single cycle of manufacture (one or more upstream production runs, pooled if applicable, followed by a single downstream production run).

"**BLA**" means a Biologics License Application (or successor or equivalent application) (including all supplements, amendments, and modifications thereof) for authorization for marketing of a biologic product, as defined in the applicable Laws and regulations and filed with applicable Regulatory Authorities.

"**Bulk Drug Substance**" means the active pharmaceutical ingredients in bulk form of the BridgeBio Drug Product being Manufactured by Catalent.

"**Business Day**" means a day other than a Saturday, Sunday, or other day on which commercial banks in New York are authorized or required by Law to be closed for business.

"**BWI Facility**" shall mean the clinical and commercial scale biomanufacturing facility located at 7555 Harmans Road, Baltimore, Maryland.

"**Catalent Intellectual Property**" means any Intellectual Property owned or Controlled by Catalent prior to the Effective Date, or otherwise arising outside the performance of this Agreement, without use of, reliance on, or reference to any BridgeBio Confidential Information.

"**Catalent Technology**" means Technology of Catalent developed or obtained by or on behalf of Catalent related generally to the Development or Manufacture of any of the foregoing, prior to the Effective Date or arising outside the performance of this Agreement. Catalent Technology specifically includes any Catalent Know-How, processes, procedures and controls for the Development and Manufacture of drug substances and products.

"**Clean Room Reservation Fee**" means a one-time fee of [***] to reserve the Dedicated Clean Room Suite for [***] (*i.e.*, [***]) during the Term of this Agreement. Catalent's use of the Clean Room Reservation Fee will be for the buildout, commissioning, qualification, validation, equipping and exclusive use of the clean room suite. The Clean Room Reservation Fee will be payable pursuant to the terms set forth on Section 9.1 of this Agreement.

"**Commercialize**," "**Commercializing**" or "**Commercialization**" means all activities directed to the marketing (whether through direct, in-person, electronic or other marketing channels), promotion, selling or offering for sale of a product for an indication, including planning, market research, pre-marketing activities undertaken in preparation for launch, advertising, educating, marketing, promoting, importing, exporting, distributing and post-marketing safety surveillance and reporting. For clarity, "Commercialize," "Commercializing" or "Commercialization" shall not include any activities included within the Manufacturing or Development of a product.

"**Construction Turnover**" means the date when construction on the Dedicated Clean Room Suite is substantially complete as set forth on Schedule 2.2, and the Dedicated Clean Room Suite has been cleaned and is ready for process equipment installation and commissioning, qualification and validation.

"**Control**," "**Controls**" or "**Controlled**" means, when used in reference to intellectual property, other intangible property, or materials, that a Party owns or has a license or sublicense to such intellectual property, other intangible property or materials, and has the ability to grant a license or sublicense or other right to use such intellectual property, other intangible property or materials, as applicable, as provided for herein, without (i) requiring the consent of a Third Party or (ii) violating the terms of any agreement or other arrangement with any Third Party.

"**Cover**," "**Covering**" or "**Covered**" means, with respect to a country in the Territory, but for a license granted under a valid claim of a Patent, the use or sale, or offer for sale in such country of the subject matter at issue would infringe such valid claim, or in the case of a Patent that is a Patent application, would infringe a valid claim in such Patent application if it were to issue as a Patent.

"**Dedicated Clean Room Suite**" means [***] (suite and associated corridors being approximately [***] sq. ft.) at the BWI Facility. The approximate outline of the floor plan and location of the Dedicated Clean Room Suite within the BWI Facility is set forth in **Exhibit C** attached hereto.

"**Dedicated Manufacturing Period**" means the [***], the beginning and end of which will be determined by the JSC and [***], during which Catalent shall dedicate the Dedicated Clean Room Suite for the Manufacture of BridgeBio Products.

"**Delivery**" and "**Delivered**" shall mean Catalent's delivery of the BridgeBio Product, packed and packaged in appropriate containers as directed by BridgeBio, to the BridgeBio carrier at the BWI Facility.

"**Develop**," "**Developing**" or "**Development**" means and all activities relating to research, non-clinical, preclinical and clinical trials, toxicology testing, statistical analysis, publication and presentation of research and study results and reporting, process and analytical development, analytical testing, preparation and submission of applications (including any CMC-related information) for regulatory approval of a product, necessary or reasonably useful or otherwise requested or required by a Regulatory Authority as a condition or in support of obtaining or maintaining all regulatory approvals for such product. For clarity, "Development" shall not include any activities included within the Manufacturing of a product.

"**EMA**" means the European Medicines Agency or its successor.

"**EU**" means the countries of the European Union as it exists at any time.

"**FD&C Act**" means the U.S. Federal Food, Drug and Cosmetic Act, as amended, and the regulations promulgated thereunder.

"**FDA**" means the U.S. Food and Drug Administration or its successor.

"**Fiscal Year**" means the calendar year commencing on January 1 and concluding on December 31.

"**GAAP**" means United States generally accepted accounting principles, as in effect from time to time, consistently applied.

"**Good Manufacturing Practices**" or "**cGMPs**" means the then-current good manufacturing practices required by (i) the FDA, as set forth in the FD&C Act and the regulations promulgated thereunder, for the manufacture and testing of pharmaceutical materials, including the provisions of 21 C.F.R. Parts 210 and 211, (ii) European Commission Directive 91/356/EEC, as amended by Directive 2003/94/EC, and 91/412/EEC respectively, as well as "The rules governing medicinal products in the European Union," Volume 4, Guidelines for good manufacturing practices for medicinal products for human and veterinary use, and (iii) the principles detailed in the ICH Q7A guidelines, in each case, including all applicable rules, regulations, orders and guidance applicable thereto, and as each may be amended from time to time, and any successor thereto.

"**Governmental Authority**" means any multinational, federal, state, local, municipal or other governmental authority of any nature (including any governmental division, prefecture, subdivision, department, agency, bureau, branch, office, commission, council, court or other tribunal), in each case, having jurisdiction over the applicable subject matter.

"**Invention**" means any subject matter invented during the Term by or on behalf of a Party or one or more of the Parties jointly, as determined in accordance with the provisions of U.S. patent Law governing inventions, in the performance of activities under the Dedicated Clean Room Collaboration.

"**Intellectual Property**" means all information, data, works of authorship, discoveries, concepts, technology, method, know how, designs, processes, software, algorithms and inventions, whether patentable or not, including, without limitation, those that could be the subject of patent, copyright, industrial design, trade secret or other forms of protection; including, without limitation, all (i) patent applications (including, but not limited to any and all priority applications, provisionals, non-provisionals, divisionals, continuations, continuations-in-part, reissues, reexaminations, substitutions, renewals) including the right to claim the benefit of priority to any of the foregoing; (ii) patents granting on any of (i); (iii) extensions and supplemental protection certificates based on any of (i) and (ii); (iv) trademark applications, registrations, service marks, domain names and all renewals and extensions thereto; and (v) copyright applications and registrations and all restorations, reversions, renewals and extensions thereof.

"**Know-How**" means any proprietary data, results, material(s), and nonpublic information of any type whatsoever, in any tangible or intangible form, including know-how, trade secrets, practices, techniques, methods, processes, inventions, discoveries, developments, specifications, formulations, formulae, materials or compositions of matter of any type or kind (patentable or otherwise), software, algorithms, marketing reports and plans, market research, expertise (including experts' information), test data (including pharmacological, biological, chemical, biochemical, toxicological, preclinical and clinical test data), analytical and quality control data, stability data, other study data and procedures.

"**Laws**" means, with respect to BridgeBio, all laws, statutes, rules, regulations, directives, decisions, ordinances, guidelines and other pronouncements of any Governmental Authority currently in effect or enacted or promulgated during the Term, and as amended from time to time, of each jurisdiction in which the Product is produced, marketed, distributed, used or sold; and with respect to Catalent, all laws, statutes, rules, and regulations currently in effect or enacted or promulgated during the Term, and as amended from time to time, of the jurisdiction in which Catalent Manufactures the BridgeBio Product, including cGMP.

"**Licensed Purpose**" means for the worldwide Development, Manufacture and Commercialization of BridgeBio Products that are the subject of a BridgeBio Manufacturing and Supply Agreement.

"**Manufacture**" or "**Manufacturing**" means all activities, whether performed by a Party or a Third Party designee of a Party, related to the manufacturing of a product, or any ingredient thereof, including manufacturing for clinical use or commercial sale, in process and product testing, release of product, quality assurance activities related to manufacturing and release of product, handling and storage of product and ongoing stability tests, packaging and labeling, and regulatory activities related to any of the foregoing.

"**Manufacturing Process**" or "**Process**" means the process, or applicable portion(s) thereof for the manufacture, analysis, validation, testing, documentation, quality evaluation, storage, and shipping of components, intermediates and BridgeBio Product(s) pursuant to a Definitive Agreement as such process may be developed and/or changed from time to time in accordance with a Definitive Agreement.

"**Marketing Authorization Application**" or "**MAA**" means an application to the appropriate Regulatory Authority for approval to sell a BridgeBio Product (but excluding Pricing Approval) in any particular country or regulatory jurisdiction, including such application filed with the EMA pursuant to the Centralized Procedure or with the applicable Regulatory Authority of a country in accordance with such country's national approval procedure.

"**Patents**" means (i) all national, regional and international patents and patent applications, including provisional patent applications, (ii) all patent applications filed either from such patents, patent applications or provisional applications or from an application claiming priority from either of these, including divisionals, continuations, continuations-in-part, provisionals, converted provisionals and continued prosecution applications, (iii) any and all patents that have issued or in the future issue from the foregoing patent applications ((i) and (ii)), including utility models, petty patents and design patents and certificates of invention, (iv) any and all extensions or restorations by existing or future extension or restoration mechanisms, including revalidations, reissues, re-examinations and extensions (including any supplementary protection certificates and the like) of the foregoing patents or patent applications ((i), (ii), and (iii)) and (v) any similar rights, including so-called pipeline protection or any importation, revalidation, confirmation or introduction patent or registration patent or patent of additions to any of such foregoing patent applications and patents.

"**Person**" means any corporation, limited or general partnership, limited liability company, joint venture, trust, unincorporated association, governmental body, authority, bureau or agency, any other entity or body, or an individual.

"**Pricing Approval**" means the approval, agreement, determination or decision from a Governmental Authority establishing the price and/or reimbursement for a BridgeBio Product for sale in a given country or regulatory jurisdiction, as required by applicable Laws in such country or other regulatory jurisdiction prior to the sale of the BridgeBio Product in such country or regulatory jurisdiction.

"Procurement Costs" means the actual price paid by Catalent to Third Parties for the procurement of materials and supplies used in the Manufacture of BridgeBio Products. Procurement Costs do not include the Procurement Fee.

"**Procurement Fee**" means the fee that is paid to Catalent for its services in the procurement of materials and supplies used in the Manufacture of BridgeBio Products, such fee being a certain percentage of the Procurement Costs. The Procurement Fee shall be set forth in each BridgeBio Manufacturing and Supply Agreement; *provided that*, and notwithstanding any other provision in the Definitive Agreements to the contrary, [***].

"**Product Approval**" means, with respect to a BridgeBio Product, the approval of a Governmental Authority necessary for the marketing and sale in a given country or regulatory jurisdiction, which may include the approval of an MAA (but shall not include any Pricing Approvals).

"**Quality Agreement**" means the Quality Agreements by and between BridgeBio and Catalent, entered into pursuant to a BridgeBio Manufacturing and Supply Agreement.

"**Quality Control/Quality Assurance Release**" means the certification by Catalent that the BridgeBio Product is released in compliance with the cGMPs and the applicable Quality Agreement.

"**Regulatory Acts**" means any rules, regulations, directives, decisions, ordinances, guidelines and other pronouncements of any Regulatory Authority.

"**Regulatory Approvals**" means, with respect to a BridgeBio Product or a facility for the Manufacture of a BridgeBio Product or component thereof, all filings and approvals (including, as applicable, IND filings, Product Approvals, Pricing Approvals, establishment license approvals and, in each case any supplements and amendments thereto), licenses, registrations or authorizations of any Governmental Authority necessary to obtain marketing authorization for or to Develop, Manufacture or Commercialize a BridgeBio Product, as applicable, for or in a particular country or regulatory jurisdiction.

"**Regulatory Authority**" means, in a particular country or regulatory jurisdiction, any applicable Governmental Authority involved in granting Regulatory Approval in such country or regulatory jurisdiction, including (i) in the U.S., the FDA, and (ii) in the EU, the EMA, the European Commission and relevant national medicines regulatory authorities.

"**Regulatory Exclusivity**" means, with respect to BridgeBio Products, any exclusive marketing rights or data exclusivity rights conferred by any Governmental Authority with respect to the BridgeBio Products other than a Patent right, including in the European Union, Regulation (EC) No 726/2004 and Directive 2001/83/EC (as amended).

"**Regulatory Materials**" means, with respect to BridgeBio Products or the facilities used to Manufacture BridgeBio Products or a component thereof, as applicable, regulatory applications, submissions, notifications, communications, correspondence, registrations, Regulatory Approvals and/or other filings made to, received from or otherwise conducted with a Regulatory Authority that are necessary in order to obtain marketing authorization for or to Develop, Manufacture or Commercialize a BridgeBio Product or to use a facility for the Manufacture thereof, for or in a particular country or regulatory jurisdiction, including all rights under the foregoing, including rights to clinical data and Regulatory Exclusivity. Regulatory Materials include BLAs, INDs, MAAs, presentations, responses, applications for Product Approvals and granted Product Approvals.

"**Regulatory Warning Notices**" means Form FDA 483 Inspectional Observations, Establishment Inspection Reports, warning letters, or their equivalents and any similar correspondences received from the FDA or any other Governmental Authority having jurisdiction over a BridgeBio Product or any facility for the Manufacture of a BridgeBio Product or component thereof.

"**Representatives**" means a Party's (and its Affiliates') directors, officers, full-time employees, part-time employees, temporary workers, subcontractors, consultants, agents, permitted sublicensees (if any) and legal, technical, and business advisors.

"**Strategic Partners**" means the individuals or entities that are part of a strategic partnership, which is a relationship between two commercial enterprises formalized by one or more business contracts.

"**Technology**" means all inventions, methods, techniques, trade secrets, copyrights, Know-How, knowledge, data, developments, discoveries, documentation, experience, formulas and formulations, proprietary information, processes, test procedures, hardware, software and other intellectual property of any kind, whether or not protectable under patent, trademark, copyright or similar Law.

"**Territory**" means worldwide.

"**Third Party**" means any Person other than the Parties.

"**U.S.**" means the United States of America and its possessions and territories.

1.2 Additional Definitions. The following terms have the meanings set forth in the corresponding Sections of this Agreement:

Defined Term	**Section**
AAV	Recitals
Action	11.3(b)
Additional Manufacturing and Supply Agreement	1.3
Auditing Party	5.6
BEqs	Exh. C
BridgeBio Arising IP	10.5
BridgeBio Entities	Recitals
BridgeBio Products	Recitals
BridgeBio Indemnitee	11.6
BridgeBio-Requested Equipment Use Fee	9.3
BridgeBio-Requested Equipment Cost	9.3
BridgeBio Manufacturing and Supply Agreement	Recitals
Catalent Arising IP	10.4
Catalent Indemnitee	11.7
Catalent Use Credit	9.2(b)
Catalent Use Request	9.2(b)
Clean Room Use Fee	3.1(b)
Clean Room Use Fee Invoice	9.2(a)
CMC	5.1
Dedicated Clean Room Collaboration	Recitals
Definitive Agreements	1.1
Development Services	Exh. C
Disclosing Party	8.3(a)
Disclosure Agreement	8.2
Effective Date	Preamble
Force Majeure Event	7.1

GMP Agreement	8.2
Joint Steering Committee	4.1
Licensed Subject Matter	6.2(b)
Paragon	8.2
Proposed Transaction	Recitals
Readiness Determination	3.1(b)
Receiving Party	8.3(a)
Repeat Supply Failure	Exh. C
Retained Copies	12.2(g)
Supply Failure	Exh. C
Term	12.1(a)

EXHIBIT B

[***]

[***] Certain confidential portions (indicated by brackets and asterisks) have been omitted from this exhibit in accordance with the rules of the Securities and Exchange Commission.

EXHIBIT B

MINIMUM ANNUAL THRESHOLD AND FORECASTING

The Dedicated Clean Room Collaboration was formed under the Collaboration Agreement to establish the overall dedication and governance of the Dedicated Clean Room Suite that have been dedicated for the Manufacture of BridgeBio's Products. As part of the Dedicated Clean Room Collaboration, the Parties agreed to and have formed a Joint Steering Committee ("**JSC**") that is comprised of members from each Party and, among other things, reviews, coordinates and schedules the use of the Dedicated Clean Room Suite for clinical and commercial Manufacturing and the forecasting, ordering and Delivery of Batches of BridgeBio Product that are the subject of an Additional Manufacturing and Supply Agreement, including a BridgeBio Manufacturing and Supply Agreement.

This Exhibit B establishes the Parties understanding as to (i) minimum annual ordering obligations for the Manufacture of clinical and/or commercial supply of BridgeBio Products in the Dedicated Clean Room Suite following the Readiness Determination, (ii) the establishment of procedures for the initial forecasting and rolling forecasts of BridgeBio's ordering of clinical and/or commercial supply Manufacturing of the BridgeBio Products in the Dedicated Clean Room Suite, and (iii) any other services to be performed by Catalent for BridgeBio to which the Parties mutually agree.

ARTICLE I
DEFINITIONS

1.1 Definitions. Unless otherwise defined in this Exhibit B or below, all capitalized terms used herein shall have the meanings specified in the Collaboration Agreement.

(a) "**Batch Fee Framework**" means the definition provided in a BridgeBio Manufacturing and Supply Agreement and any Additional Manufacturing and Supply Agreements for the applicable BridgeBio Product pertaining to the method of calculating the Batch price which takes into account, among other things, the Batch processing time and the Manufacturing Process.

(b) "**Manufacture/Release Period**" means the period of time required for the manufacture and release of the BridgeBio Product commencing on the Manufacturing Start Date (such period being determined and approved by the JSC) and concluding on the Delivery of the Batch Documentation to BridgeBio for its review.

(c) "**Manufacturing Configuration**" means the Manufacturing Process configuration involving one upstream production run using [***] and one subsequent downstream purification run.

[***] Certain confidential portions (indicated by brackets and asterisks) have been omitted from this exhibit in accordance with the rules of the Securities and Exchange Commission.

(d) "**Manufacturing Supply Pricing**" means, for clinical supply for a BridgeBio Entity during the Term, the pricing set forth in Schedule 1.1 of this Exhibit B, and for all other clinical and commercial supply Manufacturing, the definition provided in each BridgeBio Manufacturing and Supply Agreement and any Additional Manufacturing and Supply Agreements for the applicable BridgeBio Product.

(e) "**Maximum Upstream Runs**" means the maximum number of upstream production runs that can be completed in the Dedicated Clean Room Suite during a Dedicated Manufacturing Period and is based on the number of [***] that the Parties mutually agree can be safely and efficiently operated in the Dedicated Clean Room Suite.

(f) "**Minimum Annual Threshold**" means the minimum dollar amount that must be paid by, or caused to be paid by, BridgeBio to Catalent for BEqs each calendar year.

ARTICLE II
SCOPE OF THIS EXHIBIT

2.1 Batch Pricing Based on Manufacturing Configuration. Each BridgeBio Product being Manufactured by Catalent pursuant to future supply agreement/s may have differing Manufacturing Configurations. In addition, such Manufacturing Configurations may change during the Term for the same BridgeBio Product. Accordingly, the Parties have agreed to establish a Batch Fee Framework, whereby the Batch Price for commercial supply of any BridgeBio Product varies depending upon the Manufacturing Configuration utilized in the Manufacture of such Batch, which prices shall be set forth in each BridgeBio Supply Agreement. [***]

2.2 Minimum Annual Requirements. As consideration for Catalent's agreement to exclusively dedicate the Dedicated Clean Room Suite to BridgeBio, BridgeBio agrees to the minimum purchase obligations set forth in Sections 3.3 and 3.4 hereof.

ARTICLE III
CLINICAL MANUFACTURE AND COMMERCIAL SUPPLY

3.1 General Requirements. Catalent is preparing the Dedicated Clean Room Suite for the Manufacture of clinical and commercial supply of BridgeBio Products, with the initial clinical supply comprised of the BridgeBio Products. While commercial supply of BridgeBio Products is the intended ultimate use of the Dedicated Clean Room Suite, the Parties agree that the Manufacture of clinical supply of BridgeBio Products may also be conducted in the Dedicated Clean Room Suite as provided for in one or more BridgeBio Supply Agreements and as determined by the JSC.

[***] Certain confidential portions (indicated by brackets and asterisks) have been omitted from this exhibit in accordance with the rules of the Securities and Exchange Commission.

3.2 Manufacturing Start Date. For each BridgeBio Product to be Manufactured in the Dedicated Clean Room Suite, the date on which BridgeBio intends for Catalent to commence, and the date on which Catalent must be ready to commence, clinical or commercial Manufacture of Batches of BridgeBio Products has been or will be specified in writing delivered by BridgeBio to Catalent at least [***] prior to such date and is referred to herein as the "**Anticipated Manufacturing Start Date**"; and the date on which Catalent actually commences commercial Manufacture of Batches of BridgeBio Products in such suite is referred to herein as the "**Manufacturing Start Date**", which date shall not be any earlier than the Readiness Determination Date.

3.3 Minimum Annual Threshold.

3.3.1 Commencing upon the Readiness Determination through the Term, [***], BridgeBio shall submit Binding Purchase Orders (or by other mutual agreement) for (a) Batches of BridgeBio Products to be Manufactured by Catalent in the Dedicated Clean Room Suite and (b) Development and Manufacturing services associated with BridgeBio Products to be performed by Catalent outside the Dedicated Clean Room (the "**Development Services**"). For each BMP, revenue associated with Batches of BridgeBio Products Delivered by Catalent [***]. The Purchase Orders for each BMP shall not exceed the Maximum Batches (defined below). Subject to BridgeBio's right to make adjustments to the Initial and Rolling Forecasts as provided for in Section 3.5 (and thereby to any Purchase Order relating thereto), BridgeBio shall issue each binding Purchase Order at least [***] prior to the start of the BMP to which the Purchase Order applies.

3.3.2 Upon the Readiness Determination, the Minimum Annual Threshold shall be based upon the Manufacturing Supply Pricing of [***] Batches of BridgeBio Products to be Manufactured in the Dedicated Clean Room Suite during the BMP for that FY (referred to herein as the "**Minimum Batches**") and shall be **[***]**. The Manufacturing Supply Pricing that used for calculating the Minimum Annual Threshold is set forth in Schedule 1.1 to this Exhibit B. Starting in 2022, the Minimum Annual Threshold may be increased year over year [***] Fees or expenses for the procurement of Raw Materials or other direct costs that are charged at cost plus a Procurement Fee do not count towards meeting the Minimum Annual Threshold.

3.3.3 In the event that BridgeBio fails to order, or fails to cause BridgeBio Entities or Strategic Partners to order, sufficient quantities of Batches of BridgeBio Products to meet the Minimum Annual Threshold, Catalent shall submit an invoice to BridgeBio following the conclusion of the BMP during which the minimums were not achieved for the difference between the aggregate Batch Price associated with the Batches of BridgeBio Products ordered by BridgeBio for Delivery in such BMP and the applicable minimum threshold amount. BridgeBio shall make payment on undisputed invoices within [***] of receipt.

[***] Certain confidential portions (indicated by brackets and asterisks) have been omitted from this exhibit in accordance with the rules of the Securities and Exchange Commission.

3.4 Purchase Orders; Forecasts; Procedures.

3.4.1 Upon receipt of a Purchase Order from BridgeBio pursuant to a BridgeBio Manufacturing and Supply Agreement and/or one or more Additional Manufacturing and Supply Agreements, Catalent shall Manufacture Batches of BridgeBio Product at the BWI Facility in accordance with the Product Requirements, cGMPs, the then-current Quality Agreement and any applicable Laws and otherwise in accordance with the applicable Definitive Agreement. The maximum number of Batches of BridgeBio Product that can be Manufactured in the Dedicated Clean Room Suite (the "**Maximum Batches**") at any time during the Term is based upon the Manufacturing Configuration established for each BridgeBio Product and the maximum number of upstream production runs that can be safely and efficiently completed in the Dedicated Clean Room Suite (the "**Maximum Upstream Runs**") during each BMP. The Maximum Upstream Runs, and the corresponding Maximum Batches, shall be determined by the JSC. The JSC will make an initial determination of the Maximum Batches and Maximum Upstream Runs upon the Readiness Determination and the JSC will review the Maximum Upstream Runs periodically (no less than annually) and make appropriate adjustments thereto.

3.4.2 With respect to orders of Batches of the BridgeBio Product and subject to the Maximum Batches, BridgeBio shall provide forecasts of its ordering needs and place with Catalent Purchase Orders for the supply of BridgeBio Products being Manufactured by Catalent pursuant to one or more BridgeBio Manufacturing and Supply Agreement and/or one or more Additional Manufacturing and Supply Agreements.

3.5 Initial Forecast.

3.5.1 At least [***] prior to the initial Anticipated Manufacturing Start Date of one or more BridgeBio Products in the Dedicated Clean Room Suite, BridgeBio or another BridgeBio Entity shall provide to Catalent forecasts of its Batch requirements for the Delivery of BridgeBio Product for the [***] immediately following the period of time required for the manufacture and release of the BridgeBio Product commencing on the Manufacturing Start Date (such period being determined and approved by the JSC and referred to herein as the "**Manufacture/Release Period**") (the forecast being the "**Initial Forecast**"). BridgeBio may also include in the Initial Forecast the Batch needs of the other BridgeBio Entities and Strategic Partners that are being Manufactured by Catalent pursuant to an Additional Manufacturing and Supply Agreement. However, for the avoidance of doubt and notwithstanding the Batches being Manufactured by Catalent for the BridgeBio Entities or Strategic Partners, BridgeBio shall not be relieved of its obligation to meet the Minimum Annual Threshold. [***]

3.5.2 Subject to the Initial Forecast Refresh (defined below) and the rights to make other adjustments set forth herein, the Initial Forecasts will be binding as to the [***] Dedicated Manufacturing Period (each such period for the purpose of this section being the "**Binding Manufacturing Period**" or "**BMP**") and non-binding as to the subsequent Dedicated Manufacturing Period (such period for the purpose of this section being the "**Non-Binding Manufacturing Period**" or "**NBMP**"). [***]. Thus, the Initial Forecast periods are summarized as follows:

[***]

[***] Certain confidential portions (indicated by brackets and asterisks) have been omitted from this exhibit in accordance with the rules of the Securities and Exchange Commission.

It is the intention of the Parties that the BMP for each FY shall commence on [***]. For each BMP in the Initial Forecast, BridgeBio may adjust the number of Batches no later than [***] prior to the start of [***] (the "**Initial Forecast Refresh**"), provided that BridgeBio shall be obligated to purchase services that utilize the Dedicated Clean Room Suite and/or the number of Batches of any BridgeBio Product equivalent to, or otherwise make payment to Catalent, of an amount equal to or greater than the Minimum Annual Threshold. The Initial Forecast and subsequent Rolling Forecasts shall be provided by BridgeBio to Catalent in a form of notice substantially similar to the example notice provided in Attachment A.

3.5.3 Rolling Forecast. Prior to the first day of [***] of the Initial Forecast and every year thereafter, BridgeBio will refresh its forecast, and the [***] (such forecasting then becomes the "**Rolling Forecast**").

3.5.4 Forecast Modification; Monitoring. In addition to the [***], BridgeBio will be afforded the flexibility to make modification requests to the Initial and Rolling Forecasts, as set forth below (each a "**Forecast Modification**"). If a Forecast Modification is made prior to or [***] that requests additional Batches of BridgeBio Product over what was originally forecast (the "**Additional Batches**"), Catalent shall use commercially reasonable efforts, but shall not be obligated, to Manufacture the Additional Batches. If the Forecast Modification results in a reduction of Batches to be Delivered by Catalent during the [***], BridgeBio shall be obligated to pay Catalent for all Batches ordered for [***]. During the period in which Catalent is Manufacturing BridgeBio Product, the JSC will have periodic teleconferences or meetings to monitor and review the status of Manufacturing operations and to address any issues that may arise.

3.5.5 Delivery Dates. Within [***] following Catalent's receipt of the Initial Forecast and each Rolling Forecast thereafter, Catalent shall prepare, with input from BridgeBio, and submit to the JSC a Batch production schedule for the next [***] which includes the order of production of each Batch of BridgeBio Product forecasted and the anticipated delivery of the Batch Documentation for each such Batch to BridgeBio (the "**Proposed Production Schedule**"). Within [***] following receipt of the Proposed Production Schedule from Catalent, the JSC shall review and adjust as necessary the Proposed Production Schedule, [***] For each Batch of BridgeBio Product being Manufactured during [***], the Approved Production Schedule for that Batch shall be based upon reasonable time estimates for the Manufacture/Release Period, delivery of Batch Documentation, BridgeBio's review and approval of the Batch Documentation and a reasonable amount of time for the investigation and clearance of deviations that may have occurred during the Manufacture/Release Period. Within [***] upon BridgeBio's approval of the Approved Production Schedule, each BridgeBio Entity and Strategic Partner shall submit to Catalent Purchase Orders specifying the number of Batches and the anticipated delivery dates (as specified in the Approved Production Schedule). [***] All Purchase Orders submitted in compliance with a BridgeBio Manufacturing and Supply Agreement and/or one or more Additional Manufacturing and Supply Agreements shall be binding on Catalent. No later than [***] after BridgeBio's

[***] Certain confidential portions (indicated by brackets and asterisks) have been omitted from this exhibit in accordance with the rules of the Securities and Exchange Commission.

submission of a Purchase Order, Catalent shall provide BridgeBio with written acknowledgment of receipt of the Purchase Order. Catalent shall timely Manufacture and Deliver the amounts ordered by BridgeBio in accordance with this Section 3.5.5, and Catalent shall use commercially reasonably efforts to Manufacture and Deliver any Additional Batches; it being understood that Catalent's failure to supply such Additional Batches shall not constitute a breach under this Agreement.

3.5.6 Supply Failure. [***]

3.5.7 Delays and Suspensions. The provisions in this Section 3.5 are intended to apply to situations involving the ongoing, uninterrupted Manufacture of BridgeBio Products, including orders for [***] In the event of delays in approval or commercial launch or suspension of production after initial launch (for reasons other than the negligence (or more culpable conduct) of Catalent or a breach of this Agreement by Catalent) and if (for reasons other than the negligence (or more culpable conduct) of Catalent or a breach of this Agreement by Catalent) BridgeBio is unable to increase orders for the Manufacture of other BridgeBio Products in the Dedicated Clean Room Suite, BridgeBio shall pay to Catalent the Minimum Annual Threshold (as the same may be offset by work conducted in such suites pursuant to a Scope of Work or Purchase Orders) for as long as the Manufacture of the BridgeBio Product is delayed or suspended, and there shall be no additional payments or costs arising from BridgeBio's provision of the Rolling Forecast (including the binding portion thereof) or actual Purchase Orders placed other than for the Manufacture of Batches which have commenced and for the non-cancelable orders of Raw Materials.

3.6 Clean Room Use Fee Credits.

3.6.1 Batch Credit. [***].

3.6.2 Catalent Use Credit. If the Dedicated Clean Room Suite is not being fully utilized for the Manufacture of BridgeBio Products, Catalent may make a request to BridgeBio to use the underutilized suite for Manufacturing on behalf of other Catalent customers (a "**Catalent Use Request**"). Each Catalent Use Request submitted to BridgeBio shall provide the schedule during which the suite (or rooms within the suite) will be used and the nature of the Manufacturing activities that will be performed in the suite (or rooms), subject to any confidentiality requirements between Catalent and its customers. [***]

3.6.3 Reconciliation. The CRUF Credits shall be determined by Catalent prior to issuing the Clean Room Use Fee Invoice (as defined in the Collaboration Agreement[***] The maximum combined CRUF Credits in a BMP is equal to [***] of the Clean Room Use Fee. [***].

[***] Certain confidential portions (indicated by brackets and asterisks) have been omitted from this exhibit in accordance with the rules of the Securities and Exchange Commission.

EXHIBIT B, ATTACHMENT A
[***]

To:

From: _____

Date: _____

BridgeBio's Initial & Rolling Forecast for Batches of Bulk Drug Substance

Name of BB Entity (and SP)	Product Name	Product Ref #	Batch Requirements for [***] & Order of Delivery	Batch Requirements for [***]
	[●]	[●]		
[●]	[●]	[●]		
[●]	[●]	[●]		
[●]	[●]	[●]		
[●]	[●]	[●]		
		Totals		

[***] Certain confidential portions (indicated by brackets and asterisks) have been omitted from this exhibit in accordance with the rules of the Securities and Exchange Commission.

EXHIBIT B, SCHEDULE 1.1
Manufacturing Supply Pricing*

Clinical Supply	**Manufacturing Configurations**		
Description	**BMC: [***]****	**MC2: [***]**	**MC3: [***]**
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	**[***]**	**[***]**	**[***]**

[***]

Engineering Batches	**Manufacturing Configurations**		
Description	**BMC: [***]**	**MC2: [***]**	**MC3: [***]**
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]

[***] Certain confidential portions (indicated by brackets and asterisks) have been omitted from this exhibit in accordance with the rules of the Securities and Exchange Commission.

EXHIBIT B, SCHEDULE 3.6.1
Illustrations of Batch Credit Calculation

Manufacturing Fees, BEqs and Batch Credit per BMP

Manufacturing Fees (USD)*	BEqs	Batch Credit (%)
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]

* Based upon the current Manufacturing Supply Pricing for the BMC, See Schedule 1.1 of Exhibit B [***].

[***] Certain confidential portions (indicated by brackets and asterisks) have been omitted from this exhibit in accordance with the rules of the Securities and Exchange Commission.

EXHIBIT B, SCHEDULE 3.6.1 (CONT.)
Illustrations of Batch Credit Calculation

The following examples are for the sole purpose of illustrating the Batch Credit calculation. Batch credits start with BEqs in [***] increments over [***]. For each [***] BEqs, Catalent will provide a credit of [***] towards the Clean Room Use Fee.

Example 1.

[***]

Example 2.

[***]

Example 3.

[***]

[***] Certain confidential portions (indicated by brackets and asterisks) have been omitted from this exhibit in accordance with the rules of the Securities and Exchange Commission.

EXHIBIT B, SCHEDULE 3.6.2
Illustrations of Catalent Use Credit Calculation

The following examples are for the sole purpose of illustrating the Catalent Use Credit calculation.

Example 1.

[***]

Example 2.

[***]

[***] Certain confidential portions (indicated by brackets and asterisks) have been omitted from this exhibit in accordance with the rules of the Securities and Exchange Commission.

EXHIBIT C

DEDICATED CLEAN ROOM SUITE FLOOR PLAN

[***]

[***] Certain confidential portions (indicated by brackets and asterisks) have been omitted from this exhibit in accordance with the rules of the Securities and Exchange Commission.

EXHIBIT C – DEDICATED CLEAN ROOM FLOOR PLAN (YELLOW HIGHLIGHTED AREA)

[***]

EXHIBIT C – DEDICATED CLEAN ROOM FLOOR PLAN (CONT.) (YELLOW HIGHLIGHTED AREA – ZOOMED IN)

[***]

[***] Certain confidential portions (indicated by brackets and asterisks) have been omitted from this exhibit in accordance with the rules of the Securities and Exchange Commission.

EXHIBIT D

BASE EQUIPMENT PACKAGE

[***]

[***] Certain confidential portions (indicated by brackets and asterisks) have been omitted from this exhibit in accordance with the rules of the Securities and Exchange Commission.

SCHEDULE 3.1(b)

READINESS DETERMINATION CHECK LIST

[***] Certain confidential portions (indicated by brackets and asterisks) have been omitted from this exhibit in accordance with the rules of the Securities and Exchange Commission.

SCHEDULE 2.2

SUMMARY OF KEY MILESTONES
FOR DEDICATED CLEAN ROOM SUITE AT THE BWI FACILITY

Milestone	Approx. Start Date	Approx. Finish Date
Process Equipment Procurement and Installation	[***]	[***]
Construction Turnover	[***]	
Commissioning/ Qualification/ Validation	[***]	[***]
cGMP Manufacturing	[***]	[***]

[***] Certain confidential portions (indicated by brackets and asterisks) have been omitted from this exhibit in accordance with the rules of the Securities and Exchange Commission.

February 18, 2020

Jim Momtazee
Sent Via Email

Re: BridgeBio Services Employment

Dear Jim:

BridgeBio Services, Inc. is pleased to offer you employment on the following terms:

1. **Position.** Your title will be Senior Advisor - Transactions. You will report to the Chief Executive Officer, Neil Kumar, with such powers, duties, responsibilities, and accountabilities as set forth below, or as may from time to time be prescribed by the Company's senior executives or the Board of Directors of BridgeBio Pharma, Inc. (the "Board"), provided that such duties are consistent with your position. In your role, you would also act as a Management Committee Member. The position is a part-time, exempt position and you will be required to devote at least 20 hours per week, on average, to the business and affairs of the Company. By signing this letter agreement, you confirm to the Company that you have no contractual commitments or other legal obligations that would prohibit you from performing your duties for the Company. As used in this letter agreement, the "Company" shall refer to BridgeBio Pharma, Inc. and its subsidiaries, including without limitation BridgeBio Services, Inc.; provided, that your direct employer will be BridgeBio Services, Inc.

2. **Salary.** The Company will pay you a starting salary beginning as of your start date at the annual rate of $50,000, payable in accordance with the Company's standard payroll schedule and subject to tax- related deductions and withholdings. This salary will be subject to adjustment pursuant to the Company's employee compensation policies in effect from time to time. Unless otherwise approved by the Board (or a committee thereof) in its sole discretion, you will not be eligible to receive any annual cash bonuses.

3. **Equity Grants**.

(a) **Stock Option**. Subject to approval by the Board (or a committee thereof), following your Start Date, you will be granted an option to purchase shares of BridgeBio Pharma, Inc.'s common stock (the "Option") valued at $293,750 on the date of grant, at an exercise price per share equal to the fair market value of a share of BridgeBio Pharma, Inc.'s common stock on the effective grant date of the Option. The number of shares of BridgeBio Pharma, Inc. common stock subject to the Option will equal $293,750 divided by the Black-Scholes value of an option to purchase one share of BridgeBio Pharma, Inc.'s common stock on the date of grant, rounded down to the nearest whole share. The Option shall be fully vested as of your Start Date and will be subject to the terms and conditions of the BridgeBio Pharma, Inc. 2019 Stock Option and Incentive Plan (as amended from time to time, the "Plan") and the stock option agreement thereunder, which you will be required to sign as a condition to receiving your Option.

(b) **Restricted Stock Units**. In addition, subject to approval by the Board (or a committee thereof), following your Start Date, you will be granted restricted stock units ("RSUs") valued at $293,750. Each RSU entitles you to one share of common stock of BridgeBio Pharma, Inc. if and when the RSU vests. The number of shares of common stock of BridgeBio Pharma, Inc. underlying the RSUs will be determined by dividing $293,750 by the average closing market price of one share of the common stock of BridgeBio Pharma, Inc. as reported on the NASDAQ Global Select Market over the 20 trading days ending on the grant date. All of the RSUs will vest on the 16th of the first February, May, August or November following your Start Date. The value of the vested shares will be includable in your gross income for the taxable year in which you receive the shares, and such value will be subject to applicable withholding taxes and other deductions required by law (the "Shares Withholding Taxes"). The Company will use reasonable best efforts to structure the grant of the Shares so that the Shares Withholding Taxes will be paid using a broker-assisted sell-to-cover arrangement. You should consult with your own personal tax advisor regarding the tax consequences of this letter agreement. The RSUs will be subject to the terms and conditions of the Plan and the restricted stock unit award agreement thereunder, which you will be required to sign as a condition to receiving your RSUs.

4. **Employee Benefits.** You will be eligible to participate in or receive benefits under the Company's employee benefit plans in effect from time to time (including, without limitation, any group health care plan, Paid Time Off, and 401(k)), subject to the terms of such plans.

5. **Employment Relationship**. It is understood that you are an "at-will" employee. You are not being offered employment for a definite period of time, and either you or the Company may terminate the employment relationship at any time and for any reason, with or without cause or prior notice and without additional compensation to you. Any contrary representations that may have been made to you are superseded by this letter agreement. Although your job duties, title, reporting relationship, compensation and benefits, as well as the Company's personnel policies and procedures, may change from time to time (except as otherwise provided herein), the "at will" nature of your employment may only be changed in an express written agreement signed by you and a duly authorized officer of the Company (other than you).

6. **Proprietary Information and Inventions Agreement.** Like all Company employees, you will be required, as a condition of your employment with the Company, to sign the Company's standard Proprietary Information and Inventions Agreement (the "Confidentiality Agreement"), a copy of which is attached hereto as Exhibit A.

7. **Background Check; Employment Eligibility.** This offer is contingent upon a background check clearance, reference check, and satisfactory proof of your right to work in the United States. You agree to assist as needed and to complete any documentation at the Company's request to meet these conditions. The Immigration Reform and Control Act requires employers to verify the employment eligibility and identity of new employees. You will be required to complete a Form I-9 which will be provided to you before your Start Date. Please bring the appropriate documents listed on that form with you when you report for work. We will not be able to employ you if you fail to comply with this requirement. Also, this offer is subject to satisfactory reference checks if necessary.

8. **Interpretation, Amendment and Enforcement**. This letter agreement and the Confidentiality Agreement constitute the complete agreement between you and the Company regarding your employment with the Company, contain all of the terms of your employment with the Company and supersede any prior agreements, representations or understandings (whether written, oral or implied) between you and the Company. This letter agreement may not be amended or modified, except by an express written agreement signed by both you and a duly authorized officer of the Company, although your job duties, title, reporting relationship, compensation and benefits may change from time to time. In the event the terms of this letter contradict or are in any way different from the terms contained any other document(s) provided by the Company, this letter shall control unless otherwise expressly set forth in such other document(s). The terms of this letter agreement and the resolution of any disputes as to the meaning, effect, performance or validity of this letter agreement or arising out of, related to, or in any way connected with, this letter agreement, your employment with the Company or any other relationship between you and the Company will be governed by California law, excluding laws relating to conflicts or choice of law.

We hope that you will accept our offer to join the Company. You may indicate your agreement with these terms and accept this offer by signing and dating both the enclosed duplicate original of this letter agreement and the enclosed Confidentiality Agreement and returning them to me. Should you accept this offer, your start date of employment will be February 12, 2020, or any other date agreed upon between you and the Company (the "Start Date").

Sincerely,

/s/ Neil Kumar

Neil Kumar, Chief Executive Officer, and the BridgeBio Team

I have read and accept this employment offer.

/s/ Jim Momtazee

Jim Momtazee

February 23, 2020

Date

Exhibit 10.39

BridgeBio Pharma, Inc.

Director Compensation Policy

The purpose of this Director Compensation Policy (the "Policy") of BridgeBio Pharma, Inc., a Delaware corporation (the "Company"), is to provide a total compensation package that enables the Company to attract and retain, on a long-term basis, high-caliber directors who are not serving as the Chief Executive Officer of the Company ("Outside Directors"). This Policy will become effective as of the date of its adoption by the Company's Board of Directors (the "Effective Date"). In furtherance of the purpose stated above, all Outside Directors shall be paid compensation for services provided to the Company as set forth below:

I. Cash Retainers

Annual Retainer for Board Membership: $50,000 for general availability and participation in meetings and conference calls of our Board of Directors. No additional compensation for attending individual Board meetings, serving on committees of the Board of Directors or attending committee meetings.

All cash retainers will be paid quarterly, in arrears, or upon the earlier resignation or removal of the Outside Director. Cash retainers owing to Outside Directors shall be annualized, meaning that with respect to directors who join the Board of Directors during the calendar year, such amounts shall be pro-rated based on the number of calendar days served by such director.

II. Equity Retainers

All grants of equity retainer awards to Outside Directors pursuant to this Policy will be automatic and nondiscretionary and will be made in accordance with the following provisions:

(a) Value. For purposes of this Policy, "Value" means with respect to (i) any award of stock options the grant date fair value of the option (i.e., Black-Scholes Value) determined in accordance with the reasonable assumptions and methodologies employed by the Company for calculating the fair value of options under ASC 718; and (ii) any award of restricted stock and restricted stock units the product of (A) the average closing market price of one share of the Company's common stock as reported on the Nasdaq Global Select Market (or such other market on which the Company's common stock is then principally listed) over the 20 trading days ending on the [last] day [of the month] immediately prior to [the month of] the grant date, and (B) the aggregate number of shares pursuant to such award.

(b) Revisions. The Compensation Committee in its discretion may change and otherwise revise the terms of awards to be granted under this Policy, including, without limitation, the number of shares subject thereto, for awards of the same or different type granted on or after the date the Compensation Committee determines to make any such change or revision.

(c) Sale Event Acceleration. In the event of a Sale Event (as defined in the Company's 2019 Stock Option and Incentive Plan (as amended from time to time, the "2019 Plan")), the equity retainer awards granted to Outside Directors pursuant to this Policy shall become 100% vested and exercisable.

(d) Initial Grant. Upon initial election to the Board of Directors, each new Outside Director will receive an initial, one-time grant of a non-statutory stock option (the "Initial Grant") with a Value of $1,200,000, with an exercise price per share equal to the closing price of a share of the Company's common stock on the date of grant and a term of ten years, that vests in three equal annual installments over three years; provided, however, that all vesting ceases if the director resigns from the Company's Board of Directors or otherwise ceases to serve as a director, unless the Board of Directors determines that the circumstances warrant continuation of vesting.

(e) Annual Grant. On the date of the Company's Annual Meeting of Stockholders, each Outside Director who will continue as a member of the Board of Directors following such Annual Meeting of Stockholders and who has not received an Initial Grant in the same calendar year will receive a grant of a non-statutory stock option on the date of such Annual Meeting (the "Annual Grant") with a Value of $1,200,000, with an exercise price per share equal to the closing price of a share of the Company's common stock on the date of grant and a term of ten years, that vests in three equal annual installments over three years; provided, however, that all vesting ceases if the director resigns from the Company's Board of Directors or otherwise ceases to serve as a director, unless the Board of Directors determines that the circumstances warrant continuation of vesting.

III. Expenses

The Company will reimburse all reasonable out-of-pocket expenses incurred by Outside Directors in attending meetings of the Board of Directors or any Committee thereof.

IV. Maximum Annual Compensation

The aggregate amount of compensation, including both equity compensation and cash compensation, paid to any Outside Director in a calendar year period shall not exceed $1,250,000 (or such other limits as may be set forth in Section 3(b) of the 2019 Plan or any similar provision of a successor plan). For this purpose, the "amount" of equity compensation paid in a calendar year shall be determined based on the grant date fair value thereof, as determined in accordance with ASC 718 or its successor provision, but excluding the impact of estimated forfeitures related to service-based vesting conditions.

Date Policy Approved: December 12, 2019

Exhibit 21

BridgeBio Pharma LLC
List of Subsidiaries

Entity Name	State of Incorporation
BridgeBio Pharma LLC	Delaware
TheRas, Inc.	Delaware
BridgeBio Services Inc.	Delaware
Origin Biosciences, Inc.	Delaware
Fortify Therapeutics, Inc.	Delaware
Sub20, Inc.	Delaware
Eidos Therapeutics, Inc.	Delaware
Molecular Skin Therapeutics, Inc.	Delaware
Quartz Therapeutics, Inc.	Delaware
PellePharm, Inc.	Delaware
Navire Pharma, Inc.	Delaware
CoA Therapeutics, Inc.	Delaware
Dermecular Therapeutics, Inc.	Delaware
Phoenix Tissue Repair, Inc.	Delaware
QED Therapeutics, Inc.	Delaware
Adrenas Therapeutics, Inc.	Delaware
Orfan Biotech Inc.	Delaware
Ferro Therapeutics, Inc.	Delaware
Venthera, Inc.	Delaware
Aspa Therapeutics, Inc.	Delaware
Retinagenix Therapeutics, Inc.	Delaware
Audition Therapeutics, Inc.	Delaware
Calcilytix Therapeutics, Inc.	Delaware
BridgeBio Gene Therapy LLC	Delaware
BridgeBio Gene Therapy Research, Inc.	Delaware
ML Bio Solutions Inc.	Delaware

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement Nos. 333-234803 and 333-232491 on Form S-8 of our report dated March 2, 2020, relating to the consolidated financial statements of BridgeBio Pharma, Inc. appearing in this Annual Report on Form 10-K for the year ended December 31, 2019.

DELOITTE & TOUCHE LLP

San Francisco, California
March 2, 2020

Exhibit 31.1

CERTIFICATIONS

I, Neil Kumar, certify that:

1. I have reviewed this Annual Report of BridgeBio Pharma, Inc. on Form 10-K for the period ended December 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report");

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(s) 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; and

   (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(s) 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.

March 2, 2020

/s/ Neil Kumar
Neil Kumar
Chief Executive Officer
(Principal Executive Officer)

ACTIVE/102476079.2

Exhibit 31.2

CERTIFICATIONS

I, Brian Stephenson, certify that:

1. I have reviewed this Annual Report of BridgeBio Pharma, Inc. on Form 10-K for the period ended December 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report");

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(s) 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; and

   (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(s) 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.

March 2, 2020

/s/ Brian Stephenson
Brian Stephenson
Chief Financial Officer
(Principal Financial and Accounting Officer)

ACTIVE/102476076.2

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906
OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of BridgeBio Pharma, Inc. (the "Company") on Form 10-K for the period ended December 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Neil Kumar, the Chief Executive Officer of BridgeBio Pharma, Inc. (the "Company"), do hereby certify in accordance with 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002 that, based upon my knowledge:

1. This Annual Report on Form 10-K of the Company, to which this certification is attached as an exhibit (the "Report"), fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

March 2, 2020

/s/ Neil Kumar
Neil Kumar
Chief Executive Officer
(Principal Executive Officer)

A signed original of this written statement required by Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. Section 1350), has been provided to BridgeBio Pharma, Inc. and will be retained by BridgeBio Pharma, Inc. and furnished to the Securities and Exchange Commission or its staff upon request. This certification accompanies the 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 BridgeBio Pharma, 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.

Exhibit 32.2

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906
OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of BridgeBio Pharma, Inc. (the "Company") on Form 10-K for the period ended December 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Brian Stephenson, Chief Financial Officer (Principal Financial and Accounting Officer) of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. Information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

March 2, 2020

/s/ Brian Stephenson
Brian Stephenson
Chief Financial Officer
(Principal Financial and Accounting Officer)

A signed original of this written statement required by Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. Section 1350), has been provided to BridgeBio Pharma, Inc. and will be retained by BridgeBio Pharma, Inc. and furnished to the Securities and Exchange Commission or its staff upon request. This certification accompanies the 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 BridgeBio Pharma, 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.