UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 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 Number: 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	BBIO	The Nasdaq Global Select Market

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 ☒

As of August 9, 2019 the registrant had 116,755,512 shares of common stock, $0.001 par value per share, outstanding.

Table of Contents

BRIDGEBIO PHARMA, INC.

Condensed Balance Sheets
(unaudited)
(in thousands)

	June 30, 2019	May 17, 2019
Assets		
Total assets	$ —	$ —
Liabilities		
Total liabilities	$ —	$ —
Commitments and contingencies		
Stockholders' Deficit		
Undesignated preferred stock, $0.001 par value; 25,000,000 and no shares authorized as of June 30, 2019 and May 17, 2019; no shares issued and outstanding as of June 30, 2019 and May 17, 2019	$ —	$ —
Common stock, $0.001 par value; 500,000,000 and 1,000 shares authorized as of June 30, 2019 and May 17, 2019; no shares issued and outstanding as of June 30, 2019 and May 17, 2019	—	—
Additional paid-in capital	69	—
Accumulated deficit	(69)	—
Total liabilities and stockholders' deficit	$ —	$ —

The accompanying notes are an integral part of these unaudited condensed financial statements.

BRIDGEBIO PHARMA, INC.

Condensed Statement of Operations and Comprehensive Loss
(unaudited)
(in thousands)

	May 17, 2019 – June 30, 2019
Operating expenses:	
General and administrative	$ 69
Total operating expenses	69
Net loss and comprehensive loss	$ (69)

The accompanying notes are an integral part of these unaudited condensed financial statements.

BRIDGEBIO PHARMA, INC.

Condensed Statement of Changes in Stockholders' Deficit
(unaudited)
(in thousands)

	Common Stock	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
Balances as of May 17, 2019	$ —	$ —	$ —	$ —
Stock-based compensation	—	69	—	69
Net loss	—	—	(69)	(69)
Balances as of June 30, 2019	$ —	$ 69	$ (69)	$ —

The accompanying notes are an integral part of these unaudited condensed financial statements.

1. Organization and Background

BridgeBio Pharma, Inc. (the "Corporation") was formed as a Delaware corporation on May 17, 2019. The Corporation was formed for the purpose of completing an initial public offering of the Corporation's common stock (the "IPO") and related transactions in order to carry on the business of BridgeBio Pharma LLC (the "Reorganization"). From incorporation through June 30, 2019, the Corporation did not have any shares of common stock outstanding. Accordingly, basic and diluted net loss attributable to common stockholders has not been presented.

Upon the closing of the IPO on July 1, 2019, all unitholders of BridgeBio Pharma LLC exchanged their units for shares of common stock of the Corporation, and BridgeBio Pharma LLC became a wholly-owned subsidiary of the Corporation as part of the Reorganization. As the sole managing member, the Corporation will operate and control all of BridgeBio Pharma LLC's businesses and affairs after the Reorganization. As of June 30, 2019, these condensed financial statements, including share and per share amounts, do not give effect to the Reorganization or the IPO as these transactions were completed subsequent to June 30, 2019. Refer to Note 5 for additional information.

2. Summary of Significant Accounting Policies

Basis of Presentation

The unaudited condensed balance sheets, condensed statement of operations and comprehensive loss and condensed statement of changes in stockholders' deficit are presented in accordance with generally accepted accounting principles in the United States of America ("GAAP"). A statement of cash flows has not been presented because there have been no cash activities in this entity from inception on May 17, 2019 and through June 30, 2019.

The unaudited condensed financial statements have been prepared on the same basis that would be applied to the annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary to present fairly the Corporation's financial position as of June 30, 2019 and the results of operations and comprehensive loss from inception on May 17, 2019 and through June 30, 2019. The results of operations for the period from May 17, 2019 through June 30, 2019 are not necessarily indicative of the results to be expected for the period from May 17, 2019 through December 31, 2019 or for any other future annual or interim period.

Underwriting Commissions and Offering Costs

Underwriting commissions and offering costs incurred in connection with the Corporation's offering of its common stock will be reflected as a reduction of additional paid-in capital subsequent to June 30, 2019. Underwriting commissions and offering costs are not recorded in the Corporation's balance sheet because such costs did not become the Corporation's liability until the Corporation completed the Reorganization and the IPO subsequent to June 30, 2019.

Organizational Costs

Organizational costs are not recorded in the Corporation's balance sheet as of June 30, 2019 because such costs are not the Corporation's liability until the Corporation completes the Reorganization and the IPO. Thereafter, costs incurred to organize the Corporation will be expensed as incurred.

Equity-Based Compensation

Equity-based compensation is measured at the grant date for all equity-based awards made to employees and non-employees based on the fair value of the awards and is recognized as expense on a straight-line basis over the requisite service period, which is generally the vesting period. The Corporation has elected to recognize the actual forfeitures by reducing the equity-based compensation in the same period as the forfeitures occur. The description of fair value measurement method for the awards is presented in Note 4. The Corporation granted stock options to employees and non-employees of BridgeBio Pharma LLC and its affiliates. These awards generally have only a service condition and vest over a period of four years. The Corporation classifies equity-based compensation in its unaudited statement of operations in the same manner in which the award recipients' payroll costs or the award recipients' service payments would be classified, if any were made during the reporting period.

3. Stockholders' Deficit

On May 17, 2019, the Corporation was authorized to issue 1,000 shares of common stock, par value $0.001 per share.

On June 26, 2019, the Corporation amended and restated its certificate of incorporation to increase the authorized capital stock to 500,000,000 shares of common stock with a par value of $0.001 and to 25,000,000 shares of undesignated preferred stock with a par value of $0.001.

No shares of common stock or preferred stock had been issued or are outstanding as of June 30, 2019.

4. Stock-based Compensation

2019 Stock Option and Incentive Plan

On June 22, 2019, the Corporation 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 equity-based incentive awards. The Corporation initially reserved 11,500,000 shares of common stock for issuance of awards under the 2019 Plan. 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 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 June 21, 2019, the Board of Directors approved the grant of options to purchase 3,696,429 shares of common stock to certain employees and non-employees of BridgeBio Pharma LLC and its affiliates at an exercise price equal to the IPO price of its common stock, which was $17.00 per share. On June 26, 2019, the Board of Directors approved the grant of options to purchase an additional 48,200 shares of common stock to certain employees and non-employees of BridgeBio Pharma LLC and its affiliates at the same exercise price. The options granted have a service condition and vest over a period of four years. All expenses included in the Corporation's statement of operations represent recorded stock-based compensation in relation to these June 2019 grants.

The following table summarizes the Corporation's stock option activity for the period from May 17, 2019 through June 30, 2019:

	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 May 17, 2019	—	—	$ —	—	$ —
Authorized	11,500,000	—	$ —		
Granted	(3,744,629)	3,744,629	$ 17.00		
Outstanding as of June 30, 2019	7,755,371	3,744,629	$ 17.00	6.02	$ 37,334
Exercisable as of June 30, 2019		—	$ —	—	$ —

Determination of Fair Value

The fair value of each stock option grant was determined by the Corporation at the grant date using a Black-Scholes option-pricing model with the following assumptions:

	May 17, 2019 – June 30, 2019
Expected term (in years)	6.02-6.08
Expected volatility	37.5%
Risk-free interest rate	1.86%
Dividend yield	—
Weighted average fair value of share-based awards granted	$ 6.64

As of June 30, 2019, there was $24.8 million of total unrecognized compensation cost related to unvested equity-based compensation arrangements under the 2019 Plan. The unrecognized equity-based compensation cost is expected to be recognized over a weighted-average period of 4.0 years.

2019 Employee Stock Purchase Plan

On June 22, 2019, the Corporation 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.

As of June 30, 2019, no shares were issued and outstanding under the ESPP.

5. Subsequent Events

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 $366.3 million from the IPO, after deducting underwriters' discounts and commissions of $28.0 million and offering costs of $6.5 million.

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.

On July 1, 2019, upon execution of the Reorganization, all outstanding units of BridgeBio Pharma, LLC were cancelled and exchanged for shares of common stock of the Corporation, as shown in the below table by unit class:

BridgeBio Pharma, LLC unit class	Number of BridgeBio Pharma, Inc. 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

The unvested outstanding management incentive units and common units of BridgeBio Pharma LLC were exchanged for shares of the Corporation's restricted common stock. Such unvested restricted shares are subject to the same time-based vesting conditions as the original management incentive units and common units terms and conditions.

On July 1, 2019, Merger Sub LLC was merged with and into BridgeBio Pharma 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.

Non-Binding Proposal to Acquire Common Stock of Eidos Therapeutics, Inc.

On August 8, 2019, the Corporation submitted to the board of directors of Eidos Therapeutics, Inc. ("Eidos"), a subsidiary of BridgeBio Pharma LLC, a non-binding proposal to acquire the outstanding shares of common stock of Eidos that are not owned by BridgeBio Pharma LLC. The proposal includes a suggested fixed exchange ratio of 1.30 shares of the Corporation's common stock for each share of common stock of Eidos.

The proposal is subject to a number of contingencies, including the approval by the Board of Directors of Eidos and its special committee of independent directors. Additionally, the transaction will require an approval by a majority of the aggregate voting power represented by the shares of common stock of Eidos that are not owned by BridgeBio Pharma LLC.

BRIDGEBIO PHARMA LLC

Condensed Consolidated Balance Sheets
(unaudited)
(in thousands)

	June 30, 2019	December 31, 2018
Assets		(1)
Current assets:		
Cash and cash equivalents	$ 293,803	$ 436,086
Prepaid expenses and other current assets	12,906	9,137
Total current assets	306,709	445,223
Property and equipment, net	1,865	1,575
PellePharm investment	7,495	17,050
Other assets	9,471	1,093
Total assets	$ 325,540	$ 464,941
Liabilities, Redeemable Convertible Preferred Units, Redeemable Founder Units, Redeemable Common Units, Management Incentive Units, Redeemable Convertible Noncontrolling Interests, and Members' Deficit		
Current liabilities:		
Accounts payable	$ 16,065	$ 13,509
Accrued compensation and benefits	4,736	4,047
Accrued research and development liabilities	9,419	8,915
Accrued distributions to unitholders	—	997
LEO call option liability	4,297	3,009
Other accrued liabilities	4,188	2,100
Total current liabilities	38,705	32,577
Term loans, noncurrent	74,997	54,507
Other liabilities	347	495
Total liabilities	114,049	87,579
Commitments and contingencies (Note 8)		
Redeemable convertible preferred units	479,044	478,865
Redeemable founder units	1,754	1,754
Redeemable common units	1,672	1,619
Management incentive units	6,523	3,221
Redeemable convertible noncontrolling interests	175	122
Members' deficit:		
Accumulated deficit	(326,068)	(170,580)
Total BridgeBio members' deficit	(326,068)	(170,580)
Noncontrolling interests	48,391	62,361
Total members' deficit	(277,677)	(108,219)
Total liabilities, redeemable convertible preferred units, redeemable founder units, redeemable common units, management incentive units, redeemable convertible noncontrolling interests, and members' deficit	$ 325,540	$ 464,941

The accompanying notes are an integral part of these unaudited condensed 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.

BRIDGEBIO PHARMA LLC

Condensed Consolidated Statements of Operations and Comprehensive Loss
(unaudited)
(in thousands, except units and per unit amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	**2018**	**2019**	**2018**
Operating expenses:				
Research and development	$ 52,331	$ 23,892	$ 97,184	$ 57,723
General and administrative	16,918	10,891	35,817	18,898
Total operating expenses	69,249	34,783	133,001	76,621
Loss from operations	(69,249)	(34,783)	(133,001)	(76,621)
Other income (expense), net:				
Interest income	1,662	2	3,769	3
Interest expense	(1,941)	(205)	(3,612)	(212)
Loss from PellePharm	(4,956)	—	(9,555)	—
LEO call option income (expense)	226	—	(1,288)	—
Other income (expense)	(7)	(716)	(14)	(1,302)
Total other income (expense), net	(5,016)	(919)	(10,700)	(1,511)
Net loss and comprehensive loss	(74,265)	(35,702)	(143,701)	(78,132)
Net loss attributable to redeemable convertible noncontrolling interests and noncontrolling interests	8,370	9,151	16,621	17,425
Net loss and comprehensive loss attributable to BridgeBio	(65,895)	(26,551)	(127,080)	(60,707)
Cumulative returns on redeemable convertible preferred units (Series A, Series B and Series C)	—	(3,854)	—	(6,975)
Net loss attributable to redeemable founder units and redeemable common units	$ (65,895)	$ (30,405)	$ (127,080)	$ (67,682)
Net loss per unit attributable to redeemable founder unitholders and redeemable common unitholders, basic and diluted	$ (3.46)	$ (1.71)	$ (6.69)	$ (3.83)
Total weighted-average redeemable founder units and redeemable common units used in computing net loss per unit, basic and diluted	19,033,838	17,821,117	18,995,957	17,654,249

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

BRIDGEBIO PHARMA LLC

Condensed Consolidated Statements of Redeemable Convertible Preferred Units, Redeemable Founder Units, Redeemable Common Units, Management Incentive Units, Redeemable Convertible Noncontrolling Interests and Members' Deficit
(*unaudited*)
(in thousands, except units and per unit amounts)

	Redeemable Convertible Preferred Units		Redeemable Founder Units		Redeemable Common Units		Management Incentive Units		Redeemable Convertible Noncontrolling Interests	Accumulated Deficit	Noncontro-lling Interests	Total Members' Deficit
	Units	Amount	Units	Amount	Units	Amount	Units	Amount				
Balances as of December 31, 2018	407,955,726	$ 478,865	11,420,741	$ 1,754	7,197,783	$ 1,619	19,117,628	$ 3,221	$ 122	$ (170,580)	$ 62,361	$ (108,219)
Issuance and vesting of redeemable common units and associated equity-based compensation	—	—	—	—	335,427	26	—	—	—	—	—	—
Issuance and vesting of management incentive units and associated equity-based compensation	—	—	—	—	—	—	2,831,171	1,210	—	—	—	—
Repayment of nonrecourse notes	—	179	—	—	—	—	—	—	—	—	—	—
Issuance (repurchase) of noncontrolling interest	—	—	—	—	—	—	—	—	—	—	1,320	1,320
Transfers to (from) noncontrolling interest	—	—	—	—	—	—	—	—	870	(2,968)	2,098	(870)
Net loss and comprehensive loss	—	—	—	—	—	—	—	—	(790)	(61,185)	(7,461)	(68,646)
Balances as of March 31, 2019	407,955,726	479,044	11,420,741	1,754	7,533,210	1,645	21,948,799	4,431	202	(234,733)	58,318	(176,415)
Issuance and vesting of redeemable common units and associated equity-based compensation	—	—	—	—	335,427	27	—	—	—	—	—	—
Issuance and vesting of management incentive units and associated equity-based compensation	—	—	—	—	—	—	3,629,209	2,092	—	—	—	—
Issuance (repurchase) of noncontrolling interest	—	—	—	—	—	—	—	—	—	—	(27,024)	(27,024)
Transfers to (from) noncontrolling interest	—	—	—	—	—	—	—	—	658	(25,440)	24,782	(658)
Net loss and comprehensive loss	—	—	—	—	—	—	—	—	(685)	(65,895)	(7,685)	(73,580)
Balances as of June 30, 2019	407,955,726	$ 479,044	11,420,741	$ 1,754	7,868,637	$ 1,672	25,578,008	$ 6,523	$ 175	$ (326,068)	$ 48,391	$ (277,677)

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

BRIDGEBIO PHARMA LLC

Condensed Consolidated Statements of Redeemable Convertible Preferred Units, Redeemable Founder Units, Redeemable Common Units, Management Incentive Units, Redeemable Convertible Noncontrolling Interests and Members' Deficit
(*unaudited*)
(in thousands, except units and per unit amounts)

	Redeemable Convertible Preferred Units		Redeemable Founder Units		Redeemable Common Units		Management Incentive Units		Redeemable Convertible Noncontrolling Interests	Accumulated Deficit	Noncontro-lling Interests	Total Members' Deficit
	Units	Amount	Units	Amount	Units	Amount	Units	Amount				
Balances as of December 31, 2017	219,406,923	$ 143,867	11,420,741	$ 1,754	5,856,075	$ 1,431	9,835,925	$ 226	$ 833	$ (61,427)	$ 2,498	$ (58,929)
Issuance and vesting of redeemable common units and associated equity-based compensation	—	—	—	—	335,427	47	—	—	—	—	—	—
Issuance and vesting of management incentive units and associated equity-based compensation	—	—	—	—	—	—	2,275,572	275	—	—	—	—
Issuance (repurchase) of noncontrolling interest	—	—	—	—	—	—	—	—	15,617	—	553	553
Transfers to (from) noncontrolling interest	—	—	—	—	—	—	—	—	(11,286)	3,876	7,410	11,286
Net loss and comprehensive loss	—	—	—	—	—	—	—	—	(3,614)	(34,156)	(4,660)	(38,816)
Balances as of March 31, 2018	219,406,923	143,867	11,420,741	1,754	6,191,502	1,478	12,111,497	501	1,550	(91,707)	5,801	(85,906)
Issuance and vesting of redeemable common units and associated equity-based compensation	—	—	—	—	335,427	48	—	—	—	—	—	—
Issuance and vesting of management incentive units and associated equity-based compensation	—	—	—	—	—	—	2,283,905	277	—	—	—	—
Issuance of Series C redeemable convertible preferred units at $0.9656 per unit, net of issuance costs of $0	37,593,206	36,300	—	—	—	—	—	—	—	—	—	—
Issuance (repurchase) of noncontrolling interest	—	—	—	—	—	—	—	—	46,710		96,689	96,689
Transfers to (from) noncontrolling interest	—	—	—	—	—	—	—	—	(41,450)	56,182	(14,732)	41,450
Net loss and comprehensive loss	—	—	—	—	—	—	—	—	(3,618)	(26,551)	(5,533)	(32,084)
Balances as of June 30, 2018	257,000,129	$ 180,167	11,420,741	$ 1,754	6,526,929	$ 1,526	14,395,402	$ 778	$ 3,192	$ (62,076)	$ 82,225	$ 20,149

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

BRIDGEBIO PHARMA LLC

Condensed Consolidated Statements of Cash Flows
(unaudited)
(in thousands)

	Six Months Ended June 30,	
Operating activities:	**2019**	**2018**
Net loss	$ (143,701)	$ (78,132)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	244	68
Equity-based compensation	5,521	1,768
Loss on disposal of property and equipment, net	8	7
Loss from PellePharm	9,555	—
Accretion of term loans and convertible promissory notes	702	264
Acquired in-process research and development assets	2,500	17,886
Shares issued under license agreements	220	134
LEO call option expense	1,288	—
Change in fair value of Eidos financial instruments	—	1,146
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(3,345)	(8,118)
Other assets	(2,077)	133
Accounts payable	146	8,856
Accrued compensation and benefits	689	588
Accrued research and development liabilities	505	3,097
Other accrued liabilities	505	273
Other liabilities	(148)	123
Net cash used in operating activities	(127,388)	(51,907)
Investing activities		
Cash paid for in-process research and development assets acquired	(2,500)	(16,000)
Purchases of property and equipment	(510)	(832)
Net cash used in investing activities	(3,010)	(16,832)
Financing activities		
Proceeds from the issuance of Series C preferred units, net of issuance costs	—	36,300
Proceeds from issuance of common stock in connection with the initial public offering of Eidos, net of underwriting discounts and commissions	—	96,723
Proceeds from issuance of promissory notes	—	1,000
Proceeds from repayment of nonrecourse notes	179	—
Proceeds from term loans, net of issuance costs	19,787	36,590
Proceeds from third-party investors in redeemable convertible noncontrolling interests	—	58,430
MyoKardia distributions (Note 13)	(997)	—
Repurchase of noncontrolling interest	(28,628)	—
Proceeds from repayment of the loans received by noncontrolling interest shareholder	—	(17)
Payment of deferred offering costs	(2,499)	—
Proceeds from subsidiary stock option exercises	538	75
Net cash provided by (used in) financing activities	(11,620)	229,101
Net increase (decrease) in cash, cash equivalents and restricted cash	(142,018)	160,362
Cash, cash equivalents and restricted cash at beginning of period	436,245	92,376
Cash, cash equivalents and restricted cash at end of period	$ 294,227	$ 252,738
Supplemental Disclosures of Cash Flow Information:		
Cash paid for interest	$ 2,583	$ 19
Supplemental Disclosures of Non-Cash Investing and Financing Information:		
Transfers to (from) noncontrolling interest (Note 6)	$ 28,408	$ 60,058
Deferred offering costs included in accounts payable and other accrued liabilities	$ 3,961	$ 1,187
Conversion of redeemable noncontrolling interest into noncontrolling interest	$ —	$ 12,252
Conversion of promissory note into redeemable convertible noncontrolling interest	$ —	$ 1,005
Fair value of redeemable convertible noncontrolling interest issued for acquired in-process research and development assets	$ —	$ 1,886

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements

1. Organization and Description of Business

BridgeBio Pharma LLC ("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. 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, the "Company"). BridgeBio is headquartered in Palo Alto, California.

BridgeBio Pharma, Inc. (the "Corporation") was formed as a Delaware corporation on May 17, 2019. The Corporation was formed for the purpose of completing an initial public offering of the Corporation's common stock (the "IPO") and related transactions in order to carry on the business of BridgeBio Pharma LLC (the "Reorganization").

Upon the closing of the Corporation's IPO on July 1, 2019, all unitholders of BridgeBio Pharma LLC exchanged their units for shares of common stock of the Corporation, and BridgeBio Pharma LLC became a wholly-owned subsidiary of the Corporation. As the sole managing member, the Corporation will operate and control all of BridgeBio Pharma LLC businesses and affairs. These condensed consolidated financial statements as of June 30, 2019, including unit and per unit amounts, do not give effect to the Reorganization or the IPO as these transactions were completed subsequent to June 30, 2019. Refer to Note 17 for additional information.

Liquidity

The Company has incurred significant losses and negative cash flows from operations since its inception and has an accumulated deficit of $326.1 million as of June 30, 2019. The Company had cash and cash equivalents of $293.8 million as of June 30, 2019, of which $112.4 million was held by BridgeBio. The remaining cash and cash equivalents were held by the Company's wholly-owned subsidiaries and controlled entities and these funds are designated for specific entity usage, except in limited circumstances.

The Company has historically financed its operations primarily through the sale of its equity securities and, to a lesser extent, debt borrowings. To date, none of the Company's product candidates have been approved for sale and therefore the Company has not generated any revenue from product sales. Management expects to incur additional losses in the future to fund its operations and conduct product research and development and recognizes the need to raise additional capital to fully implement its business plan.

The Company intends to raise such additional capital through the issuance of equity securities, debt financings or other sources in order to further implement its business plan. However, if such financing is not available at adequate levels, the Company will need to reevaluate its operating plan and may be required to delay the development of its product candidates. The Company expects that its cash and cash equivalents, along with the $366.3 million of net proceeds received from the completion of the IPO in July 2019, will be sufficient to fund its operations for a period of at least one year from the date the condensed consolidated financial statements are filed with the Securities and Exchange Commission ("SEC").

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States ("GAAP") and applicable rules and regulations of SEC regarding interim financial reporting.

The interim condensed consolidated balance sheet as of June 30, 2019, the condensed consolidated statements of operations and comprehensive loss for the three and six months ended June 30, 2019 and 2018, the condensed consolidated statements of redeemable convertible preferred units, redeemable founder units, redeemable common units, management incentive units, redeemable convertible noncontrolling interests and members' deficit for the three and six months ended June 30, 2019 and 2018 and the statements of cash flows for the six months ended June 30, 2019 and 2018 are unaudited.

The condensed consolidated financial statements have been prepared on the same basis as the annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for a fair statement of the Company's financial position, its results of operations and comprehensive loss, and its cash flows for the periods presented. The financial data and the other financial information contained in these notes to the condensed consolidated financial statements related to the three and six-month periods are also unaudited. The results of operations for the three and six months ended June 30, 2019 are not necessarily indicative of the results to be expected for the year ending December 31, 2019 or for any other future annual or interim period. These condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements included in the prospectus dated June 26, 2019 ("Prospectus") that forms a part of the Company's Registration Statements on Form S-1 (File Nos. 333-231759 and 333-232376), as filed with the SEC pursuant to Rule 424(b)(4) promulgated under the Securities Act of 1933, as amended.

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.

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 5.

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 5.

BridgeBio has either created or made investments in the following entities:

Consolidated Entities	Relationship as of June 30, 2019	Date Control First Acquired	Ownership % as of June 30, 2019 (unaudited)	Ownership % as of December 31, 2018
TheRas, Inc.	Wholly-owned subsidiary	August 2016	100%	100%
BridgeBio Services, Inc.	Wholly-owned subsidiary	April 2017	100%	100%
Fortify Therapeutics, Inc.	Wholly-owned subsidiary	June 2018	100%	100%
Sub20, Inc.	Wholly-owned subsidiary	June 2018	100%	100%
Unnamed Entity #1	Wholly-owned subsidiary	December 2018	100%	100%
Unnamed Entity #2	Wholly-owned subsidiary	April 2019	100%	—
Unnamed Entity #3	Wholly-owned subsidiary	May 2019	100%	—
Eidos Therapeutics, Inc.(1)	Partially-owned subsidiary	April 2016	65.1%	62.5%
Molecular Skin Therapeutics, Inc.	Controlled VIE	July 2016	58.2%	61.7%
Quartz Therapeutics, Inc.	Controlled VIE	October 2016	89.0%	89.0%
PellePharm, Inc.(2)	VIE	December 2016	43.3%	43.3%
Navire Pharma, Inc.	Controlled VIE	February 2017	78.9%	78.8%
CoA Therapeutics, Inc.	Controlled VIE	February 2017	99.6%	99.5%
Dermecular Therapeutics, Inc.	Controlled VIE	April 2017	87.6%	87.6%
Phoenix Tissue Repair, Inc.	Controlled VIE	July 2017	56.4%	56.7%
QED Therapeutics, Inc.	Controlled VIE	January 2018	96.6%	94.4%
Adrenas Therapeutics, Inc.	Controlled VIE	January 2018	88.7%	90.1%
Orfan Biotech, Inc.	Controlled VIE	January 2018	89.6%	85.1%
Ferro Therapeutics, Inc.	Controlled VIE	March 2018	90.0%	89.4%
Origin Biosciences, Inc.	Controlled VIE	April 2018	99.8%	100%
Venthera, Inc.	Controlled VIE	April 2018	81.8%	82.0%
Aspa Therapeutics, Inc.	Controlled VIE	June 2018	90.3%	92.5%

(1) Subsequent to the Eidos Therapeutics, Inc. ("Eidos") initial public offering in June 2018 and through June 30, 2019, BridgeBio has a majority voting interest in Eidos and consolidates Eidos under the VOE model. Refer to Note 5.

(2) 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 7.

Use of Estimates

The preparation of condensed 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 condensed consolidated financial statements, and the reported amounts of expenses during the reporting period. Significant estimates and assumptions made in the accompanying condensed consolidated financial statements include, but are not limited to, the fair value of the Preferred Units, the fair value of the Founder Units, the fair value of the LEO Call Option liability, the valuation of equity-based awards, income tax uncertainties and accruals for research and development activities. The Company bases its estimates on historical experience and on various other assumptions that are believed to be reasonable. Actual results may differ from those estimates or assumptions.

Cash, Cash Equivalents and Restricted Cash

As of June 30, 2019 and December 31, 2018, the Company had restricted cash of $0.4 million and $0.2 million. Restricted cash is classified in prepaid expenses and other current assets and other assets in the accompanying condensed consolidated balance sheets as of June 30, 2019 and December 31, 2018, respectively.

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the condensed consolidated balance sheets that sum to the total of the amounts shown in the condensed consolidated statements of cash flows:

	June 30, 2019	June 30, 2018
	(in thousands)	
Cash and cash equivalents	$ 293,803	$ 252,379
Restricted cash	424	359
Total cash, cash equivalents and restricted cash shown in the condensed consolidated statements of cash flows	$ 294,227	$ 252,738

As of June 30, 2019 and December 31, 2018, total cash and cash equivalents held by BridgeBio was $112.4 million and $238.7 million. The remaining cash and cash equivalents were held by the Company's wholly-owned subsidiaries and controlled entities and these funds are designated for specific entity usage, except in limited circumstances.

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 exercised by the Company 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 fair value of the Company's outstanding term loans with Hercules Capital, Inc. (see Note 9) 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 the Company's outstanding term loans approximates the carrying amount, as the term loan bears a floating rate that approximates the market interest rate.

Deferred Offering Costs

The Company has deferred offering costs, consisting of legal, accounting, printer and filing fees related to the IPO, that were deferred and were offset against the offering proceeds upon the completion of the IPO on July 1, 2019. As of June 30, 2019, $6.5 million of deferred offering costs were recorded within other assets on the condensed consolidated balance sheet. As of December 31, 2018, no amounts were deferred.

Net Loss per Unit

The holders of the Company's Preferred Units are entitled to receive distributions, including cumulative returns on their units outstanding, prior and in preference to any distributions on any of the Company's Founder Units and Common Units, which are also entitled to cumulative returns. Cumulative returns for Preferred Units, Common Units and Founder Units no longer accumulate subsequent to the Series D Preferred Unit financing in November 2018. For the three and six months ended June 30, 2019 and 2018, the Company determined that its Founder Units and Common Units are common stock equivalents.

Basic net loss per unit is the same as diluted net loss per unit as the inclusion of all potentially dilutive. Preferred Units, unvested Common Units, and Management Incentive Units would have been anti-dilutive.

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. The Company adopted this guidance on January 1, 2018. The condensed consolidated balance sheets as of June 30, 2019 and December 31, 2018 are presented in accordance with this guidance.

Recently Issued Accounting Pronouncements Not Yet Adopted

ASU 2016-02 Leases (Topic 842). In February 2016, the FASB issued *ASU 2016-02, Leases ("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, on a generally straight-line basis. A modified retrospective transition approach is required for leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, including a number of optional practical expedients that entities may elect to apply. ASU 2016-02 is effective for fiscal years beginning after December 15, 2019 and interim periods within fiscal years beginning after December 15, 2020, with early adoption permitted. The Company is currently evaluating the appropriate transition method and impact of this guidance on its consolidated financial statements and related disclosures.

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 amendments in ASU 2016-15 will be applied using a retrospective transition method to each period presented. The adoption of ASU 2016-15 is not expected to materially impact the Company's 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. The adoption of ASU 2018-13 is not expected to materially impact the Company's consolidated financial statements.

3. Fair Value Measurement

The following table presents information about the Company's financial assets and liabilities that are measured at fair value on a recurring basis and indicates the fair value hierarchy of the valuation:

	June 30, 2019			
	Total	Level 1	Level 2	Level 3
	(in thousands)			
Assets:				
Money market funds	$ 249,138	$ 249,138	$ —	$ —
Total assets	$ 249,138	$ 249,138	$ —	$ —
Liabilities:				
LEO Call Option liability	$ 4,297	$ —	$ —	$ 4,297
Total liabilities	$ 4,297	$ —	$ —	$ 4,297

	December 31, 2018			
	Total	Level 1	Level 2	Level 3
	(in thousands)			
Assets:				
Money market funds	$ 395,780	$ 395,780	$ —	$ —
Total assets	$ 395,780	$ 395,780	$ —	$ —
Liabilities:				
LEO Call Option liability	$ 3,009	$ —	$ —	$ 3,009
Total liabilities	$ 3,009	$ —	$ —	$ 3,009

There were no financial assets outside of cash and cash equivalents as of June 30, 2019 and December 31, 2018. There were no transfers between Level 1, Level 2 or Level 3 during the periods presented.

LEO Call Option Liability

The valuation of the LEO Call Option (see Note 7) 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.

The Company 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:

	June 30, 2019	December 31, 2018
Probability of milestone achievement	12.0%-84.0%	12.0%-84.0%
Discount rate	1.8%-15.3%	2.7%-11.0%
Expected term (in years)	0.75-4.37	0.58-4.38
Expected volatility	67.5%-78.0%	67.0%-79.0%
Risk-free interest rate	2.92%-3.20%	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 December 31, 2018	$ 3,009
Change in fair value upon remeasurement recognized in other (income) expense	1,288
Balance as of June 30, 2019	$ 4,297

4. Balance Sheet Components

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following:

	June 30, 2019	December 31, 2018
	(in thousands)	
Prepaid clinical and research related expenses	$ 7,532	$ 7,087
Other current assets	5,374	2,050
Total prepaid expenses and other current assets	$ 12,906	$ 9,137

Other Accrued Liabilities

Other accrued liabilities consist of the following:

	June 30, 2019	December 31, 2018
	(in thousands)	
Accrued professional services	$ 3,320	$ 772
Accrued other liabilities	868	1,328
Total other accrued liabilities	$ 4,188	$ 2,100

5. 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 condensed consolidated financial statements for the three and six months ended June 30, 2019 and 2018. As of June 30, 2019, there were no significant restrictions on the VIE assets or liabilities except for the cash held by its 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 as of June 30, 2019 and December 31, 2018. At each reporting period, the Company reassesses whether it has a majority voting interest for entities consolidated under the VOE model and whether it remains the primary beneficiary for VIEs consolidated under the VIE model.

Eidos

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 June 30, 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 June 30, 2019 and December 31, 2018.

In May 2019, the Company purchased 1,103,848 shares of Eidos common stock from an existing Eidos stockholder for $28.6 million in a private purchase transaction.

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 June 30, 2019. BridgeBio also had a majority ownership interest in these entities as of June 30, 2019 and December 31, 2018.

During the six months ended June 30, 2019, BridgeBio made investments in QED of $40.0 million, Quartz of $0.4 million, CoA of $5.1 million, Orfan of $3.5 million, Ferro of $4.5 million, Aspa of $8.0 million, Adrenas of $8.0 million, Origin of $10.0 million, Venthera of $1.5 million and Navire of $4.5 million in exchange for shares of redeemable convertible preferred stock of the respective entities. Based on the above noted equity financing transactions, BridgeBio concluded that there was no change in the consolidation conclusion during the period ended June 30, 2019.

The following table provides the assets and liabilities for all consolidated VIEs as of June 30, 2019:

	Adrenas	Aspa	PTR	QED	Venthera	All Other	Total
				(in thousands)			
Assets:							
Current assets:							
Cash and cash equivalents	$ 1,912	$ 3,697	$ 1,704	$ 5,579	$ 1,957	$ 19,364	$ 34,213
Prepaid expenses and other current assets	820	843	451	4,502	—	383	6,999
Total current assets	2,732	4,540	2,155	10,081	1,957	19,747	41,212
Property and equipment, net	566	310	76	321	—	290	1,563
Other assets	8	—	1	348	—	—	357
Total assets	$ 3,306	$ 4,850	$ 2,232	$ 10,750	$ 1,957	$ 20,037	$ 43,132
Liabilities:							
Current liabilities:							
Accounts payable	$ 1,338	$ 1,814	$ 420	$ 2,625	$ 836	$ 2,621	$ 9,654
Accrued compensation and benefits	278	31	247	1,204	—	750	2,510
Accrued research and development liabilities	82	99	145	3,151	32	2,469	5,978
Other accrued liabilities	171	10	134	267	—	117	699
Total current liabilities	1,869	1,954	946	7,247	868	5,957	18,841
Other liabilities	—	—	—	159	—	24	183
Total liabilities	$ 1,869	$ 1,954	$ 946	$ 7,406	$ 868	$ 5,981	$ 19,024

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. Going forward, BridgeBio may not provide any further investment in certain of these VIEs.

6. Noncontrolling Interests

As of June 30, 2019, the Company has 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 members' deficit and as part of members' deficit, respectively, in "Redeemable convertible noncontrolling interests" and "Noncontrolling interests" in the condensed consolidated balance sheets.

The Company adjusts 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 three and six months ended June 30, 2019, such adjustments in the aggregate amounts of $25.4 million and $28.4 million are recorded to accumulated deficit. During the three and six months ended June 30, 2018, such adjustments in the aggregate amounts of $56.2 million and $60.1 million are recorded to accumulated deficit. All such adjustments are disclosed within the "Transfers to (from) noncontrolling interest" line item in the Condensed Consolidated Statements of Redeemable Convertible Preferred Units, Redeemable Founder Units, Redeemable Common Units, Management Incentive Units, Redeemable Convertible Noncontrolling Interests and Members' Deficit.

The following table provides a rollforward of the redeemable convertible noncontrolling interests balance, as follows:

	Orfan	QED	Total
		(in thousands)	
Balance as of December 31, 2018	$ 8	$ 114	$ 122
Net loss attributable to redeemable convertible noncontrolling interest	(34)	(756)	(790)
Transfers to redeemable convertible noncontrolling interest	57	813	870
Balance as of March 31, 2019	31	171	202
Net loss attributable to redeemable convertible noncontrolling interest	(23)	(662)	(685)
Transfers to redeemable convertible noncontrolling interest	47	611	658
Balance as of June 30, 2019	$ 55	$ 120	$ 175

The following table provides a rollforward of the noncontrolling interests balance:

	Adrenas	Aspa	Eidos	PTR	Venthera	All Other	Total
				(in thousands)			
Balance as of December 31, 2018	$ 217	$ 245	$ 58,185	$ 2,728	$ 449	$ 537	$ 62,361
Issuance of noncontrolling interest	2	2	1,027	34	1	254	1,320
Transfers to (from) noncontrolling interest	874	472	(337)	(10)	(1)	1,100	2,098
Net loss attributable to noncontrolling interest	(451)	(222)	(4,365)	(1,580)	(192)	(651)	(7,461)
Balance as of March 31, 2019	642	497	54,510	1,172	257	1,240	58,318
Issuance (repurchase) of noncontrolling interest	3	2	(27,030)	—	—	1	(27,024)
Transfers to (from) noncontrolling interest	32	208	23,751	4	273	514	24,782
Net loss attributable to noncontrolling interest	(554)	(471)	(5,200)	(552)	(353)	(555)	(7,685)
Balance as of June 30, 2019	$ 123	$ 236	$ 46,031	$ 624	$ 177	$ 1,200	$ 48,391

7. 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, the Company increased its 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 with LEO, 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. The Company accounts for the LEO Call Option as a current liability in its condensed 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. The Company will remeasure the LEO Call Option to fair value at each subsequent condensed consolidated 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 the Company's 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.

Subsequent to the deconsolidation of PellePharm, BridgeBio accounted for its retained common stock investment as an equity method investment and its retained preferred stock investment as a cost method investment. As of June 30, 2019 and December 31, 2018, the aggregate carrying amount of the Company's equity method investment in PellePharm was zero and $0.2 million. As of June 30, 2019 and December 31, 2018, the aggregate carrying amount for the Company's cost method investment in PellePharm was $7.5 million and $16.8 million. 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 62%. The carrying amount of BridgeBio's investment in PellePharm in the condensed consolidated balance sheets represents its maximum loss exposure related to its VIE investment in PellePharm.

8. Commitments and Contingencies

On December 31, 2018, Children Hospital Research Center at Oakland ("CHRCO") filed, but did not serve, a civil complaint against Dr. Ervin Epstein, Co-Founder and Chief Medical Officer of PellePharm and PellePharm in the Northern District of California. CHRCO asserts four causes of action against Dr. Epstein (conversion, breach of contract, breach of the implied covenant of good faith and fair dealing, and specific performance), and one related cause of action against PellePharm (constructive trust). All five causes of action are generally directed to a set of accusations relating to Dr. Epstein's prior employment at CHRCO. In its complaint, CHRCO seeks monetary damages as well as equitable relief in the form of a constructive trust and an injunction. CHRCO has since withdrawn its complaint in the Northern District of California and filed, and as of May 16, 2019, has not yet served a revised civil complaint against PellePharm and Dr. Epstein in the Superior Court of the State of California, County of San Francisco, asserting the same five causes of action. On April 11, 2019, CHRCO filed an unopposed ex parte application with the Court to extend the deadline to serve the complaint to June 11, 2019. Dr. Epstein and PellePharm dispute all of CHRCO's allegations and believe they lack merit and they intend to contest the case vigorously. No responsive pleading is required at this time, nor has Dr. Epstein or PellePharm provided one.

From time to time, the Company may become involved in legal proceedings arising in the ordinary course of business. The Company is unable to predict the outcome of these matters or the ultimate legal and financial liability, and at this time cannot reasonably estimate the possible loss or range of loss and accordingly has not accrued a related liability.

9. Hercules Term Loan

Hercules Loan and Security Agreement

In June 2018, the Company executed a Loan and Security Agreement with Hercules Capital, Inc. ("Hercules"), under which the Company 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. 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 4.35% and (ii) 9.35% (9.85% as of June 30, 2019 based on the prime rate as of that date), payable monthly.

In December 2018, the Company executed the First Amendment to the Loan and Security Agreement, whereby the Company 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") and the maturity date for the entire facility was July 1, 2022 (the "Amended Maturity Date"). 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 3.35% and (ii) 9.10% (9.10% as of June 30, 2019), payable monthly.

In May 2019, the Company executed the Second Amendment to the Loan and Security Agreement whereby the Company borrowed an additional $20.0 million ("Tranche III") to increase the total principal balance outstanding to $75.0 million (the "Amended Hercules Term Loan"). 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 June 30, 2019), payable monthly. The outstanding balance of the Amended Hercules Term Loan is to be repaid monthly beginning on the Amended Amortization Date and extending through the Amended Maturity Date.

During the three and six months ended June 30, 2019, the Company recognized interest expense related to the Amended Hercules Term Loan of $1.9 million and $3.6 million, of which $0.3 million and $0.7 million relate to amortization of debt discount. No material interest expense was recognized in relation to Hercules Term Loan during the six months ended June 30, 2018.

10. 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. During the three and six months ended June 30, 2019, Eidos recognized research and development expense of zero and $0.2 million in connection with this agreement.

The University of Texas License Agreement

In March 2017, Navire entered into a collaboration and license agreement with The Board of Regents of The University of Texas System ("Board of Regents") and The University of Texas M.D. Anderson Cancer Center ("MD Anderson" and collectively "University of Texas") relating to Navire's drug discovery and development initiatives. Under this agreement, Navire and the University of Texas will carry out the development, manufacture and commercialization of licensed product under exclusive licenses granted by the University of Texas. The Company issued the Board of Regents shares of common stock of Navire valued at zero and $0.2 million during the three and six months ended June 30, 2019 that was recognized as research and development expense. During the three and six months ended June 30, 2019, Navire recognized additional research and development expense of $0.5 million and $1.0 million in connection with this agreement.

The Regents of the University of California License Agreement

In September 2016, TheRas, Inc. ("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"). Nominal expense was recognized in connection with this agreement during the three and six months ended June 30, 2019.

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 three and six months ended June 30, 2019, TheRas recognized research and development expenses of $0.4 million and $0.6 million in connection with the Leidos Agreements.

St. Jude License Agreement

In April 2017, CoA entered into a license agreement with St. Jude Children's Research Hospital, Inc., ("St. Jude") relating to CoA's drug discovery and development initiatives. Under this agreement, CoA has been granted a worldwide exclusive license to use a licensed compound. During the three and six months ended June 30, 2019, CoA recognized research and development expense of $0.2 million and $0.3 million in connection with this agreement.

K-Gen License Agreement

In March 2018, Ferro entered into a license agreement with K-Gen, Inc. ("K-Gen") relating to Ferro's drug discovery and development initiatives. Under this agreement, Ferro has been granted certain worldwide exclusive licenses to use the licensed compounds. Nominal expense was recognized in connection with this agreement during the three and six months ended June 30, 2019.

Memorial Sloan Kettering Cancer Center License Agreement

In April 2018, Venthera Inc. ("Venthera") entered into a license agreement with Memorial Sloan Kettering Cancer Center ("MSK") relating to Venthera's drug discovery and development initiatives. Under this agreement, Venthera has been granted certain worldwide exclusive licenses to use the licensed products. No expense was recognized in connection with this agreement during the three and six months ended June 30, 2019.

University of Massachusetts License Agreement

In April 2018, Aspa entered into a license agreement with the University of Massachusetts ("UM") relating to Aspa's drug discovery and development initiatives. Under this agreement, Aspa has been granted certain worldwide exclusive licenses to use the licensed compounds. During the three and six months ended June 30, 2019, Aspa recognized nominal research and development expense in connection with this agreement.

NeuroVive License Agreement

In June 2018, Fortify Therapeutics, Inc. ("Fortify") entered into a license agreement with NeuroVive Pharmaceutical AB ("NeuroVive") relating to Fortify's drug discovery and development initiatives. Under this agreement, Fortify has been granted certain worldwide exclusive licenses to use the licensed compounds. During the three and six months ended June 30, 2019, Fortify recognized nominal research and development expense in connection with this agreement.

Life License Agreement

In August 2018, BridgeBio entered into a license agreement with Life Technologies Corporation ("Life") relating to Adrenas' and Aspa's drug discovery and development initiatives. Under this agreement, BridgeBio, Adrenas and Aspa have been granted certain worldwide non-exclusive licenses to use the licensed compounds. During the three and six months ended June 30, 2019, Aspa recognized research and development expense of $0.4 million and $0.4 million in connection with this agreement.

Unnamed Entity #1 License Agreement

In December 2018, Unnamed Entity #1 entered into a license agreement relating to its drug discovery and development initiatives. Under this agreement, Unnamed Entity #1 has been granted certain worldwide exclusive licenses to use the licensed compounds. No expense was recognized in connection with this agreement during the three and six months ended June 30, 2019.

Foundation Medicine Diagnostics Agreement

In November 2018, QED and Foundation Medicine, Inc. ("FMI") entered into a diagnostics agreement relating to QED's drug discovery and development initiatives. During the three and six months ended June 30, 2019, QED recognized research and development expenses of $0.3 million and $0.3 million in connection with this agreement.

Other License and Collaboration Agreements

In addition to the agreements described above, the Company has 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.

11. Asset Acquisitions

Unnamed Entity #2 Asset Acquisition

In June 2019, Unnamed Entity #2 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. Unnamed Entity #2 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, in-process research and development ("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 $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, Unnamed Entity #2 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.

Phoenix Tissue Repair, Inc. ("PTR") 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.

During the three and six months ended June 30, 2019, PTR made a milestone payment of zero and $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.

If certain substantive milestones are met in the future, PTR could be required to pay up to $25.0 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.

12. Related Party Transactions

Nonrecourse Notes

In 2016 and 2017 the Company entered into nonrecourse notes (the "Notes") with two founders. The Notes were issued to facilitate the purchase of Series B Preferred Units by two founders. The principal amount of the Notes was $0.3 million and mature in May 2021. The Notes were accounted for as an option for which the Company recognized equity-based compensation expense on issuance. The repayment of the Notes is recorded as an addition to the Series B Preferred Units balance as payments are received and the Notes were paid in full in February 2019.

PellePharm

During the three and six months ended June 30, 2019, the Company provided nominal services to PellePharm.

13. Redeemable Convertible Preferred Units, Founder Units, Common Units and Management Incentive Units

As of June 30, 2019, the Fourth Amended and Restated Limited Liability Company Agreement provided for the issuance of Series A Preferred Units, Series B Preferred Units, Series C Preferred Units, Series D Preferred Units, Founder Units, Common Units and Management Incentive Units.

Outstanding Preferred Units, Founder Units and Common Units consist of the following:

	Units Issued and Outstanding	Original Issue Price Per Unit	Carrying Value	Liquidation Preference
	(in thousands, except unit and per unit amounts)			
Series A Preferred Units	24,935,281	$ 0.2627	$ 4,919	$ 13,542
Series B Preferred Units	90,909,090	$ 0.4400	39,945	47,096
Series C Preferred Units	141,155,758	$ 0.9656	135,482	147,155
Series D Preferred Units	150,955,597	$ 1.9823	298,698	299,239
Total Preferred Units as of June 30, 2019	407,955,726		479,044	507,032
Founder Units	11,420,741	$ —	1,754	6,202
Common Units	7,868,637	$ —	1,672	4,274
Total outstanding units as of June 30, 2019	427,245,104		$ 482,470	$ 517,508

	Units Issued and Outstanding	Original Issue Price Per Unit	Carrying Value	Liquidation Preference
	(in thousands, except unit and per unit amounts)			
Series A Preferred Units	24,935,281	$ 0.2627	$ 4,919	$ 13,542
Series B Preferred Units	90,909,090	$ 0.4400	39,766	47,096
Series C Preferred Units	141,155,758	$ 0.9656	135,482	147,155
Series D Preferred Units	150,955,597	$ 1.9823	298,698	299,239
Total Preferred Units as of December 31, 2018	407,955,726		478,865	507,032
Founder Units	11,420,741	$ —	1,754	6,202
Common Units	7,197,783	$ —	1,619	3,910
Total outstanding units as of December 31, 2018	426,574,250		$ 482,238	$ 517,144

As of June 30, 2019 and December 31, 2018, BridgeBio has classified all of its outstanding Preferred Units, Founder Units, Common Units, and Management Incentive Units outside of members' deficit in the accompanying condensed consolidated financial statements because these units contain certain redemption features that are not solely within the control of BridgeBio. Specifically, in the event an IPO does not take place by a pre-defined date, the majority preferred unitholders could force a "liquidation event" that is not solely within BridgeBio's control. The Company did not adjust the carrying values of the Preferred Units, Founder Units and Common Units to their deemed liquidation values of such units since a liquidation event was not probable as of June 30, 2019 and December 31, 2018.

As discussed in Note 17, immediately prior to the closing of the IPO on July 1, 2019, holders of units of BridgeBio Pharma LLC exchanged all such units for an aggregate of 99,999,967 shares of common stock of the Corporation. At the completion of the Reorganization, there were no units outstanding.

MyoKardia Distribution

In April 2015, the Company acquired an interest in MyoKardia, Inc. for $1.0 million. This investment was subsequently disposed of in 2016 and the Company recognized a gain on disposal of $1.2 million in the year ended December 31, 2016. Prior to the execution of the merger of BridgeBio and BridgeBio LLC in June 2017, the Company distributed $1.2 million to its members in proportion to the number of units then outstanding and was required to distribute the remaining proceeds of $1.0 million. This liability is included in accrued distributions to unitholders in the condensed consolidated balance sheet as of December 31, 2018. The accrued distributions of $1.0 million were paid to unitholders in February 2019.

14. Equity-Based Compensation

The Company recorded equity-based compensation in the following expense categories in its condensed consolidated statements of operations for employees and non-employees:

	Six Months Ended June 30, 2019			
	BridgeBio	Eidos	Other	Total
		(in thousands)		
Research and development	$ —	$ 1,004	$ 19	$ 1,023
General and administrative	3,355	1,126	17	4,498
Total equity-based compensation	$ 3,355	$ 2,130	$ 36	$ 5,521

	Six Months Ended June 30, 2018			
	BridgeBio	Eidos	Other	Total
		(in thousands)		
Research and development	$ —	$ 620	$ 62	$ 682
General and administrative	646	386	54	1,086
Total equity-based compensation	$ 646	$ 1,006	$ 116	$ 1,768

For the three and six months ended June 30, 2019, total BridgeBio equity-based compensation from Common Units was less than $0.1 million and $0.1 million, and from Management Incentive Units was $2.1 million and $3.3 million.

For the three and six months ended June 30, 2018, total BridgeBio equity-based compensation from Common Units was less than $0.1 million and $0.1 million, and from Management Incentive Units was $0.3 million and $0.6 million.

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:

	Six Months Ended June 30,	
	2019	2018
Expected term (in years)	1.50	0.75-1.50
Expected volatility	48.0%-49.0%	40.0%-45.0%
Risk-free interest rate	2.34%-2.56%	1.70%-2.22%
Dividend yield	—	—

BridgeBio had 9,098,522 authorized Common Units at June 30, 2019 and December 31, 2018. The following table summarizes BridgeBio's Common Units activity:

	Number of Common Units Outstanding	Weighted-Average Grant Date Fair Value
Balance as of December 31, 2018	7,197,783	$ 0.08
Vested	670,854	$ 0.08
Balance as of June 30, 2019	7,868,637	$ 0.08

As of June 30, 2019, there were 1,229,885 unvested Common Units and total unrecognized compensation related to the unvested Common Units was $0.1 million, which the Company expects to be recognized over a weighted-average period of 0.9 years. All unvested Common Units as of June 30, 2019 will vest through May 2020.

The following table summarizes BridgeBio's authorized Management Incentive Units activity:

	Number of Authorized Units
Balance as of December 31, 2018	48,695,602
Authorized and granted	24,111,064
Cancelled	(5,000)
Balance as of June 30, 2019	72,801,666

The following table summarizes BridgeBio's vested Management Incentive Units activity:

	Number of Management Incentive Units Outstanding	Weighted-Average Grant Date Fair Value
Balance as of December 31, 2018	19,117,628	$ 0.08
Vested	6,460,380	$ 0.36
Balance as of June 30, 2019	25,578,008	$ 0.14

As of June 30, 2019, there were 47,223,658 unvested Management Incentive Units and unrecognized compensation related to the unvested Management Incentive Units was $30.1 million, which the Company expects to recognize over a weighted-average period of 4.0 years. All unvested Management Incentive Units as of June 30, 2019 will vest through February 2024.

Eidos

Common stock

Eidos has reserved shares of common stock for issuance as follows:

	As of June 30,	
	2019	2018
Options issued and outstanding	1,454,461	881,612
Options available for future grants	537,345	490,360
Eidos ESPP shares available for future grants	104,540	143,520
Total	2,096,346	1,515,492

Stock options

The following table summarizes Eidos's stock option activity for the six months ended June 30, 2019:

	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
Granted	(209,712)	209,712	$ 27.22		
Exercised	—	(85,013)	$ 1.32		
Outstanding as of June 30, 2019	537,345	1,454,461	$ 11.66	9.07	$ 28,246
Vested and expected to vest as of June 30, 2019		251,447	$ 6.26	8.69	$ 6,240
Exercisable as of June 30, 2019		1,454,461	$ 11.66	9.07	$ 28,246

Employee stock options valuation

The fair value of employee and non-employee director stock option awards was estimated at the date of grant using a Black-Scholes option-pricing model with the following assumptions:

	Six Months Ended June 30,	
	2019	2018
Expected term (in years)	6.07	6.08
Expected volatility	72.31%	69.59%
Risk-free interest rate	2.10%	2.78%
Dividend yield	—	—
Weighted average fair value of share-based awards granted	$ 18.22	$ 7.50

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 the stock options granted to non-employees was calculated at each reporting date using the Black-Scholes option-pricing model with the following assumptions:

	Six Months Ended June 30,	
	2019	2018
Expected term (in years)	6.08	9.70
Expected volatility	73.54%	68.31%
Risk-free interest rate	2.74%	2.84%
Dividend yield	—	—

During the three and six months ended June 30, 2019 and 2018, Eidos granted 0, 18,500, 35,880 and 35,880 shares, respectively, to non-employee consultants. Eidos recognized stock-based compensation expense for non-employee awards during the three and six months ended June 30, 2019 and 2018 of $0.1 million and $0.1 million, and $0.1 million and $0.2 million, respectively.

Stock-based compensation

As of June 30, 2019, there was $12.5 million of total unrecognized compensation cost related to unvested equity-based compensation arrangements under the Eidos 2016 Equity Incentive Plan and Eidos 2018 Stock Option and Incentive Plan. The unrecognized equity-based compensation cost is expected to be recognized over a weighted-average period of 2.66 years.

15. Income Taxes

BridgeBio is a "pass-through" entity under the Internal Revenue Code of 1986, as amended (the "Code") and the members are taxed directly on their respective ownership interests in the condensed consolidated income. Therefore, no provision or liability for federal income tax has been included in the accompanying condensed consolidated financial statements related to BridgeBio. Upon conversion to a corporation, the Company will become subject to U.S. federal and state income taxes.

The Company's tax provision and the resulting effective tax rate for interim periods is determined based upon its estimated annual effective tax rate adjusted for the effect of discrete items arising in that quarter.

The Company's policy is to recognize interest and penalties associated with uncertain tax benefits as part of the income tax provision and include accrued interest and penalties with the related income tax liability on the consolidated balance sheet. To date, the Company has not recognized any interest and penalties in its consolidated statements of operations, nor has it accrued for or made payments for interest and penalties. The Company's unrecognized gross tax benefits would not reduce the estimated annual effective tax rate if recognized because it has recorded a full valuation allowance on its deferred tax assets.

16. Net Loss per Unit

The following outstanding units were excluded from the computation of the diluted net loss per unit for the periods presented because their effect would have been anti-dilutive.

	June 30,	
	2019	2018
Preferred Units	407,955,726	257,000,129
Management Incentive Units	72,801,666	45,678,102
Unvested Common Units	1,229,885	2,571,593
Total	481,987,277	305,249,824

17. Subsequent Events

Initial Public Offering

On July 1, 2019, the Corporation completed 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 $366.3 million from the IPO, after deducting underwriters' discounts and commissions of $28.0 million and deferred offering costs of $6.5 million.

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. On July 1, 2019, upon execution of the Reorganization, all outstanding units of BridgeBio Pharma, LLC were cancelled and exchanged for shares of common stock of the Corporation, as shown in the below table:

BridgeBio Pharma, LLC unit class	Number of BridgeBio Pharma, Inc. 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

The unvested outstanding Management Incentive Units and Common Units of BridgeBio Pharma LLC were exchanged for shares of the Corporation's restricted common stock. Such unvested restricted shares are subject to the same time-based vesting conditions as the vesting terms and conditions of the original Management Incentive Units and Common Units.

On July 1, 2019, Merger Sub LLC was merged with and into BridgeBio Pharma 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.

Hercules Loan and Security Agreement

Following the completion of the IPO on July 1, 2019, the terms of the Amended Hercules Term Loan were amended as follows: (i) a six month interest-only extension to July 1, 2021, (ii) a six month maturity extension to January 1, 2023, (iii) a reduction of 0.5% on the effective interest rate on Tranches I and II, and (iv) the 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.

Significant financing events in relation to controlled VIEs

Subsequent to June 30, 2019, BridgeBio made an additional investment in QED of $40.0 million, PTR of $7.0 million, Aspa of $3.6 million, Adrenas of $3.6 million and Fortify of $1.5 million.

Other financing events

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 July 2019, BridgeBio purchased preferred stock of a biopharmaceutical entity for $7.0 million. BridgeBio may be required to purchase additional shares of preferred stock of up to $24.5 million upon achievement of certain development milestones by the biopharmaceutical entity.

Item 2. 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 our condensed financial statements and related notes included in this Quarterly Report on Form 10-Q and our audited combined and consolidated financial statements and related notes thereto for the year ended December 31, 2018, included in our prospectus dated June 26, 2019 (the "Prospectus"), as filed with the Securities and Exchange Commission (the "SEC"), pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended, (the "Securities Act"), relating to our Registration Statements on Form S-1 (File Nos. 333-231759 and 333-232376).

This Quarterly Report on Form 10-Q 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 Quarterly Report on Form 10-Q and the Prospectus. The forward-looking statements in this Quarterly Report on Form 10-Q represent our views as of the date of this Quarterly Report on Form 10-Q. 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 Quarterly Report on Form 10-Q.

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 15 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 four product candidates in clinical trials that, if positive, we believe could support the filing of an application for marketing authorization. Two of these product candidates are in Phase 3 clinical trials, one is in a Phase 2/3 clinical trial, and one is in a Phase 2 clinical trial.

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 IPO, we engaged in a series of transactions whereby BridgeBio Pharma LLC became a wholly-owned subsidiary of BridgeBio Pharma, Inc. As part of the transactions, holders of Preferred Units, Founder Units, Common Units and Management Incentive Units of BridgeBio Pharma LLC exchanged all such units for an aggregate of 99,999,967 shares of common stock of BridgeBio Pharma, Inc.

As of June 30, 2019, we had cash and cash equivalents of $293.8 million, of which $112.4 million was held at BridgeBio and $131.4 million at Eidos. On July 1, 2019, we completed an 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. In July 2019, we received net proceeds of approximately $366.3 million from the IPO, after deducting underwriters' discounts and commissions of $28.0 million and estimated offering costs of $6.5 million.

Since our inception, we have incurred significant operating losses. For the years ended December 31, 2018 and 2017, we incurred net losses of $169.5 million and $43.8 million. For the three months ended June 30, 2019 and 2018, we incurred net losses of $74.3 million and $35.7 million, and for the six months ended June 30, 2019 and 2018, we incurred net losses of $143.7 million and $78.1 million. We had an accumulated deficit as of June 30, 2019 of $326.1 million. 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.

The following table summarizes our results of operations for the three and six months ended June 30, 2019:

	Three Months Ended June 30, 2019			Six Months Ended June 30, 2019		
	Eidos (1)	Other BridgeBio Operations	Total	Eidos (1)	Other BridgeBio Operations	Total
	(in thousands)					
Operating expenses:						
Research and development	$ 12,311	$ 40,020	$ 52,331	$ 20,899	$ 76,285	$ 97,184
General and administrative	1,723	15,195	16,918	5,758	30,059	35,817
Total operating expenses	14,034	55,215	69,249	26,657	106,344	133,001
Loss from operations	(14,034)	(55,215)	(69,249)	(26,657)	(106,344)	(133,001)
Other income (expense), net:						
Interest income	790	872	1,662	1,644	2,125	3,769
Interest expense	—	(1,941)	(1,941)	—	(3,612)	(3,612)
Loss from PellePharm	—	(4,956)	(4,956)	—	(9,555)	(9,555)
LEO call option income (expense)	—	226	226	—	(1,288)	(1,288)
Other income (expense)	(49)	42	(7)	(52)	38	(14)
Total other income (expense), net	741	(5,757)	(5,016)	1,592	(12,292)	(10,700)
Net loss and comprehensive loss	$ (13,293)	$ (60,972)	$ (74,265)	$ (25,065)	$ (118,636)	$ (143,701)

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

The following table summarizes our cash flows for the six months ended June 30, 2019:

	Six months ended June 30, 2019		
	Eidos	Other BridgeBio Cash Flows	Total
	(in thousands)		
Net cash used in operating activities	$ (26,132)	$ (101,256)	$ (127,388)
Net cash used in investing activities	(35)	(2,975)	(3,010)
Net cash provided by (used in) financing activities	420	(12,040)	(11,620)
Net decrease in cash and cash equivalents	(25,747)	(116,271)	(142,018)
Cash, cash equivalents and restricted cash, beginning of Period	157,147	279,098	436,245
Cash, cash equivalents and restricted cash, end of period	$ 131,400	$ 162,827	$ 294,227

In the tables above, we have elected to present the results of operations and cash flows of Eidos separately from those of our other operations because Eidos is a public company subject to public reporting requirements under the Securities Exchange Act of 1934, as amended (since June 2018).

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 three and six months ended June 30, 2018, we recorded $0.7 million and $1.3 million in other income (expense) in the condensed 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 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. Subsequent to the Eidos IPO and through June 30, 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 condensed 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 was $1.9 million and increased to $4.3 million as of June 30, 2019. We will remeasure the LEO Call Option to fair value at each subsequent consolidated 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 PellePharm under the equity method and cost method.

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 condensed consolidated balance sheets. Losses attributed to redeemable convertible noncontrolling interests and noncontrolling interests are reported separately in our condensed consolidated statements of operations and comprehensive loss.

Financial Operations Overview

Revenue

To date, we have not generated any revenue from product sales and do not expect to generate any revenue from the sale of products in the foreseeable future. If our development efforts for our product candidates are successful and result in regulatory approval, we may generate revenue in the future from product sales. We cannot predict if, when, or to what extent we will generate revenue from the commercialization and sale of our product candidates. We may never succeed in obtaining regulatory approval for any of our product candidates.

Operating Expenses

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for our research activities, including our drug discovery efforts, and the development of our product candidates, which include:

- employee-related expenses, including salaries, related benefits, equity-based compensation and travel expenses for employees engaged in research and development functions;
- expenses incurred in connection with the preclinical and clinical development of our product candidates, including under agreements with contract research organizations, or CROs;
- the cost of consultants and contract manufacturing organizations, or CMOs, that manufacture drug products for use in our preclinical studies and clinical trials;
- facilities, depreciation and amortization, insurance and other direct and allocated expenses incurred as a result of research and development activities; and
- payments made under third-party licensing and asset acquisition agreements.

We expense research and development costs as incurred. Nonrefundable advance payments that we make for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. The prepaid amounts are expensed as the related goods are delivered or the services are performed.

Our direct research and development costs are tracked on a program-by-program basis and consist primarily of external costs, such as fees paid to consultants, contractors, CMOs and CROs in connection with our preclinical and clinical development activities. 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 direct research and development expenses for that program. 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:

	Three months ended June 30,		Six months ended June 30,	
	2019	2018	2019	2018
	(in thousands)		(in thousands)	
BBP-265 (Eidos)(1)	$ 12,311	$ 6,196	$ 20,899	$ 11,847
BBP-831 (QED)	17,086	2,800	31,813	21,164
BBP-631 (Adrenas)	4,414	1,266	8,105	1,733
BBP-454 (TheRas)	1,139	820	2,134	1,390
BBP-009 (PellePharm)(2)	—	5,232	—	8,881
Other Programs	17,381	7,578	34,233	12,708
Total	$ 52,331	$ 23,892	$ 97,184	$ 57,723

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

(2) Results for PellePharm are not disclosed subsequent to the deconsolidation date in November 2018.

We have separately provided additional detail for the research and development expenses incurred in connection with the research and development activities conducted for the product candidates being developed by Eidos, QED, Adrenas, and TheRas, certain of our consolidated entities, as we believe they represent key portfolio value drivers. We have provided additional detail for BBP-009 (PellePharm) as it is the first of our product candidates for which a third party has provided research and development funding and secured an option to acquire. Subsequent to the LEO Agreement through which LEO has obtained the irrevocable option to acquire PellePharm, PellePharm is accounted for as an equity method and cost method investment and we record our percentage of the net income/loss associated with our percentage of PellePharm ownership. Expenses for other programs in the table above represent the research and development expenses incurred by us in connection with research on our programs conducted by all of our other consolidated entities.

We are heavily dependent on the success of our product candidates, many of which are in preclinical or the early stages of 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.

Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect that our research and development expenses will increase substantially in connection with our planned clinical and preclinical development activities in the near term and in the future. In particular, we expect to incur significant near-term research and development expenses in connection with our ongoing Phase 3 clinical trial of BBP-265 in ATTR-CM, our planned Phase 3 clinical trial of BBP-265 in ATTR-PN and our planned Phase 3 clinical trials for BBP-831 in advanced cholangiocarcinoma as a first-line therapy and adjuvant urothelial carcinoma.

General and Administrative Expenses

Our general and administrative costs consist primarily of employee-related costs, travel expenses, expenses for outside professional services, including legal, human resource, audit, accounting and tax services, and allocated facilities-related costs. Employee-related costs include salaries, related benefits and equity-based compensation expense. We expect to incur additional expenses as a result of operating as a public company, including expenses related to compliance with the rules and regulations of the SEC and listing standards applicable to companies listed on a national securities exchange, additional insurance expenses, investor relations activities and other administrative and professional services. We also expect to increase the size of our administrative, finance and legal functions to support the anticipated growth of our business.

For the three months and six months ended June 30, 2019, our general and administrative expenses were $16.9 million and $35.8 million, of which $1.7 million and $5.8 million were related to Eidos. For the three months and six months ended June 30, 2018, our general and administrative expenses were $10.9 million and $18.9 million of which $1.9 million and $4.2 million were related to Eidos.

Other Income (Expense), Net

Interest Income

Interest income consists of interest income earned on our cash and cash equivalents.

Interest Expense

Interest expense consists primarily of interest expense incurred under our term loans with Hercules Capital, Inc., or Hercules.

Loss from PellePharm

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 period ended March 31, 2019, we recognize our percentage of net losses consistent with our preferred stock ownership percentage.

LEO Call Option Income (Expense)

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 consolidated balance sheet date until the LEO Call Option is either exercised or expires.

Other Expense

Other expense 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

BridgeBio Pharma LLC is a “pass-through” entity under the Internal Revenue Code of 1986, as amended, or the Code, and the members are taxed directly on their respective ownership interests in the condensed consolidated income. Therefore, no provision or liability for federal income tax has been included in our condensed consolidated financial statements. For our consolidated entities, income taxes are accounted for under the asset and liability method. Under this method, deferred income tax assets and liabilities are determined based upon the difference between the condensed 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.

Upon the Reorganization, we will become subject to typical corporate U.S. federal and state income taxation. To the extent we incur operating losses in future 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.

Net Loss Attributable to Redeemable Convertible Noncontrolling Interests and Noncontrolling Interests

Net loss attributable to noncontrolling interests in our condensed consolidated statements of operations is a result of our investments in our consolidated entities, which include PellePharm, Inc. (through November 2018), Eidos Therapeutics, Inc., QED Therapeutics, Inc., Adrenas Therapeutics, Inc., Orfan Biotech, Inc., Venthera, Inc., Aspa Therapeutics, Inc., Phoenix Tissue Repair, Inc., Quartz Therapeutics, Inc., Navire Pharma, Inc., Ferro Therapeutics, Inc., Dermecular Therapeutics, Inc., Molecular Skin Therapeutics, Inc., CoA Therapeutics, Inc. and Origin Biosciences, Inc. and 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.

Critical Accounting Polices and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with United States generally accepted accounting principles. The preparation of these condensed 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 condensed consolidated financial statements, as well as 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.

There have been no significant changes in our critical accounting policies and estimates as compared to the critical accounting policies and estimates disclosed in the section titled "Management's Discussion and Analysis of Financial Condition and Operations" included in the Prospectus.

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 condensed 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) the last day of our first fiscal year in which we have total annual gross revenues of $1.07 billion or more, (ii) the last day of the fiscal year following the fifth anniversary of completion of our IPO, (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.

Recent Accounting Pronouncements

See Note 2, "Summary of Significant Accounting Policies—Recently Adopted Accounting Pronouncements" to our unaudited condensed consolidated financial statements appearing under Part 1, Item 1 for more information.

Results of Operations

Three Months Ended June 30, 2019 and 2018

	Three months ended June 30,			
	2019	2018	Increase/ (Decrease)	% Change
	(in thousands)			
Operating expenses:				
Research and development	$ 52,331	$ 23,892	$ 28,439	119%
General and administrative	16,918	10,891	6,027	55%
Total operating expenses	69,249	34,783	34,466	99%
Loss from operations	(69,249)	(34,783)	(34,466)	99%
Other income (expense), net:				
Interest income	1,662	2	1,660	*
Interest expense	(1,941)	(205)	(1,736)	847%
Loss from PellePharm	(4,956)	—	(4,956)	*
LEO call option income	226	—	226	*
Other expense	(7)	(716)	709	(99)%
Total other income (expense), net	(5,016)	(919)	(4,097)	446%
Net loss and comprehensive loss	(74,265)	(35,702)	(38,563)	108%
Net loss attributable to redeemable convertible noncontrolling interests and noncontrolling interests	8,370	9,151	(781)	(9)%
Net loss and comprehensive loss attributable to us	$ (65,895)	$ (26,551)	$ (39,344)	148%

* *Not meaningful*

Research and Development Expenses

Research and development expenses increased by $28.4 million to $52.3 million for the three months ended June 30, 2019, from $23.9 million for the same period in 2018, largely attributable to an increase in the number of product candidates under development increasing and the initiation of more clinical trials as compared to the prior period. The increase was primarily comprised of a $4.3 million increase in clinical development costs for our product candidates, a $6.6 million increase in salaries and employee-related benefits, a $6.1 million increase in allocated facility and other expenses, and a $13.4 million increase in development and drug discovery efforts for our research programs. This increase was partially offset by a $1.4 million decrease in professional and consulting services to advance our product candidates, and a $0.6 million decrease in license fees.

General and Administrative Expenses

General and administrative expenses increased by $6.0 million to $16.9 million for the three months ended June 30, 2019, from $10.9 million for the same period in 2018, largely due to our operations expanding as we added more controlled entities and development programs and as we prepared to become a public company. The increase was primarily comprised of a $3.8 million increase in salaries and employee-related benefits, a $2.2 million increase in equity-based compensation expense resulting from management incentive units and common units granted by us and from equity-based awards granted to employees of consolidated entities, a $1.3 million increase in patent fees, and a $0.3 million increase in allocated facility and other expenses. This was partially offset by a $1.6 million decrease in legal fees.

Interest Income

Interest income for the three months ended June 30, 2019, primarily consisted of the interest earned on our investments in cash equivalents during the period. Interest income was not material for the same period in 2018.

Interest Expense

Interest expense for the three months ended June 30, 2019, primarily consisted of the interest accrued on the $75.0 million Hercules term loans drawn in June 2018, December 2018 and May 2019. Interest expense for the three months ended June 30, 2018, was primarily related to the PellePharm SVB Loan, prior to the deconsolidation of PellePharm in November 2018.

LEO Call Option Income

The LEO Call Option liability was recorded at fair value upon execution of the LEO Agreement in November 2018 and remeasured to fair value as of June 30, 2019, resulting in other income being recognized due to a reduction in the corresponding liability. There was no such liability subject to be recorded and remeasured as of or prior to June 30, 2018.

Loss from PellePharm

Due to the deconsolidation of PellePharm, we accounted for part of our remaining investment in PellePharm under the equity method and we recognized our share of PellePharm earnings or losses through June 30, 2019. PellePharm was a consolidated entity as of June 30, 2018 and as such no such gains or losses were recognized during the period.

Other Expense

Other expense for the three months ended June 30, 2018, consisted primarily of the change in fair value of the Eidos financial instruments issued and settled in 2018. Other expense was not material for the same period in 2019.

Six Months Ended June 30, 2019 and 2018

	Six months ended June 30,			
	2019	2018	Increase/ (Decrease)	% Change
	(in thousands)			
Operating expenses:				
Research and development	$ 97,184	$ 57,723	$ 39,461	68%
General and administrative	35,817	18,898	16,919	90%
Total operating expenses	133,001	76,621	56,380	74%
Loss from operations	(133,001)	(76,621)	(56,380)	74%
Other income (expense), net:				
Interest income	3,769	3	3,766	*
Interest expense	(3,612)	(212)	(3,400)	1,604%
Loss from PellePharm	(9,555)	—	(9,555)	*
LEO call option expense	(1,288)	—	(1,288)	*
Other expense	(14)	(1,302)	1,288	(99)%
Total other income (expense), net	(10,700)	(1,511)	(9,189)	608%
Net loss and comprehensive loss	(143,701)	(78,132)	(65,569)	84%
Net loss attributable to redeemable convertible noncontrolling interests and noncontrolling interests	16,621	17,425	(804)	(5)%
Net loss and comprehensive loss attributable to us	$ (127,080)	$ (60,707)	$ (66,373)	109%

* *Not meaningful*

Research and Development Expenses

Research and development expenses increased by $39.5 million to $97.2 million for the six months ended June 30, 2019, from $57.7 million for the same period in 2018, largely attributable to an increase in the number of product candidates under development increasing substantially as of June 30, 2018 to June 30, 2019 and the initiation of more clinical trials as compared to 2018. The increase was primarily comprised of a $5.7 million increase in professional and consulting services to advance our product candidates, a $10.0 million increase in clinical development costs for our product candidates, a $17.0 million increase in development and drug discovery efforts for our research programs, a $11.9 million increase in salaries and employee-related benefits, a $10.1 million increase in allocated facility and other expenses and a $0.3 million increase in equity-based compensation expense resulting from equity-based awards granted to employees of consolidated entities. This increase was partially offset by a $15.3 million decrease in license fees to acquire various technologies, as in early 2018 we had significant asset acquisitions, and $0.2 million in legal fees.

General and Administrative Expenses

General and administrative expenses increased by $16.9 million to $35.8 million for the six months ended June 30, 2019, from $18.9 million for the same period in 2018, largely due to our operations expanding as we added more controlled entities and development programs. The increase was primarily comprised of a $5.2 million increase in professional and consulting services such as administrative, accounting, finance, human resources and information technology services, a $1.0 million increase in allocated facility and other expenses, a $7.2 million increase in salaries and employee-related benefits, a $1.3 million increase in patent fees, and a $3.4 million increase in equity-based compensation expense resulting from management incentive units and common units granted by us and from equity-based awards granted to employees of consolidated entities. The increase was partially offset by a $1.2 million decrease in legal fees.

Interest Income

Interest income for the six months ended June 30, 2019, primarily consisted of the interest earned on our investments in cash equivalents. Interest income was not material for the same period in 2018.

Interest Expense

Interest expense for the six months ended June 30, 2019, primarily consisted of the interest accrued on the $75.0 million Hercules term loans drawn in June 2018, December 2018 and May 2019. Interest expense for the six months ended June 30, 2018, was primarily related to the PellePharm SVB Loan, prior to the deconsolidation of PellePharm in November 2018.

Loss from PellePharm

Due to the deconsolidation of PellePharm, we accounted for part of our remaining investment in PellePharm under the equity method and we recognized our share of PellePharm earnings or losses through June 30, 2019. PellePharm was a consolidated entity as of June 30, 2018 and as such, no such gains or losses were recognized during the period.

LEO Call Option Expense

The LEO Call Option liability was recorded at fair value upon execution of the LEO Agreement in November 2018. The LEO Call Option liability was remeasured to fair value as of June 30, 2019. There was no such liability subject to be recorded and remeasured as of and prior to June 30, 2018.

Other Expense

Other expense for the six months ended June 30, 2018, consisted primarily of the change in fair value of the Eidos financial instruments issued and settled in 2018. Other expense was not material for the same period in 2019.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have incurred significant operating losses. We have historically financed our operations primarily through the sale of our equity securities and, to a lesser extent, debt borrowings. 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 to continue to incur significant expenses and increasing operating losses for at least the next several years.

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 June 30, 2019, we held 23,693,148 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.

We had cash and cash equivalents of $293.8 million as of June 30, 2019, of which $112.4 million was held at BridgeBio. The remaining cash and cash equivalents, including $131.4 million held at Eidos, were held by our wholly-owned subsidiaries and controlled entities, with these funds available for specific entity usage, except in limited circumstances.

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 $366.3 million from the IPO, after deducting underwriters' discounts and commissions of $28.0 million and deferred offering costs of $6.5 million.

Secured Loans

In June 2018, we executed a Loan and Security Agreement with Hercules Capital, Inc., or Hercules, under which we borrowed $35.0 million, or Tranche I. The term of the loan was approximately 42 months, with a maturity date of January 1, 2022, or 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, or 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%, payable monthly.

In December 2018, we executed the First Amendment to the Loan and Security Agreement, whereby we borrowed an additional $20.0 million, or Tranche II, to increase the total principal balance outstanding to $55.0 million. Upon draw of Tranche II, the interest-only period on the entire facility was extended until January 1, 2021, or the Amended Amortization Date. The outstanding balance of the original $35.0 million Tranche I and the additional borrowing of $20.0 million Tranche II is to be repaid monthly beginning on the Amended Amortization Date and extending through July 1, 2022, or 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%, payable monthly.

In May 2019, we executed the Second Amendment to the Loan and Security Agreement, whereby we borrowed an additional $20.0 million, or Tranche III, to increase the total principal balance outstanding to $75.0 million. The outstanding balance of Tranche I, Tranche II and Tranche III is to be repaid monthly beginning on the Amended Amortization Date and extending through the Amended Maturity Date. 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%, 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 $35.0 million principal amount of the Tranche I term loan, or $2.2 million, 5.75% of the $20.0 million principal amount of the Tranche II term loan, or $1.2 million, and 5.75% of the $20.0 million principal amount of the Tranche III term loan, or $1.2 million.

Effective upon the completion of our IPO, we received: (i) a further six month interest-only extension to July 1, 2021, (ii) a further six month maturity extension to January 1, 2023, (iii) a reduction of 0.5% on the then effective interest rate on Tranches I and II, and (iv) the 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. All PIK Interest shall be capitalized and added to the outstanding principal balance under the Amended Hercules Term Loan, which shall then accrue further cash interest and fees pursuant to the terms of the Amended Hercules Term Loan.

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 has no covenants that limit or restrict the ability of a wholly-owned subsidiary or controlled entity that is predominantly involved in advancing our development programs to incur indebtedness. At the time of the close of the Amended Hercules Term Loan, there is no liquidity covenant on us. Under the Amended Hercules Term Loan, we are required to maintain $20.0 million in unrestricted cash, or the Minimum Cash Requirement, unless either of these conditions are achieved: (i) our market capitalization is in excess of $750 million, (ii) Part A of Eidos' Phase III ATTRibute trial produces positive data that would be supportive of an NDA filing, or (iii) the acceptance of an NDA by the FDA related to any product filed by any of our wholly-owned subsidiaries or controlled entities. 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 of 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.

Liquidity Risks

As of June 30, 2019, we had cash and cash equivalents of $293.8 million, of which $112.4 million was held at BridgeBio and $131.4 million at Eidos. Prior to our IPO, our operations have been financed primarily by net proceeds from the sale and issuance of our preferred units and term loans. On July 1, 2019, in connection with our IPO, we issued and sold an aggregate of 23,575,000 shares of common stock (inclusive of 3,075,000 shares of common stock from the exercise of the over-allotment option granted to the underwriters) at a price of $17.00 per share. We received proceeds of $366.3 million, net of underwriting discounts and commissions of $28.0 million and offering costs of $6.5 million. We believe that our currently available resources and the net proceeds received in the IPO will enable us to fund our projected operating expenses and capital expenditures through at least the next 12 months.

We will not generate revenue from product sales unless and until we successfully complete clinical development and obtain regulatory approval for our product candidates. If we obtain regulatory approval for any of our product candidates and do not enter into a commercialization partnership, we expect to incur significant expenses related to developing our internal commercialization capability to support product sales, marketing and distribution. Further, we expect to incur additional costs associated with operating as a public company. As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. If we do raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Further, we may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements as, and when, needed, we may have to significantly delay, scale back or discontinue the development and commercialization of one or more of our product candidates.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

Cash Flows

The following table summarizes our cash flows during the periods indicated:

	Six months ended June 30,	
	2019	2018
	(in thousands)	
Net cash used in operating activities	$ (127,388)	$ (51,907)
Net cash used in investing activities	(3,010)	(16,832)
Net cash provided by (used in) financing activities	(11,620)	229,101
Net increase (decrease) in cash and cash equivalents and restricted cash	$ (142,018)	$ 160,362

Net Cash Flows from Operating Activities

Net cash used in operating activities for the six months ended June 30, 2019 was $127.4 million, which included $26.1 million of net cash used in operating activities by Eidos. It primarily consisted of our net loss of $143.7 million and changes in net operating assets and liabilities of $3.7 million, which were partially offset by non-cash charges of $20.0 million. The net change in operating assets and liabilities was primarily due to an increase of $3.3 million in prepaid expenses and other assets and of $2.1 million in other assets, both increases were primarily due to the advance payments made for research due to increased activities at CROs and CMOs, an increase of $0.5 million in accrued research and development liabilities and of $0.5 million in other liabilities primarily related to the timing of payments, and an increase in accrued compensation and benefits of $0.7 million.

Our non-cash charges primarily consisted of a $9.6 million loss from PellePharm, $5.5 million for equity-based compensation expense, $2.5 million for acquired in-process research and development assets and $1.3 million of expense related to the revaluation of the LEO Call Option liability.

Net cash used in operating activities for the six months ended June 30, 2018 was $51.9 million, which included $14.8 million of net cash used in operating activities by Eidos. It primarily consisted of our net loss of $78.1 million, which was partially offset by non-cash charges of $21.3 million and a change in net operating assets and liabilities of $4.9 million. Our non-cash charges primarily consisted of $17.9 million for acquired in-process research and development assets due to asset acquisition by QED in January 2018 and Origin in June 2018, $1.8 million in equity-based compensation expense and $1.1 million from change in fair value of Eidos financial instruments. The net change in operating assets and liabilities was primarily due to an increase of $8.9 million in accounts payable, increase of $3.1 million in accrued research and development liabilities, and increase in other accrued liabilities of $0.3 million due to due to an increase in the level of research and development expenses and timing of receipt of invoices from and payments to vendors. These amounts were partially offset by an increase of $8.1 million in prepaid expenses and other current assets primarily due to increase in prepaid research and development costs at QED.

Net Cash Flows from Investing Activities

Net cash used in investing activities for the six months ended June 30, 2019 was $3.0 million, which consisted of $2.5 million paid for in-progress research and development assets acquired in connection with asset acquisitions and $0.5 million related to purchase of property and equipment.

Net cash used in investing activities for the six months ended June 30, 2018 was $16.8 million, which consisted of $16.0 million paid for in-progress research and development assets acquired in connection with asset acquisitions and $0.8 million related to purchase of property and equipment.

Net Cash Flows from Financing Activities

Net cash used in financing activities of $11.6 million for the six months ended June 30, 2019 was primarily to the proceeds from term loan of $19.8 million offset by $28.6 million payment in relation to repurchase of common stock of Eidos from a noncontrolling interest holder and $2.5 million payment of deferred offering costs.

Net cash provided by financing activities of $229.1 million for the six months ended June 30, 2018 was primarily related to net proceeds of $96.7 million from the issuance of common stock in connection with the Eidos IPO, proceeds of $58.4 million from third-party investors in redeemable noncontrolling interests, net proceeds of $36.6 million received from term loans, net proceeds of $36.3 million from the issuance of our redeemable convertible Series C preferred units and proceeds from the issuance of promissory notes for $1.0 million. The net cash proceeds from the Eidos initial public offering cannot be used by us or our other subsidiaries and may only be used by Eidos or its subsidiaries, if any.

Contractual Obligations

There have been no material changes outside the ordinary course of business to our contractual obligations as of June 30, 2019 from those disclosed in "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in the Prospectus, except that in May 2019, we executed the Second Amendment to the Loan and Security Agreement whereby we borrowed an additional $20.0 million ("Tranche III") to increase the total principal balance outstanding to $75.0 million.

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.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. We held cash and cash equivalents of $293.8 million as of June 30, 2019. We generally hold our cash in interest-bearing demand deposit accounts. Cash equivalents consist of amounts invested in money market accounts. Due to the nature of our cash and cash equivalents, a hypothetical 100 basis point change in interest rates would not have a material effect on the fair value of our cash and cash equivalents.

As of June 30, 2019, we had $75.0 million in variable rate debt outstanding. The Amended Hercules Term Loan matures in July 2022, with interest-only monthly payments until January 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 4.35% and (ii) 9.35% (9.85% as of June 30, 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 3.35% and (ii) 9.10% (9.10% as of June 30, 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 June 30, 2019).

Item 4. Controls and Procedures.

Evaluation of disclosure controls and procedures.

Our management, with the participation and supervision of our Chief Executive Officer and our Chief Financial Officer, have evaluated our 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) as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of the end of the period covered by this Quarterly Report on Form 10-Q, our disclosure controls and procedures are effective to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Remediation Efforts on Previously Identified Material Weakness

During the audit of our financial statements for the year ended December 31, 2017, material weaknesses were identified in our internal control over financial reporting. 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:

- 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 the hiring of additional finance and accounting personnel becomes economically feasible, we intend to take appropriate and reasonable steps to remediate these material weaknesses 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 or remediate the material weaknesses described above. As of June 30, 2019, the material weaknesses had not been remediated.

In addition, in connection with the audit of the 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. While Eidos intends to implement a plan to remediate the material weakness, it has not completed the implementation of this plan and can give no assurance that its current and planned implementation will remediate this deficiency in internal control or that additional material weaknesses or significant deficiencies in its internal control over financial reporting will not be identified in the future.

Changes in internal control over financial reporting.

There was no change in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the period covered by this Quarterly Report on Form 10-Q that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Inherent limitation on the effectiveness of internal control.

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls or our internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the controls. The design of any system of controls is also based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and may not be detected.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

On December 31, 2018, Children Hospital Research Center at Oakland ("CHRCO") filed, but did not serve, a civil complaint against Dr. Ervin Epstein, Co-Founder and Chief Medical Officer of PellePharm and PellePharm in the Northern District of California. CHRCO asserts four causes of action against Dr. Epstein (conversion, breach of contract, breach of the implied covenant of good faith and fair dealing, and specific performance), and one related cause of action against PellePharm (constructive trust). All five causes of action are generally directed to a set of accusations relating to Dr. Epstein's prior employment at CHRCO. In its complaint, CHRCO seeks monetary damages as well as equitable relief in the form of a constructive trust and an injunction. CHRCO has since withdrawn its complaint in the Northern District of California and filed, and as of May 16, 2019, has not yet served a revised civil complaint against PellePharm and Dr. Epstein in the Superior Court of the State of California, County of San Francisco, asserting the same five causes of action. On April 11, 2019, CHRCO filed an unopposed ex parte application with the Court to extend the deadline to serve the complaint to June 11, 2019. Dr. Epstein and PellePharm dispute all of CHRCO's allegations and believe they lack merit and they intend to contest the case vigorously. No responsive pleading is required at this time, nor has Dr. Epstein or PellePharm provided one.

From time to time, we may become involved in legal proceedings arising in the ordinary course of business. We are unable to predict the outcome of these matters or the ultimate legal and financial liability, and at this time cannot reasonably estimate the possible loss or range of loss and accordingly has not accrued a related liability.

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 Quarterly Report on Form 10-Q, including "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the 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 Quarterly Report on Form 10-Q 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 Quarterly Report.

Risks 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 six months ended June 30, 2019 and the years ended December 31, 2018 and 2017 were $143.7 million, $169.5 million and $43.8 million, respectively. As of June 30, 2019, we had an accumulated deficit of $326.1 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 June 30, 2019, we had working capital of $268.0 million and cash and cash equivalents of $293.8 million, not including net proceeds from our initial public offering of $366.3 million, which we received in July 2019. We expect that our cash and cash equivalents and net proceeds received in the IPO will be sufficient to fund our operations through at least the next 24 months. 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; our Phase 3 clinical trial of BBP-009 in Gorlin syndrome and Phase 2b clinical trial in high frequency basal cell carcinoma; 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 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 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 a combination of 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.

We may not realize the anticipated benefits and synergies from our proposed Eidos Buyout Offer.

On August 8, 2019, we announced a non-binding proposal to acquire all of the outstanding shares of common stock of Eidos that are not then owned by us or our subsidiaries (the "Eidos Buyout Offer"). While we and Eidos will continue to operate independently until the completion of the Eidos Buyout Offer, the success of the proposal will depend, in part, on our ability to realize the anticipated benefits of acquiring all of the shares of Eidos. Nonetheless, difficulties may arise during the process of the Eidos Buyout Offer that could result in the failure to achieve the benefits that we anticipate, the loss of key employees that may be difficult to replace in the very competitive biopharmaceutical field, the disruption of each company's ongoing businesses or inconsistencies in standards, controls, procedures and policies that adversely affect our ability to maintain relationships with suppliers, distributors, alliance partners, creditors, clinical trial investigators or managers of its clinical trials. As a result, the anticipated benefits of the proposal may not be realized fully within the expected timeframe or at all or may take longer to realize or cost more than expected, which could materially impact the business, cash flow, financial condition or results of operations as well as adversely impact the price of our shares or the shares of Eidos.

In addition, at times, the attention of certain members of each company's management and each company's resources may be focused on completion of the Eidos Buyout Offer and diverted from day-to-day business operations, which may disrupt each company's ongoing business.

We and Eidos may have difficulty attracting, motivating and retaining executives and other key employees in light of the proposed Eidos Buyout Offer.

Due to the specialized scientific and managerial nature of our business, we and Eidos rely heavily on our ability to attract and retain qualified scientific, technical and managerial personnel. The competition for qualified personnel in the pharmaceutical field is intense and our success after the transaction will depend in part on our ability to retain scientific and technical personnel and other key employees of Eidos. Uncertainty about the effect of the Eidos Buyout Offer on our and Eidos' business may have an adverse effect on the continuing business of each of us and Eidos. This uncertainty may impair our and/or Eidos' ability to attract, retain and motivate key personnel.

If our pending proposed Eidos Buyout Offer is consummated, our stockholders' ownership percentage will be diluted.

If the proposed Eidos Buyout Offer is consummated, we will issue to Eidos stockholders shares of our common stock. As a result of the issuance of these shares of our common stock, our stockholders will own a smaller percentage of our company after the Eidos Buyout Offer and will therefore have a reduced voting interest.

We may be subject to litigation in connection with the pending Eidos Buyout Offer.

Lawsuits may be filed against us, Eidos, our subsidiaries, or our respective directors or executive officers in connection with the pending proposal and the related transactions, which could result in substantial costs and may delay or prevent the Eidos Buyout Offer from being completed. In addition, if the pending proposal is completed, lawsuits may be filed against the combined company following the pending proposal. If any such lawsuit is filed, it could result in a reduction in our current stock price and our stock price following the pending proposal, substantial costs and diversion of management's attention and resources, which could adversely affect our business, financial condition or results of operations, whether or not a settlement or other resolution is achieved.

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;
- successfully negotiating a proposed acquisition, in-license or investment in a timely manner and at a price or on terms and conditions favorable to us;
- successfully combining and integrating 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.

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, 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. For example, on October 30, 2018, the FDA notified our subsidiary Phoenix Tissue Repair 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. Although we believe the existing product lot for BBP-589 identified in the IND, which is not subject to the partial clinical hold, is sufficient to complete our proposed Phase 1/2 clinical trial, we will need to reconcile the identified deficiency in the potency assay and provide the FDA with the requested information before we can release additional lots of BBP-589 for clinical use. We cannot assure you that the FDA will deem our response satisfactory to address its request and we may never be able to secure a release of the partial clinical hold. 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 Phase 2 and planned Phase 3 clinical trials of BBP-831 and our ongoing Phase 3 clinical trial 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.

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. 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, including Vyndamax (tafamidis) and Vyndaqel (tafamidis meglumine), for which Pfizer Inc. has been approved for the treatment of ATTR-CM in the United States and Japan (Vyndaqel only) and is approved in certain countries outside the United States for the treatment of ATTR-PN (Vyndaqel only), 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. Many product candidates that initially show promise in early-stage testing may later be found to cause side effects that prevent further development. In addition, in ongoing IND-enabling toxicology studies, we have observed toxicity in a non-rodent species for BBP-671. We believe the toxicity observed is consistent with a species and chemotype-specific mechanism and we are now instead pursuing two backup BBP-671 compounds. 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 would have a material adverse effect on our business, and the value of our common stock would decline.

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 of study data from clinical trials conducted outside the United States or another jurisdiction by the FDA or comparable foreign regulatory authority 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 designation for BBP-009 for 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-587 for the treatment of dystrophic epidemolysis bullosa and BBP-870 for treatment of molybdenum cofactor deficiency type A. We have obtained from the EMA orphan drug designation for BBP-009 for 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 and BBP-870 for treatment of molybdenum cofactor deficiency type A. 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 or fast track 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 and fast track designation.

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.

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 and 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, we may elect not to pursue either of breakthrough therapy or fast track designation 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 or fast track designation, we cannot assure you that the FDA would decide to grant it. Breakthrough therapy designation and fast track 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 designation or fast track designation. Thus, even if we do receive breakthrough therapy or fast track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw breakthrough therapy or fast track 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 are unable to establish or manage such strategic collaborations on terms favorable to us in the future, our R&D efforts and potential to generate revenue may be limited.

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.

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 clinical trial 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.

For example, in December 2018, the Children's Hospital and Research Center at Oakland d/b/a UC Benioff Children's Hospital-Oakland, or CHRCO, filed a complaint in the U.S. District Court of the Northern District of California alleging, among other things, that PellePharm infringed certain patent rights of CHRCO.

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, including CHRCO, 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 up to $100,000 for each violation, 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 ranging from $11,181 to $22,363 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;
- 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.

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.

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. While the Trump Administration and CMS have both stated that the ruling will have no immediate effect, and on December 30, 2018 the Texas District Court Judge issued an order staying the judgment pending appeal, 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. 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. 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 has recently published a final rule that would give 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 2027 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 2019 contains further drug price control measures that could be enacted during the 2019 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. For example, in September 2018, CMS announced that it will allow Medicare Advantage Plans the option to use step therapy for Part B drugs beginning January 1, 2019. Additionally, on May 10, 2019, the Centers for Medicare and Medicaid Services announced a new pricing transparency rule, which goes into effect on July 9, 2019. This final rule requires direct-to-consumer television advertisements for prescription drugs and biological products for which reimbursement is available, directly or indirectly, through or under Medicare or Medicaid to include the list price of that product, except for a prescription drug or biological product that has a list price of less than $35 per month for a 30-day supply or typical course of treatment. The pricing transparency rule could have a negative effect on our business. 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.

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 drivers are pursuing, including: 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 competitors or 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; Ali Satvat serves 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 operating officer of Origin Biosciences, Inc. and chief executive officer of 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 June 30, 2019, we had 25 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 June 30, 2019, we had 185 full-time employees. 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 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.

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 Data Protection Directive, 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.

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

Earthquakes 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. 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 anticipated 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 international operations, but 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, 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 initial public offering, 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 control 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 the hiring of additional finance and accounting personnel becomes economically feasible, we intend to take appropriate and reasonable steps to remediate these material weaknesses 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 or remediate the material weaknesses described above. As of June 30, 2019, the material weaknesses have not been remediated.

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. While Eidos intends to implement a plan to remediate the material weakness, it has not completed the implementation of this plan and can give no assurance that its current and planned implementation will remediate this deficiency in internal control or that additional material weaknesses or significant deficiencies in its 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 combined and 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 initial public offering, provide a management report on internal control over financial reporting. However, while we remain an emerging growth company, we will not 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 will 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) the last day of the fiscal year (a) following the fifth anniversary of the completion of our initial public offering, (b) in which we have total annual gross revenue of at least $1.07 billion or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

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 equity-based awards to our employees, directors and consultants. 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 and lock-up agreements, the early release of these agreements, 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.

All shares of common stock not sold in our initial public offering will be able to be sold in the public market beginning 180 days after the date of our initial public offering. J.P. Morgan Securities LLC and Goldman Sachs & Co. LLC may, in their sole discretion, release all or some portion of the shares subject to lock-up agreements at any time and for any reason. In addition, 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 or lock-up agreements. 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 and lock-up agreements, and Rule 144 and Rule 701 under the Securities Act of 1933, as amended, or the Securities Act. See the section titled "Shares eligible for future sale" for additional information.

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 statement on Form S-8 registering the issuance of 13.5 million shares of common stock issued or reserved for future issuance under our equity compensation plans. Shares registered under this registration statement on Form S-8 can be freely sold in the public market upon issuance and once vested, subject to volume limitations applicable to affiliates and the lock-up agreements described above. 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 June 30, 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 29.9% 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 shall also agree to comply with the terms of the Amended and Restated Loan and Security Agreement.

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 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 2. Unregistered Sales of Equity Securities and Use of Proceeds.

Sales of Unregistered Securities

On July 1, 2019, immediately prior to the completion of the IPO, we engaged in a series of transactions whereby BridgeBio Pharma LLC became a wholly-owned subsidiary of BridgeBio Pharma, Inc. As part of the transactions, holders of Preferred Units, Founder Units, Common Units and Management Incentive Units of BridgeBio Pharma LLC exchanged all such units for an aggregate of 99,999,967 shares of common stock of BridgeBio Pharma, Inc. We deemed the exchange to be exempt from registration under the Securities Act, in accordance with Section 4(a)(2) of the Securities Act.

Use of Proceeds from Public Offering of Common Stock

On June 26, 2019, our Registration Statements on Form S-1 (File Nos. 333-231759 and 333-232376) relating to our IPO were declared effective by the SEC. On July 1, 2019, we issued and sold an aggregate of 23,575,000 shares of common stock (inclusive of 3,075,000 shares sold pursuant to the underwriters' option to purchase additional shares) at a price of $17.00 per share for aggregate cash proceeds of $366.3 million, net of underwriting discounts and commissions of $28.0 million and estimated offering costs of $6.5 million, upon the closing of our IPO. No payments for such expenses were made directly or indirectly to (i) any of our officers or directors or their associates, (ii) any persons owning 10% or more of any class of our equity securities, or (iii) any of our affiliates, except for the following: KKR Capital Markets LLC, an underwriter in the IPO, received a portion of the underwriting discounts and commissions paid by us in connection with the IPO, and affiliates of KKR Capital Markets LLC own more than 10% of our common stock.

J.P. Morgan Securities LLC, Goldman Sachs & Co. LLC, Jefferies LLC and SVB Leerink LLC are the representatives of the underwriters.

There has been no material change in the planned use of proceeds from our IPO from that described in the Prospectus.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. 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/A	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	8-K	001-38959	4.1	July 3, 2019
10.1#	2019 Stock Option and Incentive Plan and forms of award agreements thereunder.	S-1/A	333-231759	10.1	June 24, 2019
10.2#	2019 Employee Stock Purchase Plan.	S-1/A	333-231759	10.2	June 24, 2019
10.3#	Senior Executive Cash Incentive Bonus Plan.	S-1/A	333-231759	10.3	June 24, 2019
10.4	Form of Indemnification Agreement, between the Registrant and each of its directors.	S-1/A	333-231759	10.4	June 24, 2019
10.5	Form of Indemnification Agreement, between the Registrant and each of its executive officers.	S-1/A	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

Exhibit Number	Exhibit Title	Form	File No.	Exhibit	Filing Date
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
10.15†	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/A	333-231759	10.19	June 11, 2019
10.20	Offer Letter, between BridgeBio Services, Inc. and Brian Stephenson, dated October 28, 2018.	S-1/A	333-231759	10.20	June 11, 2019

Exhibit Number	Exhibit Title	Form	File No.	Exhibit	Filing Date
10.21	Offer Letter, between Eidos Therapeutics, Inc. and Uma Sinha, dated June 1, 2016, as amended on May 24, 2018.	S-1/A	333-231759	10.21	June 11, 2019
10.22	Offer Letter, between BridgeBio Services, Inc. and Charles Homcy, dated February 20, 2019.	S-1/A	333-231759	10.22	June 11, 2019
10.23	Offer Letter, between BridgeBio Services, Inc. and Richard Scheller, dated April 5, 2019.	S-1/A	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/A	333-231759	10.24	June 11, 2019
10.25	Offer Letter, between BridgeBio Services, Inc. and Cameron Turtle, dated December 13, 2016, as amended on May 5, 2017.	S-1/A	333-231759	10.25	June 11, 2019
10.26	Offer Letter, between Eidos Therapeutics, Inc. and Cameron Turtle, dated June 13, 2018.	S-1/A	333-231759	10.26	June 11, 2019
10.27	Form of Tax Sharing Agreement, between the Registrant and each of its subsidiaries.	S-1/A	333-231759	10.27	June 24, 2019
10.28	Indemnification Agreement, between BridgeBio Pharma LLC and KKR Genetic Disorder, L.P., dated March 26, 2016.	S-1/A	333-231759	10.28	June 24, 2019
21	List of Subsidiaries of the Registrant.	S-1	333-231759	21	May 24, 2019
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

Exhibit Number	Exhibit Title	Form	File No.	Exhibit	Filing Date
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 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: August 14, 2019

By: /s/ Neil Kumar

Neil Kumar, Ph.D.
Chief Executive Officer, Director
(Principal Executive Officer)

Date: August 14, 2019

By: /s/ Brian Stephenson

Brian Stephenson, Ph.D., CFA
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 31.1

CERTIFICATION 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

I, Neil Kumar, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of BridgeBio Pharma, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(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)) 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;

   (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.

Date: August 14, 2019

By: /s/ Neil Kumar

Neil Kumar, Ph.D.
Chief Executive Officer and Director
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION 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

I, Brian Stephenson, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of BridgeBio Pharma, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(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)) 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;

   (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.

Date: August 14, 2019

By: /s/ Brian Stephenson

Brian Stephenson, Ph.D., CFA
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of BridgeBio Pharma, Inc. (the "Company") on Form 10-Q for the fiscal quarter ended June 30, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: August 14, 2019

By: /s/ Neil Kumar

Neil Kumar, Ph.D.
Chief Executive Officer and Director
(Principal Executive Officer)

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 Quarterly Report of BridgeBio Pharma, Inc. (the "Company") on Form 10-Q for the fiscal quarter ended June 30, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: August 14, 2019

By: /s/ Brian Stephenson

Brian Stephenson, Ph.D., CFA
Chief Financial Officer
(Principal Financial and Accounting Officer)