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 September 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 November 5, 2019 the registrant had 123,574,967 shares of common stock, $0.001 par value per share, outstanding.

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BRIDGEBIO PHARMA, INC.

Condensed Consolidated Balance Sheets
(unaudited)
(in thousands, except shares and per share amounts)

	September 30, 2019	December 31, 2018
Assets		(1)
Current assets:		
Cash and cash equivalents	$ 413,973	$ 436,086
Short-term marketable securities	122,080	—
Prepaid expenses and other current assets	22,102	9,137
Total current assets	558,155	445,223
Property and equipment, net	2,984	1,575
Long-term marketable securities	75,886	—
PellePharm investment	907	17,050
Other assets	2,598	1,093
Total assets	$ 640,530	$ 464,941
Liabilities, Redeemable Convertible Noncontrolling Interests and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 10,270	$ 13,509
Accrued compensation and benefits	7,580	4,047
Accrued research and development liabilities	13,198	8,915
Accrued distributions to stockholders	—	997
LEO call option liability	4,021	3,009
Other accrued liabilities	4,789	2,100
Total current liabilities	39,858	32,577
Term loans, noncurrent	75,017	54,507
Other liabilities	1,388	495
Total liabilities	116,263	87,579
Commitments and contingencies (Note 10)		
Redeemable convertible noncontrolling interests	2,570	122
Stockholders' equity:		
Undesignated preferred stock, $0.001 par value; 25,000,000 and no shares authorized as of September 30, 2019 and December 31, 2018; no shares issued and outstanding as of September 30, 2019 and December 31, 2018	—	—
Common stock, $0.001 par value; 500,000,000 and 97,412,870 shares authorized as of September 30, 2019 and December 31, 2018; 117,359,502 and 92,057,704 shares issued and outstanding as of September 30, 2019 and December 31, 2018	117	92
Additional paid-in capital	826,062	494,231
Accumulated other comprehensive income	152	—
Accumulated deficit	(366,573)	(179,444)
Total BridgeBio stockholders' equity	459,758	314,879
Noncontrolling interests	61,939	62,361
Total stockholders' equity	521,697	377,240
Total liabilities, redeemable convertible noncontrolling interests and stockholders' equity	$ 640,530	$ 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 and was retroactively adjusted, including shares and per share amounts, as a result of the Reorganization. See Note 3 to the condensed consolidated financial statements for additional details.

BRIDGEBIO PHARMA, INC.

Condensed Consolidated Statements of Operations
(unaudited)
(in thousands, except shares and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
License revenue	$ 26,741	$ —	$ 26,741	$ —
Operating expenses:				
Cost of license revenue	2,500	—	2,500	—
Research and development	55,278	31,148	152,462	88,871
General and administrative	23,495	10,308	59,381	29,206
Total operating expenses	81,273	41,456	214,343	118,077
Loss from operations	(54,532)	(41,456)	(187,602)	(118,077)
Other income (expense), net:				
Interest income	2,736	528	6,505	531
Interest expense	(2,113)	(1,156)	(5,725)	(1,368)
Loss from ML Bio asset acquisition	(416)	—	(416)	—
Loss from PellePharm	(6,589)	—	(16,144)	—
LEO call option income (expense)	276	—	(1,012)	—
Other income (expense)	(26)	6	(40)	(1,296)
Total other income (expense), net	(6,132)	(622)	(16,832)	(2,133)
Net loss	(60,664)	(42,078)	(204,434)	(120,210)
Net loss attributable to redeemable convertible noncontrolling interests and noncontrolling interests	684	10,677	17,305	28,102
Net loss attributable to common stockholders of BridgeBio	$ (59,980)	$ (31,401)	$ (187,129)	$ (92,108)
Net loss per share, basic and diluted	$ (0.51)	$ (0.52)	$ (1.86)	$ (1.60)
Weighted-average shares used in computing net loss per share, basic and diluted	117,071,188	60,950,572	100,855,481	57,437,408

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

BRIDGEBIO PHARMA, INC.

Condensed Consolidated Statements of Comprehensive Loss
(unaudited)
(in thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Net loss	$ (60,664)	(42,078)	$ (204,434)	$ (120,210)
Other comprehensive income:				
Unrealized gain on available-for-sale securities	152	—	152	—
Comprehensive loss	$ (60,512)	$ (42,078)	$ (204,282)	$ (120,210)

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

BRIDGEBIO PHARMA, INC.

Condensed Consolidated Statements of Redeemable Convertible Noncontrolling Interests and Stockholders' Equity
(*unaudited*)
(in thousands, except shares and per share amounts)

	Redeemable Convertible Noncontrolling Interests	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total BridgeBio Stockholders' Equity	Noncontrolling Interests	Total Stockholders' Equity
Balances as of December 31, 2018 (1)	$ 122	92,057,704	$ 92	$ 494,231	$ —	$ (179,444)	$ 314,879	$ 62,361	$ 377,240
Issuance and vesting of restricted common stock and associated equity-based compensation expense	—	518,511	1	1,235	—	—	1,236	—	1,236
Repayment of nonrecourse notes	—	—	—	179	—	—	179	—	179
Issuance (repurchase) of noncontrolling interest	—	—	—	—	—	—	—	1,320	1,320
Transfers to (from) noncontrolling interest	870	—	—	(2,968)	—	—	(2,968)	2,098	(870)
Net loss	(790)	—	—	—	—	(61,185)	(61,185)	(7,461)	(68,646)
Balances as of March 31, 2019	202	92,576,215	93	492,677	—	(240,629)	252,141	58,318	310,459
Vesting of restricted common stock and related equity-based compensation expense	—	604,144	—	2,119	—	—	2,119	—	2,119
Equity-based compensation expense	—	—	—	69	—	—	69	—	69
Issuance (repurchase) of noncontrolling interest	—	—	—	—	—	—	—	(27,024)	(27,024)
Transfers to (from) noncontrolling interest	658	—	—	(25,440)	—	—	(25,440)	24,782	(658)
Net loss	(685)	—	—	—	—	(65,964)	(65,964)	(7,685)	(73,649)
Balances as of June 30, 2019	175	93,180,359	93	469,425	—	(306,593)	162,925	48,391	211,316
Vesting of restricted common stock and associated equity-based compensation expense	—	604,143	—	2,120	—	—	2,120	—	2,120
Equity-based compensation expense related to stock option plan	—	—	—	1,554	—	—	1,554	—	1,554
Equity-based compensation expense related to employee stock ownership plan	—	—	—	279	—	—	279	—	279
Issuance of common stock at $17.00 per share in connection with the initial public offering, net of issuance costs of $34,538	—	23,575,000	24	366,213	—	—	366,237	—	366,237
Issuance (repurchase) of noncontrolling interest	3,196	—	—	—	—	—	—	(98)	(98)
Transfers to (from) noncontrolling interest	(166)	—	—	(13,529)	—	—	(13,529)	13,695	166
Unrealized gains on available-for-sale securities	—	—	—	—	152	—	152	—	152
Net loss	(635)	—	—	—	—	(59,980)	(59,980)	(49)	(60,029)
Balances as of September 30, 2019	$ 2,570	117,359,502	$ 117	$ 826,062	$ 152	$ (366,573)	$ 459,758	$ 61,939	$ 521,697

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

(1) The consolidated balances as of December 31, 2018 are derived from the audited consolidated financial statements as of that date and were retroactively adjusted, including shares and per share amounts, as a result of the Reorganization. See Note 3 to the condensed consolidated financial statements for additional details.

BRIDGEBIO PHARMA, INC.

Condensed Consolidated Statements of Redeemable Convertible Noncontrolling Interests and Stockholders' Equity
(*unaudited*)
(in thousands, except share and per share amounts)

	Redeemable Convertible Noncontrolling Interests	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Deficit	Total BridgeBio Stockholders' Equity	Noncontro-lling Interests	Total Stockholders' Equity
Balances as of December 31, 2017 (1)	$ 833	51,314,794	$ 51	$ 134,495	$ (48,695)	$ 85,851	$ 2,498	$ 88,349
Vesting of restricted common stock and related equity-based compensation expense	—	449,371	1	321	—	322	—	322
Issuance (repurchase) of noncontrolling interest	15,617	—	—	—	—	—	553	553
Transfers to (from) noncontrolling interest	(11,286)	—	—	3,876	—	3,876	7,410	11,286
Net loss	(3,614)	—	—	—	(34,156)	(34,156)	(4,660)	(38,816)
Balances as of March 31, 2018	1,550	51,764,165	52	138,692	(82,851)	55,893	5,801	61,694
Vesting of restricted common stock and related equity-based compensation expense	—	450,775	—	325	—	325	—	325
Issuance of common stock at $4.29 per share, net of issuance costs of $0	—	8,455,861	8	36,292	—	36,300	—	36,300
Issuance (repurchase) of noncontrolling interest	46,710	—	—	—	—	—	96,689	96,689
Transfers to (from) noncontrolling interest	(41,450)	—	—	56,182	—	56,182	(14,732)	41,450
Net loss	(3,618)	—	—	—	(26,551)	(26,551)	(5,533)	(32,084)
Balances as of June 30, 2018	3,192	60,670,801	60	231,491	(109,402)	122,149	82,225	204,374
Vesting of restricted common stock and related equity-based compensation expense	—	451,560	1	325	—	326	—	326
Issuance (repurchase) of noncontrolling interest	—	—	—	—	—	—	974	974
Transfers to (from) noncontrolling interest	75	—	—	(2,253)	—	(2,253)	2,178	(75)
Net loss	(2,355)	—	—	—	(31,401)	(31,401)	(8,322)	(39,723)
Balances as of September 30, 2018	$ 912	61,122,361	$ 61	$ 229,563	$ (140,803)	$ 88,821	$ 77,055	$ 165,876

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

(1) The consolidated balances as of December 31, 2017 are derived from the audited consolidated financial statements as of that date and were retroactively adjusted, including shares and per share amounts, as a result of the Reorganization. See Note 3 to the condensed consolidated financial statements for additional details.

BRIDGEBIO PHARMA, INC.

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

	Nine Months Ended September 30,	
Operating activities:	**2019**	**2018**
Net loss	$ (204,434)	$ (120,210)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	618	145
Net accretion and amortization of premium and discounts on marketable securities	(69)	—
Equity-based compensation	11,367	2,954
Loss on disposal of property and equipment, net	63	7
Loss from ML Bio asset acquisition	416	—
Loss from PellePharm	16,144	—
Accretion of term loans and convertible promissory notes	722	541
Acquired in-process research and development assets	3,560	17,886
Shares issued under license agreements	220	134
LEO call option expense	1,012	—
Change in fair value of Eidos financial instruments	—	1,146
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(12,541)	(11,661)
Other assets	(1,664)	129
Accounts payable	(3,239)	8,953
Accrued compensation and benefits	3,533	2,369
Accrued research and development liabilities	4,284	6,136
Other accrued liabilities	2,689	1,164
Other liabilities	(65)	78
Net cash used in operating activities	(177,384)	(90,229)
Investing activities		
Purchases of marketable securities	(197,745)	—
Cash paid for in-process research and development assets acquired	(2,500)	(16,000)
Cash and cash equivalents acquired in ML Bio asset acquisition	784	—
Purchases of property and equipment	(891)	(1,437)
Net cash used in investing activities	(200,352)	(17,437)
Financing activities		
Proceeds from issuance of BridgeBio Pharma LLC common stock equivalents, net of issuance costs	—	36,300
Proceeds from issuance of common stock in connection with the initial public offering, net of underwriting discounts and commissions	366,237	—
Proceeds from issuance of common stock in connection with the initial public offering of Eidos, net of underwriting discounts and commissions	—	95,536
Proceeds from issuance of noncontrolling interest to Alexion (Note 14)	23,309	—
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	1,500	58,430
MyoKardia distributions (Note 15)	(997)	—
Repurchase of noncontrolling interest	(55,011)	—
Issuance of loan to noncontrolling interest shareholder	—	(22)
Repayment of term loans	—	(656)
Proceeds from subsidiary stock option exercises	884	196
Net cash provided by financing activities	355,888	227,374
Net increase (decrease) in cash, cash equivalents and restricted cash	(21,848)	119,708
Cash, cash equivalents and restricted cash at beginning of period	436,245	92,376
Cash, cash equivalents and restricted cash at end of period	$ 414,397	$ 212,084
Supplemental Disclosures of Cash Flow Information:		
Cash paid for interest	$ 4,336	$ 718
Supplemental Disclosures of Non-Cash Investing and Financing Information:		
Tenant improvement paid by landlord	$ 959	$ —
Transfers to (from) noncontrolling interest (Note 8)	$ 41,937	$ 57,805
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, Inc. (the "Corporation") was formed as a Delaware corporation on May 17, 2019 for the purpose of completing an initial public offering of the Corporation's common stock (the "IPO") and related organizational transactions (the "Reorganization") in order to carry on the business of BridgeBio Pharma LLC ("BBP LLC"). The Corporation, the reporting entity in these condensed consolidated financial statements, and BBP LLC, the predecessor reporting entity before the completion of the Reorganization and the Corporation's wholly-owned subsidiary after the completion of the Reorganization, are collectively referred to as BridgeBio.

Since inception, BridgeBio has either created wholly-owned subsidiaries or has made investments in certain controlled entities, including partially-owned subsidiaries for which BridgeBio has a majority voting interest and variable interest entities ("VIEs") for which BridgeBio is the primary beneficiary (collectively, the "Company"). BridgeBio is headquartered in Palo Alto, California.

BridgeBio was established to identify and advance transformative medicines to treat patients who suffer from Mendelian diseases, which are diseases that arise from defects in a single gene, and cancers with clear genetic drivers. BridgeBio's pipeline of programs spans early discovery to late-stage development.

Reorganization and Initial Public Offering

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

Upon the closing of the IPO on July 1, 2019, BridgeBio completed the Reorganization, whereby all unitholders of BBP LLC exchanged their units for shares of common stock of the Corporation, and BBP LLC became a wholly-owned subsidiary of the Corporation. Subsequent to the Reorganization, as the sole managing member, the Corporation operates and controls all of BBP LLC's businesses and affairs. See Note 3 for additional details.

The results of operations and cash flows prior to the IPO closing on July 1, 2019 relate to BBP LLC, its subsidiaries and controlled entities. Subsequent to the IPO closing, the information relates to the Corporation, its subsidiaries and controlled entities. All share and per share amounts in these condensed consolidated financial statements and related notes have been retroactively adjusted, where applicable, for all periods presented to give effect to the exchange ratio applied in connection with the Reorganization. See Note 3 for additional details.

Liquidity

The Company has sustained operating losses and negative cash flows from operations since its inception and had an accumulated deficit of $366.6 million as of September 30, 2019. The Company's ultimate success depends on the outcome of its research and development activities as well as the ability to commercialize the Company's product candidates. The Company had cash, cash equivalents and marketable securities of $611.9 million as of September 30, 2019, of which $364.5 million was held by BridgeBio. The remaining funds were held by the Corporation'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. The Company 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 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 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 results of operations for the three and nine months ended September 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.

The condensed consolidated balance sheet as of September 30, 2019, the condensed consolidated statements of operations and the condensed consolidated statements of comprehensive loss for the three and nine months ended September 30, 2019 and 2018, the condensed consolidated statements of redeemable convertible noncontrolling interests and stockholders' equity for the three months ended March 31, 2019 and 2018, June 30, 2019 and 2018, September 30, 2019 and 2018 and the statements of cash flows for the nine months ended September 30, 2019 and 2018 are unaudited. The financial data and the other financial information contained in these notes to the condensed consolidated financial statements related to the three and nine-month periods are also unaudited.

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 7.

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 7.

The Company has either created or made investments in the following entities:

Consolidated Entities	Relationship as of September 30, 2019	Date Control First Acquired	Ownership % as of September 30, 2019 (unaudited)	Ownership % as of December 31, 2018
BridgeBio Services, Inc.	Wholly-owned subsidiary	April 2017	100%	100%
Fortify Therapeutics, Inc. (”Fortify”)	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%	—
BridgeBio Pharma LLC (”BBP LLC”)(1)	Wholly-owned subsidiary	July 2019	100%	—
BridgeBio Gene Therapy, LLC	Wholly-owned subsidiary	August 2019	100%	—
Eidos Therapeutics, Inc. (”Eidos”)(2)	Partially-owned subsidiary	April 2016	66.3%	62.5%
Molecular Skin Therapeutics, Inc. (”MOST”)	Controlled VIE	July 2016	66.2%	61.7%
TheRas, Inc. (”Theras”)	Controlled VIE	August 2016	99.8%	100%
Quartz Therapeutics, Inc. (”Quartz”)	Controlled VIE	October 2016	89.0%	89.0%
PellePharm, Inc. (”PellePharm”)(3)	VIE	December 2016	43.3%	43.3%
Navire Pharma, Inc. (”Navire”)	Controlled VIE	February 2017	78.7%	78.8%
CoA Therapeutics, Inc. (”CoA”)	Controlled VIE	February 2017	99.5%	99.5%
Dermecular Therapeutics, Inc. (”Dermecular”)	Controlled VIE	April 2017	87.6%	87.6%
Phoenix Tissue Repair, Inc. (”PTR”)	Controlled VIE	July 2017	65.7%	56.7%
QED Therapeutics, Inc. (”QED”)	Controlled VIE	January 2018	97.5%	94.4%
Adrenas Therapeutics, Inc. (”Adrenas”)	Controlled VIE	January 2018	88.9%	90.1%
Orfan Biotech, Inc. (”Orfan”)	Controlled VIE	January 2018	89.0%	85.1%
Ferro Therapeutics, Inc. (”Ferro”)	Controlled VIE	March 2018	89.3%	89.4%
Origin Biosciences, Inc. (”Origin”)	Controlled VIE	April 2018	99.8%	100%
Venthera, Inc. (”Venthera”)	Controlled VIE	April 2018	83.2%	82.0%
Aspa Therapeutics, Inc. (”Aspa”)	Controlled VIE	June 2018	90.6%	92.5%
ML Bio Solutions, Inc. (”ML Bio”)	Controlled VIE	July 2019	50.5%	—

(1) BBP LLC was the original reporting entity prior to the Reorganization executed on July 1, 2019 as further described in Note 3.

(2) Subsequent to the Eidos Therapeutics, Inc. (“Eidos”) initial public offering in June 2018 and through September 30, 2019, BridgeBio had a majority voting interest in Eidos and consolidates Eidos under the VOE model. Refer to Note 7.

(3) 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 9.

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 LEO Call Option liability, the valuation of the Company’s 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

The Company considers all highly liquid investments purchased with original maturities of 90 days or less from the purchase date to be cash equivalents. Cash equivalents consist primarily of amounts invested in money market instruments, such as money market funds and repurchase agreements collateralized with securities issued by the U.S. government or its agencies (see Note 5).

The Company's restricted cash balance is related to letters of credit issued under its lease agreements, which have been collateralized. As of September 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 September 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:

	September 30, 2019	September 30, 2018
	(in thousands)	
Cash and cash equivalents	$ 413,973	$ 211,725
Restricted cash	424	359
Total cash, cash equivalents and restricted cash shown in the condensed consolidated statements of cash flows	$ 414,397	$ 212,084

As of September 30, 2019 and December 31, 2018, total cash and cash equivalents held by BridgeBio was $166.6 million and $238.7 million. The remaining cash and cash equivalents were held by the Corporation's wholly-owned subsidiaries and controlled entities and these funds are designated for specific entity usage, except in limited circumstances.

Marketable Securities

The Company invests its excess cash in investment grade, short to intermediate-term, fixed income securities. Such investments are considered available-for-sale and are reported at fair value with related unrealized gains and losses included as a component of stockholders' equity.

Marketable securities with original maturities of greater than 90 days from the date of purchase but less than one year from the balance sheet date are classified as short-term, while marketable securities with maturities in excess of one year from the balance sheet date are classified as long-term. The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity, which is included in interest income in the statements of operations. Realized gains and losses and declines in value considered to be other-than-temporary, if any, on marketable securities are included in other income (expense), net, as appropriate. The cost of securities sold is determined using the specific identification method.

The Company periodically evaluates whether declines in fair values of its marketable securities below their book value are other-than-temporary. This evaluation consists of several qualitative and quantitative factors regarding the severity and duration of the unrealized loss as well as the Company's ability and intent to hold the marketable security until a forecasted recovery occurs. Additionally, the Company assesses whether it has plans to sell the security or it is more likely than not it will be required to sell any marketable securities before recovery of its amortized cost basis. Factors considered include quoted market prices, recent financial results and operating trends, implied values from any recent transactions or offers of investee securities, credit quality of debt instrument issuers, other publicly available information that may affect the value of the marketable security, duration and severity of the decline in value, and management's strategy and intentions for holding the marketable security. The Company has not recorded any other-than-temporary impairment charges on its marketable securities for any of the periods presented.

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 carrying amounts reflected in the accompanying unaudited condensed consolidated balance sheets for cash and cash equivalents, restricted cash, prepaid expenses and other current assets, accounts payable and accrued expenses approximate their fair values, due to their short-term nature.

The fair value of the Company's outstanding term loans with Hercules Capital, Inc. (see Note 11) 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 incurred offering costs, consisting of legal, accounting, printer and filing fees directly attributable to the Corporation's IPO. The proceeds received upon the closing of the IPO, net of the offering costs incurred, were recorded within additional paid-in capital. As of September 30, 2019 and December 31, 2018, no amounts were deferred.

Revenue Recognition

The Company recognizes revenue in accordance with ASC Topic 606, *Revenue from Contracts with Customers* ("ASC 606"), when the customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services. To determine the appropriate revenue recognition for arrangements within the scope of ASC 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the Company satisfies its performance obligation. The Company applies the five-step model to contracts when it is probable that the Company will collect the consideration the Company is entitled to in exchange for the goods or services the Company transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract and identifies, as a performance obligation, and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

As part of the accounting for these arrangements, the Company develops assumptions that require judgment to determine the standalone selling price for each performance obligation identified in the contract. These key assumptions may include forecasted revenues, clinical development timelines and costs, reimbursement rates for personnel costs, discount rates and probabilities of technical and regulatory success.

License Revenue

In the normal course of business, the Company conducts research and development programs independently pursuant to which the Company may license certain rights of the Company's intellectual property to third parties. The terms of these arrangements typically include payment to the Company of one or more of the following: up-front license fees; development, regulatory and sales milestone payments; product supply services; and royalties on net sales of licensed products.

Upfront License Fees: If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company will recognize revenue from upfront license fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, the Company determines whether the combined performance obligation is satisfied over time or at a point in time. If the combined performance obligation is satisfied over time, the Company uses judgment in determining the appropriate method of measuring progress for purposes of recognizing revenue from the up-front license fees. The Company evaluates the measure of progress at each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

Development, Regulatory or Commercial Milestone Payments: At the inception of each arrangement that includes payments based on the achievement of certain development, regulatory and commercial or launch events, the Company evaluates whether the milestones are considered probable of being achieved and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the Company's or the licensee's control, such as regulatory approvals, are not considered probable of being achieved until uncertainty associated with the approvals has been resolved.

The transaction price is then allocated to each performance obligation, on a relative standalone selling price basis, for which the Company will recognize revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, the Company will re-evaluate the probability of achieving such development and regulatory milestones and any related constraint, and if necessary, adjust the Company's estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis and recorded as part of contract revenues from collaborations during the period of adjustment.

Product Supply Services: Arrangements that include a promise for the future supply of drug product for either clinical development or commercial supply at the licensee's discretion are generally considered as options. The Company will assess if these options provide a material right to the licensee and if so, they are accounted for as separate performance obligations.

Sales-based Milestone Payments and Royalties: For arrangements that include sales-based royalties, including milestone payments based on the volume of sales, the Company will determine whether the license is deemed to be the predominant item to which the royalties or sales-based milestones relate and if such is the case, the Company will recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

Deferred Revenue and Receivable: Upfront payments and fees are recorded as deferred revenue when due and payable, and may require deferral of revenue recognition to a future period until the Company performs its obligations under these arrangements. Amounts payable to the Company are recorded as accounts receivable when the Company's right to consideration is unconditional. The Company does not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between payment by the customer and the transfer of the promised goods or services to the customer will be one year or less.

Cost of License Revenue

Cost of license revenue includes sublicensing fees payable to Stanford in the period incurred under the terms of the Stanford Agreement (see Note 12) corresponding to the recognition of license revenue from Alexion (see Note 14). Cost of license revenue does not include any allocated overhead costs.

Comprehensive Loss

The Company's comprehensive loss is comprised of changes in unrealized gains or losses on available-for-sale securities.

Net Loss per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of shares of the Corporation's common stock outstanding for the period, without consideration for potential dilutive shares of common stock, such as stock options, unvested restricted stock units and shares issuable under the employee stock purchase plan. Shares of common stock subject to repurchase are excluded from the weighted-average shares. Since the Company was in a loss position for all periods presented, basic net loss per share is the same as diluted net loss per share since the effects of potentially dilutive securities are antidilutive.

No adjustment for cumulative returns on BBP LLC's redeemable convertible preferred units has been applied to the calculation of basic and diluted net loss per share, since such units were retroactively adjusted as if the Reorganization occurred at the beginning of the earliest period to be presented in the Company's financial statements for the year ending December 31, 2019. See Note 3 to the condensed consolidated financial statements for additional details.

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 September 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 (Topic 842) ("ASU 2016-02"*), which, for operating leases, requires the lessee to recognize a right-of-use asset and a lease liability, initially measured at the present value of the lease payments, in its balance sheet. The guidance also requires a lessee to recognize single lease costs, calculated so that the cost of the lease is allocated over the lease term, generally on a straight-line basis. In July 2018, the FASB issued *ASU 2018-10, Codification Improvements to Topic 842, Leases*. Additionally, the FASB issued *ASU 2018-11, Leases (Topic 842): Targeted Improvements*, which offers a practical expedient for transitioning at the adoption date. These ASUs will be effective for the Company on January 1, 2020 and the Company has chosen to use this practical expedient and recognize a cumulative-effect adjustment to the opening balance of the accumulated deficit. The Company also plans to apply other practical expedients provided by the standard. The Company has begun an implementation plan, including the identification of its lease population and the implementation of changes to existing processes that will be required to implement the new lease standard. The Company believes the most significant changes to the financial statements will relate to the recognition of right-of-use assets and offsetting lease liabilities in the condensed consolidated balance sheet for operating leases. The impact on the condensed consolidated balance sheet will be contingent upon the Company's population of operating leases at adoption. However, the Company does not expect the standard to have a material impact on the condensed consolidated statement of cash flows or the condensed consolidated statement of operations.

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. Reorganization

On June 13, 2019, the Corporation formed BridgeBio Pharma Merger Sub LLC ("Merger Sub LLC"), a Delaware limited liability company and direct wholly-owned subsidiary. The Reorganization was executed on July 1, 2019, immediately prior to completion of the IPO of the Corporation's common stock. As part of the Reorganization, the existing ownership interest in BBP LLC held by all BBP LLC unitholders was transferred to Merger Sub LLC, and all outstanding units of BBP LLC were cancelled and exchanged for shares of common stock of the Corporation. Merger Sub LLC was then merged with and into BBP LLC, the surviving entity, which became a wholly-owned subsidiary of the Corporation. At the conclusion of the Reorganization, the Corporation became the reporting entity.

The number of shares of the Corporation's common stock issued to BBP LLC unitholders in the Reorganization is shown in the below table by unit class:

BBP LLC unit class	Number of the Corporation's Shares Issued
Series D Preferred Units	30,459,426
Series C Preferred Units	31,992,709
Series B Preferred Units	17,794,455
Series A Preferred Units	4,918,881
Founder Units	2,252,916
Common Units	1,794,823
Management Incentive Units	10,786,757
Total shares issued	99,999,967

Included in the amounts above, the unvested outstanding management incentive units and common units of BBP LLC were exchanged for 6,819,455 shares of the Corporation's unvested restricted stock, subject to the same time-based vesting conditions as the original management incentive units and common units terms and conditions. See Note 16 for additional details.

The Reorganization was accounted for as a reverse acquisition and recapitalization for financial reporting purposes. The assets and liabilities of the Corporation, the legal acquirer, were nominal and there were no material pre-combination activities. Therefore, BBP LLC, the legal acquiree, was determined to be the accounting acquirer. Accordingly, the historical financial statements of BBP LLC became the Corporation's historical financial statements, including the comparative prior periods. All share and per share amounts in these condensed consolidated financial statements and related notes have been retroactively adjusted, where applicable, for all periods presented. The shares of the Corporation's common stock for periods prior to July 1, 2019 represent the outstanding BBP LLC units recalculated to give effect to the exchange ratio applied in connection with the Reorganization.

All BBP LLC units that were previously reported as temporary equity and were converted to common stock of the Corporation upon the execution of the Reorganization, have been reclassified to equity for all periods presented, as if the Reorganization occurred at the beginning of the earliest period to be presented in the Company's financial statements for the year ending December 31, 2019, as follows:

	December 31, 2018		
	As Reported	Adjustment	As Adjusted
	(in thousands)		
Redeemable convertible preferred units	$ 478,865	$ (478,865)	$ —
Redeemable founder units	1,754	(1,754)	—
Redeemable common units	1,619	(1,619)	—
Management incentive units	3,221	(3,221)	—
Redeemable convertible noncontrolling interests	122	—	122
Stockholders' Equity (Members' Deficit):			
Undesignated preferred stock	—	—	—
Common stock	—	92	92
Additional paid-in capital	—	494,231	494,231
Accumulated deficit	(170,580)	(8,864)	(179,444)
Total BridgeBio stockholders' equity (members' deficit)	(170,580)	485,459	314,879
Noncontrolling interests	62,361	—	62,361
Total stockholders' equity (members' deficit)	$ (108,219)	$ 485,459	$ 377,240

	December 31, 2017		
	As Reported	Adjustment	As Adjusted
	(in thousands)		
Redeemable convertible preferred units	$ 143,867	$ (143,867)	$ —
Redeemable founder units	1,754	(1,754)	—
Redeemable common units	1,431	(1,431)	—
Management incentive units	226	(226)	—
Redeemable convertible noncontrolling interests	833	—	833
Stockholders' Equity (Members' Deficit):			
Undesignated preferred stock	—	—	—
Common stock	—	51	51
Additional paid-in capital	—	134,495	134,495
Accumulated deficit	(61,427)	12,732	(48,695)
Total BridgeBio stockholders' equity (members' deficit)	(61,427)	147,278	85,851
Noncontrolling interests	2,498	—	2,498
Total stockholders' equity (members' deficit)	$ (58,929)	$ 147,278	$ 88,349

4. 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:

	September 30, 2019			
	Total	Level 1	Level 2	Level 3
	(in thousands)			
Assets				
Cash equivalents:				
Money market funds	$ 256,581	$ 256,581	$ —	$ —
Repurchase agreements	100,000	100,000	—	—
Total cash equivalents	356,581	356,581	—	—
Short-term marketable securities:				
Commercial paper	65,280	—	65,280	—
Corporate debt securities	56,800	—	56,800	—
Total short-term marketable securities	122,080	—	122,080	—
Long-term marketable securities:				
U.S. treasury notes	45,480	—	45,480	—
Corporate debt securities	30,406	—	30,406	—
Total long-term marketable securities	75,886	—	75,886	—
Total cash equivalents and marketable securities	$ 554,547	$ 356,581	$ 197,966	$ —
Liabilities:				
LEO Call Option liability	$ 4,021	$ —	$ —	$ 4,021

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

There were no transfers between Level 1, Level 2 or Level 3 during the periods presented.

LEO Call Option Liability

The valuation of the LEO Call Option (see Note 9) 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:

	September 30, 2019	December 31, 2018
Probability of milestone achievement	12.0%-84.0%	12.0%-84.0%
Discount rate	1.7%-14.5%	2.7%-11.0%
Expected term (in years)	0.83-4.13	0.58-4.38
Expected volatility	60.0%-69.0%	67.0%-79.0%
Risk-free interest rate	3.12%-3.34%	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	1,012
Balance as of September 30, 2019	$ 4,021

5. Cash Equivalents and Marketable Securities

The Company invests in certain reverse repurchase agreements, classified as cash equivalents, which are collateralized by deposits in the form of U.S. treasury securities for an amount no less than 102% of their value. The Company does not record an asset or liability for the collateral as it does not intend to sell or re-pledge the collateral. The collateral has the prevailing credit rating of at least the U.S. government treasuries and agencies. The Company utilizes a third-party custodian to manage the exchange of funds and ensure that collateral received is maintained at 102% of the value of the reverse repurchase agreements on a daily basis.

Cash equivalents and marketable securities classified as available-for-sale consisted of the following:

	September 30, 2019			
	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Fair value
	(in thousands)			
Cash equivalents:				
Money market funds	$ 256,581	$ —	$ —	$ 256,581
Repurchase agreements	100,000	—	—	100,000
Total cash equivalents	356,581	—	—	356,581
Short-term marketable securities:				
Commercial paper	65,280	—	—	65,280
Corporate debt securities	56,745	62	(7)	56,800
Total short-term marketable securities	122,025	62	(7)	122,080
Long-term marketable securities:				
U.S. treasury notes	30,363	48	(5)	30,406
Corporate debt securities	45,426	65	(11)	45,480
Total long-term marketable securities	75,789	113	(16)	75,886
Total cash equivalents and marketable securities	$ 554,395	$ 175	$ (23)	$ 554,547

As of December 31, 2018, the Company had $395.8 million in money market funds and no marketable securities. There have been no significant realized gains or losses on available-for-sale securities for the periods presented.

6. Balance Sheet Components

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following:

	September 30, 2019	December 31, 2018
	(in thousands)	
Prepaid clinical and research related expenses	$ 8,750	$ 7,087
Other current assets	13,352	2,050
Total prepaid expenses and other current assets	$ 22,102	$ 9,137

Other Accrued Liabilities

Other accrued liabilities consist of the following:

	September 30, 2019	December 31, 2018
	(in thousands)	
Accrued professional services	$ 1,570	$ 772
Accrued other liabilities	3,219	1,328
Total other accrued liabilities	$ 4,789	$ 2,100

7. 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 nine months ended September 30, 2019 and 2018.

Upon the Reorganization, BBP LLC became a wholly-owned subsidiary of the Corporation through the series of transactions described in Note 3. At that time, the consolidation assessment was updated on behalf of the Corporation with no changes in the BridgeBio group composition, other than the merger of BBP LLC and Merger Sub LLC as a result of the Reorganization described in Note 3.

As of September 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 September 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 of the 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 September 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 September 30, 2019 and during the nine months then ended.

In May 2019, BridgeBio purchased 1,103,848 shares of Eidos common stock from an existing Eidos stockholder for $28.6 million in a private purchase transaction. In July 2019, BridgeBio purchased 882,353 shares of Eidos common stock from an existing Eidos investor for $26.4 million in a private purchase transaction. In September 2019, Eidos issued 556,173 shares of Eidos common stock to a third-party, which is further described in Note 14.

ML Bio

In July 2019, BridgeBio purchased shares of preferred stock of ML Bio for $7.0 million. Upon the initial investment, BridgeBio received a majority ownership interest in ML Bio and it was determined that ML Bio is a VIE and BridgeBio is the primary beneficiary. BridgeBio controlled the activities that most significantly impact ML Bio's economic performance and, through its representation within management on ML Bio's Board of Directors, also controlled the most significant decisions affecting ML Bio. BridgeBio has consolidated ML Bio under the VIE model since the initial investment date in July 2019 through September 30, 2019. Refer to Note 13 for additional details with respect to this 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 September 30, 2019. BridgeBio also had a majority ownership interest in these entities as of September 30, 2019 and December 31, 2018.

During the nine months ended September 30, 2019, BridgeBio made investments in QED of $80.0 million, Origin of $24.0 million, Aspa of $11.6 million, Adrenas of $11.6 million, PTR of $7.0 million, ML Bio of $7.0 million, CoA of $5.1 million, Theras of $5.0 million, Venthera of $4.5 million, Ferro of $4.5 million, Navire of $4.5 million, Orfan of $3.5 million, MOST of $1.4 million and Quartz of $0.4 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 conclusions during the period ended September 30, 2019.

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

	Adrenas	Aspa	PTR	QED	Venthera	All Other	Total
				(in thousands)			
Assets:							
Current assets:							
Cash and cash equivalents	$ 793	$ 904	$ 6,782	$ 24,084	$ 3,113	$ 33,557	$ 69,233
Prepaid expenses and other current assets	1,261	2,811	662	5,060	222	2,379	12,395
Total current assets	2,054	3,715	7,444	29,144	3,335	35,936	81,628
Property and equipment, net	631	292	71	310	—	279	1,583
Other assets	—	—	1	348	—	—	349
Total assets	$ 2,685	$ 4,007	$ 7,516	$ 29,802	$ 3,335	$ 36,215	$ 83,560
Liabilities:							
Current liabilities:							
Accounts payable	$ 350	$ 320	$ 131	$ 1,893	$ 600	$ 1,798	$ 5,092
Accrued compensation and benefits	466	49	368	2,249	37	1,253	4,422
Accrued research and development liabilities	927	915	93	2,380	271	3,954	8,540
Other accrued liabilities	270	274	8	677	2	238	1,469
Total current liabilities	2,013	1,558	600	7,199	910	7,243	19,523
Other liabilities	—	—	—	163	—	24	187
Total liabilities	$ 2,013	$ 1,558	$ 600	$ 7,362	$ 910	$ 7,267	$ 19,710

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.

8. Noncontrolling Interests

As of September 30, 2019, the Company had both redeemable convertible noncontrolling interests and noncontrolling interests in consolidated partially-owned entities, for which BridgeBio has a majority voting interest under the VOE model and for which BridgeBio is the primary beneficiary under the VIE model. These balances are reported as separate components outside stockholders' equity in "Redeemable convertible noncontrolling interests" and as part of stockholders' equity in "Noncontrolling interests" in the 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 nine months ended September 30, 2019, such adjustments in the aggregate amounts of $13.5 million and $41.9 million are recorded to additional paid-in capital. During the three and nine months ended September 30, 2018, such adjustments in the aggregate amounts of $2.3 million and $57.8 million are recorded to additional paid-in capital. All such adjustments are disclosed within the "Transfers to (from) noncontrolling interest" line item in the condensed consolidated statements of redeemable convertible noncontrolling interests and stockholders' equity.

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

	Orfan	QED	ML Bio	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
Issuance of redeemable convertible noncontrolling interest	—	—	3,196	3,196
Net loss attributable to redeemable convertible noncontrolling interest	(37)	(509)	(89)	(635)
Transfers to redeemable convertible noncontrolling interest	(1)	891	(1,056)	(166)
Balance as of September 30, 2019	$ 17	$ 502	$ 2,051	$ 2,570

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 (repurchase) 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
Issuance (repurchase) of noncontrolling interest	6	9	(1,205)	12	2	1,078	(98)
Transfers to (from) noncontrolling interest	388	316	8,220	2,257	506	2,008	13,695
Net income (loss) attributable to noncontrolling interest	(401)	(399)	2,326	(514)	(298)	(763)	(49)
Balance as of September 30, 2019	$ 116	$ 162	$ 55,372	$ 2,379	$ 387	$ 3,523	$ 61,939

9. 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, 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 remeasures 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 September 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 September 30, 2019 and December 31, 2018, the aggregate carrying amount for the Company's cost method investment in PellePharm was $0.9 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.

10. Commitments and Contingencies

Operating Lease Commitments

In November 2017, Eidos entered into an operating lease for an administrative facility in San Francisco, California. In March 2019, Eidos entered into an amendment to the November 2017 lease and the amended lease commenced on August 2019. In connection with the amendment, Eidos leases 10,552 rentable square feet. The amended Eidos lease is for 87 months and has $6.4 million of future minimum lease payments.

As of September 30, 2019, future minimum lease payments for all noncancelable operating leases with remaining lease terms in excess of one year, are as follows:

	Amount (in thousands)
Remainder of 2019	$ 542
Year Ending December 31:	
2020	2,462
2021	2,156
2022	1,444
2023	1,107
Thereafter	2,766
Total future minimum lease payments	$ 10,477

Contingencies

On February 13, 2019, 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 Superior Court of the State of California, County of San Francisco. CHRCO asserted 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 were generally directed to a set of accusations relating to Dr. Epstein's prior employment at CHRCO. In September 2019, CHRCO, PellePharm and Dr. Epstein reached a mutually agreeable and confidential settlement of their differences, and CHRCO voluntarily dismissed its lawsuit against PellePharm and Dr. Epstein with prejudice.

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.

11. 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"). 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 and the maturity date for the entire facility was July 1, 2022. In May 2019, the Company executed the Second Amendment to the Loan and Security Agreement (the "Amended Hercules Term Loan") whereby the Company borrowed an additional $20.0 million ("Tranche III") to increase the total principal balance outstanding to $75.0 million.

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

The interest rate for the Amended Hercules Term Loan was established as follows: (1) Tranche I bears interest at a floating rate equal to the greater of: (i) the prime rate as reported in the Wall Street Journal plus 3.85% and (ii) 8.85% (8.85% as of September 30, 2019 based on the prime rate as of that date), payable monthly; (2) Tranche II bears interest at a floating rate equal to the greater of: (i) the prime rate as reported in the Wall Street Journal plus 2.85% and (ii) 8.60% (8.60% as of September 30, 2019), payable monthly; and (3) Tranche III bears interest at a floating rate equal to the greater of: (i) the prime rate as reported in the Wall Street Journal plus 3.10% and (ii) 9.10% (9.10% as of September 30, 2019), payable monthly.

During the three and nine months ended September 30, 2019, the Company recognized interest expense related to the Amended Hercules Term Loan of $2.1 million and $5.7 million, of which $0.1 million and $0.7 million relate to amortization of debt discount, respectively. During the three and nine months ended September 30, 2018, the Company recognized interest expense related to the Amended Hercules Term Loan of $0.9 million and $1.0 million, of which $0.3 million and $0.3 million relate to amortization of debt discount, respectively.

12. 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 nine months ended September 30, 2019, Eidos recognized research and development expense of zero and $0.2 million in connection with this agreement.

Under the license agreement with Stanford, the Company will pay Stanford a portion of all nonroyalty sublicensing consideration attributable to the sublicense of the licensed compounds. The license agreement states that if this event occurred in the third year, 10% is payable to Stanford. During the three and nine months ended in September 30, 2019, the Company recognized $2.5 million and $2.5 million as a cost of license revenue upon execution of the Alexion license agreement (see Note 14).

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 nine months ended September 30, 2019 that was recognized as research and development expense. During the three and nine months ended September 30, 2019, Navire recognized additional research and development expense of $1.1 million and $2.4 million in connection with this agreement.

The Regents of the University of California License Agreement

In September 2016, TheRas entered into a license agreement with The Regents of the University of California ("UCSF") relating to TheRas' drug discovery and development initiatives. Under this agreement, TheRas has been granted certain worldwide exclusive licenses to use the licensed compounds (the "UCSF License"). Nominal expense was recognized in connection with this agreement during the three and nine months ended September 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 nine months ended September 30, 2019, TheRas recognized research and development expenses of $0.4 million and $1.0 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 nine months ended September 30, 2019, CoA recognized research and development expense of $0.1 million and $0.5 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 nine months ended September 30, 2019.

Memorial Sloan Kettering Cancer Center License Agreement

In April 2018, 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 nine months ended September 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 nine months ended September 30, 2019, Aspa recognized nominal research and development expense in connection with this agreement.

NeuroVive License Agreement

In June 2018, 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 nine months ended September 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 nine months ended September 30, 2019, Aspa recognized research and development expense of zero 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 nine months ended September 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 nine months ended September 30, 2019, QED recognized research and development expenses of zero 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.

13. Asset Acquisitions

ML Bio Asset Acquisition

As described in Note 7, as of July 2019, ML Bio was a variable interest entity. Based on the qualitative assessment performed under ASC 805 *Business Combinations*, the Company concluded that ML Bio was not considered to be a business and accounted for the initial July 2019 investment in ML Bio as an asset acquisition. The assets acquired, liabilities and noncontrolling interest assumed in the transaction were measured based on their fair values. The Company recognized a loss of $0.4 million in other income (expense). The loss was calculated as the sum of consideration paid of $7.0 million and fair value of noncontrolling interest issued of $4.0 million, less fair value of identifiable net assets acquired of $10.6 million.

The fair value of the in-process research and development assets ("IPR&D") acquired of $1.0 million was charged to research and development expense as it had no alternative future use at the time of the acquisition. BridgeBio may be required to purchase additional shares of preferred stock of up to $24.5 million upon achievement of certain development milestones by ML Bio. The assembled workforce acquired of $0.2 million was amortized during the three months ended September 30, 2019.

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, IPR&D. The assets acquired and liabilities assumed in the transaction were measured based on their fair values.

The fair value of the IPR&D acquired was $0.5 million and was charged to research and development expense as it had no alternative future use at the time of the acquisition. If certain substantive milestones are met in the future, 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. 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 nine months ended September 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.

14. License Revenue

Alexion Agreements

In September 2019, Eidos and an affiliate of Alexion Pharmaceuticals, Inc. (“Alexion”) entered into an exclusive license agreement with Alexion to develop, manufacture and commercialize the compound known as AG10 and any of its various chemical forms and any pharmaceutical products containing AG10 in Japan. Under the agreement, Eidos received an upfront nonrefundable payment of $25.0 million.

The Company accounted for the exclusive license agreement under ASC 606 and identified the exclusive license as a distinct performance obligation since Alexion can benefit from the license on its own by developing and commercializing the underlying product using its own resources. In addition, Eidos will enter into clinical and commercial supply agreements for the licensed territory. The Company determined that the optional right to future products under these supply agreements is not considered to represent a material right.

Additionally, Eidos and Alexion entered into a stock purchase agreement (collectively with the exclusive license agreement, the “Alexion Agreements”), under which Eidos sold to Alexion 556,173 shares of the common stock of Eidos at a price per share of $44.95, for an aggregate purchase price of approximately $25.0 million. The excess of the purchase price over the value of the shares of Eidos’ common stock, determined based on the closing price of a share of the common stock of Eidos of $41.91 as reported on The Nasdaq Global Select Market as of the date of execution, was $1.7 million.

During the three and nine months ended September 30, 2019, the Company recognized $26.7 million and $26.7 million, respectively, in revenues related to the Alexion Agreements. Total revenue included the $25.0 million upfront fee and $1.7 million premium paid for the Eidos common stock upon the effective date of the license agreement in September 2019. The Company determined that the license was a right to use the intellectual property of Eidos and as of the effective date, Eidos had provided all necessary information to Alexion to benefit from the license and the license term had begun.

Eidos is also eligible to receive $30.0 million in regulatory milestone payments subject to the achievement of regulatory milestones. Eidos will also receive low double-digit royalty payments based on net sales of AG10 in Japan. The royalty rate is subject to reduction if Alexion is required to obtain intellectual property rights from third parties to develop, manufacture or commercialize AG10 in Japan, or upon the introduction of generic competition into market. Eidos is also in discussions with Alexion on a supply agreement that has not yet been finalized as of the period ending September 30, 2019.

The Company considers the future potential regulatory milestones of up to approximately $30.0 million and the sales-based royalties to be variable consideration. The Company excluded the regulatory milestones from the transaction price as of September 30, 2019 because we determined such payments to be fully constrained under ASC 606 due to the inherent uncertainty in the achievement of such milestone payments and are highly susceptible to factors outside of our control. As the sales-based royalties is all related to the license of the IP, the Company will recognize revenue in the period when subsequent sales are made pursuant to the sales-based royalty exception under ASC 606-10-55-65. The Company will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

15. 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 BBP LLC equity 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 to additional paid-in capital as payments are received and the Notes were paid in full in February 2019.

PellePharm

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

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 Pharma, LLC 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.

16. 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:

	Nine Months Ended September 30, 2019			
	BridgeBio	Eidos	Other	Total
	(in thousands)			
Research and development	$ 609	$ 1,630	$ 121	$ 2,360
General and administrative	6,767	2,095	145	9,007
Total equity-based compensation	$ 7,376	$ 3,725	$ 266	$ 11,367

	Nine Months Ended September 30, 2018			
	BridgeBio	Eidos	Other	Total
	(in thousands)			
Research and development	$ —	$ 869	$ 142	$ 1,011
General and administrative	974	829	140	1,943
Total equity-based compensation	$ 974	$ 1,698	$ 282	$ 2,954

Equity-Based Awards of the Corporation

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, including common stock options and other equity-based awards. The Corporation initially reserved 11,500,000 shares of common stock for issuance of awards under the 2019 Plan, which may be allocated among stock options, awards of restricted common stock, restricted common units and other equity-based awards.

	Awards Available for Grant
Balance as of December 31, 2018	—
Authorized	11,500,000
Granted — Stock Options	(3,744,629)
Granted — Restricted Stock	(6,819,455)
Cancelled — Stock Options	15,039
Balance as of September 30, 2019	950,955

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.

Stock Option Grants of the Corporation

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

	Nine Months Ended September 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

The following table summarizes the Corporation's stock option activity under the 2019 Plan for the period through September 30, 2019:

	Options Outstanding	Weighted-Average Exercise Price per Option	Weighted-Average Remaining Contractual Life (years)	Aggregate Intrinsic Value
	(in thousands, except share and per share amounts)			
Outstanding as of December 31, 2018	—	$ —	—	$ —
Granted	3,744,629	$ 17.00		
Cancelled	(15,039)	$ 17.00		
Outstanding as of September 30, 2019	3,729,590	$ 17.00	9.7	$ 16,671
Exercisable as of September 30, 2019	232,736	$ 17.00	9.7	$ 1,040

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 the Company 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 the Company at the same exercise price. The options granted have a service condition and vest over a period of four years.

During the three and nine months ended September 30, 2019, the Company recognized equity-based compensation expense of $1.6 million and $1.6 million related to stock options under the 2019 Plan. As of September 30, 2019, there was $23.1 million of total unrecognized compensation cost related to stock options under the 2019 Plan. The unrecognized equity-based compensation cost is expected to be recognized over a weighted-average period of 3.7 years.

Restricted Stock Awards of the Corporation

As disclosed in Note 3, upon the Reorganization, all unvested outstanding management incentive units and common units of BBP LLC were cancelled and converted into shares of the Corporation's restricted stock. The following table summarizes the Corporation's restricted stock award activity under the 2019 Plan for the period through September 30, 2019:

	Unvested Shares of Restricted Stock Outstanding	Weighted-Average Grant Date Fair Value
Balance at December 31, 2018	—	$ —
BBP LLC units converted into shares of unvested restricted stock of the Corporation	6,819,455	3.38
Vested	(603,990)	2.22
Balance at September 30, 2019	6,215,465	$ 3.49

During the three and nine months ended September 30, 2019, the Company recognized equity-based compensation expense of $2.1 million and $2.1 million related to shares of restricted stock under the 2019 Plan. As of September 30, 2019, there was $28.1 million of total unrecognized compensation cost related to shares of restricted stock under the 2019 Plan. The unrecognized equity-based compensation cost is expected to be recognized over a weighted-average period of 3.7 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.

Under the ESPP, eligible employees of the Company may purchase shares of BridgeBio common stock through payroll deductions at a price equal to 85% of the lower of the fair market values of the stock as of the beginning or the end of six-month offering periods. An employee's payroll deductions under the ESPP are limited to 15% of the employee's compensation and employees may not purchase more than 3,500 of shares of BridgeBio common stock during any offering period.

During the three and nine months ended September 30, 2019, the Company recognized equity-based compensation expense of $0.3 million and $0.3 million related to the ESPP. As of September 30, 2019, 2,000,000 shares were reserved for future issuance under the ESPP.

Equity-Based Awards of BBP LLC

BBP LLC has historically issued management incentive units and common units (collectively, "BBP LLC equity-based awards"). As described in Note 3, BBP LLC equity-based awards were cancelled and exchanged for shares of BridgeBio restricted common stock. For the three and nine months ended September 30, 2019, equity-based compensation from BBP LLC equity-based awards was zero and $3.4 million. For the three and nine months ended September 30, 2018, equity-based compensation from BBP LLC equity-based awards was $0.3 million and $1.0 million.

The estimated grant-date fair value of each BBP LLC equity-based award was calculated using the Black-Scholes option pricing model, based on assumptions as follows:

	Nine Months Ended September 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	—	—

The following table summarizes authorized BBP LLC equity-based awards activity:

	Equivalent Shares of the Corporation's Restricted Common Stock
Balance as of December 31, 2018	9,994,483
Authorized and granted	2,587,939
Cancelled	(842)
Converted into common stock of the Corporation	(5,762,125)
Converted into unvested restricted common stock of the Corporation	(6,819,455)
Balance as of September 30, 2019	—

The following table summarizes vested BBP LLC equity-based awards activity:

	Equivalent Shares of the Corporation's Restricted Common Stock	Weighted-Average Grant Date Fair Value
Balance as of December 31, 2018	4,639,317	$ 0.45
Vested	1,122,808	2.10
Converted into vested restricted common stock of the Corporation	(5,762,125)	0.72
Balance as of September 30, 2019	—	$ —

Eidos

Common stock

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

	September 30,	
	2019	2018
Options issued and outstanding	1,435,668	1,041,334
Options available for future grants	486,915	371,004
Eidos ESPP shares available for future grants	104,540	143,540
Total	2,027,123	1,555,878

Stock options

The following table summarizes Eidos's stock option activity for the nine months ended September 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 share and per share amounts)				
Outstanding as of December 31, 2018	747,057	1,329,762	$ 8.55	9.4	$ 6,928
Granted	(313,712)	313,712	30.29		
Exercised	—	(154,236)	2.26		
Cancelled	53,570	(53,570)	7.24		
Outstanding as of September 30, 2019	486,915	1,435,668	14.02	8.9	$ 31,513
Vested and expected to vest as of September 30, 2019		238,717	7.17	8.5	$ 6,876
Exercisable as of September 30, 2019		1,435,668	$ 14.02	8.9	$ 31,513

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:

	Nine Months Ended September 30,	
	2019	2018
Expected term (in years)	6.07	6.08
Expected volatility	72.2%	70.9%
Risk-free interest rate	2.00%	2.79%
Dividend yield	—	—
Weighted average fair value of share-based awards granted	$ 20.09	$ 8.38

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:

	Nine Months Ended September 30,	
	2019	2018
Expected term (in years)	6.09	9.45
Expected volatility	73.7%	74.4%
Risk-free interest rate	2.52%	3.04%
Dividend yield	—	—

During the three and nine months ended September 30, 2019 and 2018, Eidos granted zero, 18,500, zero and 35,880 shares, respectively, to non-employee consultants. Eidos recognized immaterial stock-based compensation expense for non-employee awards during the three and nine months ended September 30, 2019 and 2018.

Stock-based compensation

As of September 30, 2019, there was $13.1 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 2.7 years.

17. Income Taxes

The Company is subject to U.S. federal and state income taxes as a corporation. 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. Prior to the tax-free reorganization, BBP LLC was treated as a pass-through entity for U.S. federal income tax purposes, and as such, was generally not subject to U.S. federal income tax at the entity level. Rather, the tax liability with respect to its taxable income was passed through to its unitholders.

Deferred tax assets and deferred tax liabilities are recognized based on temporary differences between the financial reporting and tax basis of assets and liabilities using statutory rates. A valuation allowance is recorded against deferred tax assets if it is more likely than not that some or all of the deferred tax assets will not be realized. Due to the uncertainty surrounding the realization of the favorable tax attributes in future tax returns, the Company has recorded a full valuation allowance against the Company's otherwise recognizable net deferred tax assets.

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.

18. Net Loss Per Share

The following common stock equivalents were excluded from the computation of diluted net loss per share, because including them would have been antidilutive:

	As of September 30,	
	2019	2018
Unvested restricted common stock	6,215,465	5,328,400
Common stock options issued and outstanding	3,729,590	—
Estimated shares issuable under the ESPP	72,949	—
	10,018,004	5,328,400

19. Subsequent Events

Significant financing events in relation to controlled VIEs

Subsequent to September 30, 2019, BridgeBio made an additional investment in Aspa of $4.0 million, Adrenas of $4.0 million, Theras of $2.0 million and Unnamed Entity #3 of $1.0 million.

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, or BBP LLC, became a wholly-owned subsidiary of BridgeBio Pharma, Inc., or BBP Inc., collectively with BBP LLC, BridgeBio. As part of the transactions, holders of Preferred Units, Founder Units, Common Units and Management Incentive Units of BBP LLC exchanged all outstanding units for an aggregate of 99,999,967 shares of common stock of BBP Inc.

On July 1, 2019, we completed 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 $366.2 million from the IPO, after deducting underwriters' discounts and commissions of $28.1 million and offering costs of $6.5 million. As of September 30, 2019, we had cash, cash equivalents and marketable securities of $611.9 million, of which $446.1 million was held at BridgeBio group of companies, excluding Eidos and $165.8 million at Eidos.

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 September 30, 2019 and 2018, we incurred net losses of $60.7 million and $42.1 million, and for the nine months ended September 30, 2019 and 2018, we incurred net losses of $204.4 million and $120.2 million. We had an accumulated deficit as of September 30, 2019 of $366.6 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 nine months ended September 30, 2019:

	Three Months Ended September 30,			Nine Months Ended September 30,		
	BridgeBio, Excluding Eidos	Eidos (1)	BridgeBio Consolidated	BridgeBio, Excluding Eidos	Eidos (1)	BridgeBio Consolidated
	(in thousands)					
License revenue	$ 50	$ 26,691	$ 26,741	$ 50	$ 26,691	$ 26,741
Operating expenses:						
Cost of license revenue	—	2,500	2,500	—	2,500	2,500
Research and development	43,373	11,905	55,278	119,658	32,804	152,462
General and administrative	17,719	5,776	23,495	47,847	11,534	59,381
Total operating expenses	61,092	20,181	81,273	167,505	46,838	214,343
Loss from operations	(61,042)	6,510	(54,532)	(167,455)	(20,147)	(187,602)
Other income (expense), net:						
Interest income	2,036	700	2,736	4,161	2,344	6,505
Interest expense	(2,113)	—	(2,113)	(5,725)	—	(5,725)
Loss from ML Bio asset acquisition	(416)	—	(416)	(416)	—	(416)
Loss from PellePharm	(6,589)	—	(6,589)	(16,144)	—	(16,144)
LEO call option income (expense)	276	—	276	(1,012)	—	(1,012)
Other income (expense)	(6)	(20)	(26)	32	(72)	(40)
Total other income (expense), net	(6,812)	680	(6,132)	(19,104)	2,272	(16,832)
Net income (loss)	$ (67,854)	$ 7,190	$ (60,664)	$ (186,559)	$ (17,875)	$ (204,434)

(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 nine months ended September 30, 2019:

	Nine Months Ended September 30, 2019		
	BridgeBio, Excluding Eidos	Eidos	BridgeBio Consolidated
	(in thousands)		
Net cash used in operating activities	$ (162,241)	$ (15,143)	$ (177,384)
Net cash used in investing activities	(200,205)	(147)	(200,352)
Net cash provided by financing activities	331,923	23,965	355,888
Net decrease in cash and cash equivalents	(30,523)	8,675	(21,848)
Cash, cash equivalents and restricted cash, beginning of period	279,098	157,147	436,245
Cash, cash equivalents and restricted cash, end of period	248,575	165,822	414,397
Add: Marketable Securities	197,966	—	197,966
Less: Restricted Cash	(424)	—	(424)
Cash, cash equivalents and marketable securities, end of period	$ 446,117	$ 165,822	$ 611,939

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 and is 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 nine months ended September 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 in the amount of $17.0 million. The Eidos Warrant was also net exercised upon the completion of the Eidos IPO. We previously determined that Eidos was a controlled VIE as of December 31, 2017 and through its initial public offering in June 2018, at which time we determined that Eidos is no longer a VIE. In May 2019, we purchased 1,103,848 shares of Eidos common stock from an existing Eidos stockholder for $28.6 million in a private purchase transaction. In July 2019, we purchased 882,353 shares of Eidos common stock from an existing Eidos investor for $26.4 million in a private purchase transaction. Subsequent to the Eidos IPO and through September 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 2018 was $1.9 million and increased to $4.0 million as of September 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.

Financial Operations Overview

Revenue

Our revenue to date is primarily related to the license agreement and related stock purchase agreement, or the Alexion Agreements, entered into by Eidos with an affiliate of Alexion Pharmaceuticals, Inc., or Alexion, in September 2019. Under the applicable GAAP rules, upon execution of the Alexion Agreements, we recognized revenue from the upfront license fee paid by Alexion and a premium to the fair market value on Eidos' common stock purchased by Alexion.

Operating Expenses

Cost of License Revenue

Cost of license revenue represents sublicensing fees payable under the Stanford License in connection with the Alexion Agreements.

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 September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
	(in thousands)		(in thousands)	
BBP-265 (Eidos)(1)	$ 11,906	$ 8,368	$ 32,805	$ 20,215
BBP-831 (QED)	17,292	4,858	49,105	26,022
BBP-631 (Adrenas)	3,069	3,429	11,174	5,162
BBP-454 (TheRas)	1,527	1,156	3,661	2,546
BBP-009 (PellePharm)(2)	—	4,802	—	13,683
Other Programs	21,484	8,535	55,717	21,243
Total	$ 55,278	$ 31,148	$ 152,462	$ 88,871

(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 included in our research and development expenses 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 early stages of clinical development, which is a lengthy and expensive process with uncertain outcomes and has 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 nine months ended September 30, 2019, our general and administrative expenses were $23.5 million and $59.4 million, of which $5.8 million and $11.5 million were related to Eidos. For the three months and nine months ended September 30, 2018, our general and administrative expenses were $10.3 million and $29.2 million of which $2.6 million and $8.6 million were related to Eidos.

Other Income (Expense), Net

Interest Income

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

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 three months ended March 31, 2019, we recognize our percentage of net losses consistent with our preferred stock ownership percentage until the cost method investment will also be reduced to zero.

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

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

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., Origin Biosciences, Inc. and ML Bio Solutions, 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 revenues and expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

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, except for the determination of the fair value of our common stock, which is used in estimating the fair value of stock-based awards at grant date. Prior to the IPO, our common stock was not publicly traded, therefore we estimated the fair value of our common stock as discussed in the Prospectus. Following our IPO, the closing sale price per share of our common stock as reported on the Nasdaq Global Select Market on the date of grant is used to determine the exercise price per share of our share-based awards to purchase common stock.

Additionally, in our unaudited condensed and consolidated financial statements for the period ended September 30, 2019, we disclosed our accounting policy for revenue recognition and accounting for marketable securities, based on the transactions we entered into subsequent to our IPO.

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 September 30, 2019 and 2018

	Three months ended September 30,			
	2019	2018	Increase/ (Decrease)	% Change
	(in thousands)			
License revenue	$ 26,741	$ —	$ 26,741	100%
Operating expenses:				
Cost of license revenue	2,500	—	2,500	100%
Research and development	55,278	31,148	24,130	77%
General and administrative	23,495	10,308	13,187	128%
Total operating expenses	81,273	41,456	39,817	96%
Loss from operations	(54,532)	(41,456)	(13,076)	32%
Other income (expense), net:				
Interest income	2,736	528	2,208	418%
Interest expense	(2,113)	(1,156)	(957)	83%
Loss from ML Bio asset acquisition	(416)	—	(416)	100%
Loss from PellePharm	(6,589)	—	(6,589)	100%
LEO call option income	276	—	276	100%
Other expense	(26)	6	(32)	*
Total other income (expense), net	(6,132)	(622)	(5,510)	*
Net loss	(60,664)	(42,078)	(18,586)	44%
Net loss attributable to redeemable convertible noncontrolling interests and noncontrolling interests	684	10,677	(9,993)	-94%
Net loss attributable to us	$ (59,980)	$ (31,401)	$ (28,579)	91%

* *Not meaningful*

License Revenue

License revenue for the three months ended September 30, 2019 consists primarily of the upfront payment received by Eidos upon execution of the Alexion Agreements and the premium to the fair market value with respect to Alexion’s equity investment.

Cost of License Revenue

Cost of license revenue for the three months ended September 30, 2019 represents the sublicensing fee payable by Eidos under the Stanford License in connection with the execution of the Alexion Agreements.

Research and Development Expenses

Research and development expenses increased by $24.1 million to $55.3 million for the three months ended September 30, 2019, from $31.1 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 $10.7 million increase in development and drug discovery efforts for our research programs, a $5.0 million increase in salaries and employee-related benefits due to increased headcount, a $2.5 million increase in license fees, which included $1.0 million expense related to ML Bio acquisition, a $2.4 million increase in clinical development costs for our product candidates, and a $1.4 million increase in allocated facility and other expenses.

General and Administrative Expenses

General and administrative expenses increased by $13.2 million to $23.5 million for the three months ended September 30, 2019, from $10.3 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 $4.2 million increase in salaries and employee-related benefits, a $3.6 million increase in equity-based compensation expense resulting from equity-based awards granted by us to our employees, a $2.0 million increase in professional and consultant fees, a $1.3 million increase in legal fees and a $1.2 million increase in allocated facility and other expenses.

Interest Income

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

Interest Expense

Interest expense for the three months ended September 30, 2019 and 2018 was primarily related the interest accrued on the Hercules term loan. Interest expense increase by $1.0 million is due to additional draws from Hercules executed in December 2018 and May 2019.

Loss from ML Bio Asset Acquisition

We accounted for the July 2019 ML Bio transaction as an asset acquisition. Since ML Bio was a variable interest entity and not a business, we recognized a loss of $0.4 million for the three months ended September 30, 2019.

Loss from PellePharm

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

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 September 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 September 30, 2018.

Nine Months Ended September 30, 2019 and 2018

	Nine months ended September 30,			
	2019	2018	Increase/ (Decrease)	% Change
	(in thousands)			
License revenue	$ 26,741	$ —	$ 26,741	100%
Operating expenses:				
Cost of license revenue	2,500	—	2,500	100%
Research and development	152,462	88,871	63,591	72%
General and administrative	59,381	29,206	30,175	103%
Total operating expenses	214,343	118,077	96,266	82%
Loss from operations	(187,602)	(118,077)	(69,525)	59%
Other income (expense), net:				
Interest income	6,505	531	5,974	*
Interest expense	(5,725)	(1,368)	(4,357)	318%
Loss from ML Bio asset acquisition	(416)	—	(416)	100%
Loss from PellePharm	(16,144)	—	(16,144)	100%
LEO call option expense	(1,012)	—	(1,012)	100%
Other expense	(40)	(1,296)	1,256	*
Total other income (expense), net	(16,832)	(2,133)	(14,699)	*
Net loss	(204,434)	(120,210)	(84,224)	70%
Net loss attributable to redeemable convertible noncontrolling interests and noncontrolling interests	17,305	28,102	(10,797)	-38%
Net loss attributable to us	$ (187,129)	$ (92,108)	$ (95,021)	103%

* *Not meaningful*

License Revenue

License revenue for the nine months ended September 30, 2019 consists primarily of the upfront payment received by Eidos upon execution of the Alexion Agreements and the premium to the fair market value with respect to Alexion's equity investment.

Cost of License Revenue

Cost of license revenue for the nine months ended September 30, 2019 represents the sublicensing fee payable by Eidos under the Stanford License in connection with the execution of the Alexion Agreements.

Research and Development Expenses

Research and development expenses increased by $63.6 million to $152.5 million for the nine months ended September 30, 2019, from $88.9 million for the same period in 2018, largely attributable to an increase in the number of product candidates under development increasing substantially as of September 30, 2018 to September 30, 2019 and the initiation of more clinical trials as compared to 2018.

The increase was primarily comprised primarily of a $27.6 million increase in development and drug discovery efforts for our research programs, a $12.4 million increase in clinical development costs for our product candidates, a $17.0 million increase in salaries and employee-related benefits, a $6.8 million increase in professional and consulting services to advance our product candidates, a $11.5 million increase in allocated facility and other expenses. This increase was partially offset by a $12.7 million decrease in license fees to acquire various technologies, as in early 2018 we had significant asset acquisitions.

General and Administrative Expenses

General and administrative expenses increased by $30.2 million to $59.4 million for the nine months ended September 30, 2019, from $29.2 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 primarily of a $11.4 million increase in salaries and employee-related benefits, a $7.2 million increase in professional and consulting services such as administrative, accounting, finance, human resources and information technology services, a $7.1 million increase in equity-based compensation expense resulting from equity-based awards granted by us to our employees, a $2.3 million increase in patent fees and a $2.1 million increase in allocated facility and other expenses.

Interest Income

Interest income for the nine months ended September 30, 2019, primarily consisted of the interest earned on our cash equivalents and marketable securities. Interest income was not material for the same period in 2018.

Interest Expense

Interest expense for the nine months ended September 30, 2019 and 2018 was primarily related the interest accrued on the Hercules term loan. Interest expense increase by $4.4 million is due to additional draws from Hercules executed in December 2018 and May 2019.

Loss from ML Bio Asset Acquisition

We accounted for the July 2019 ML Bio transaction as an asset acquisition. Since ML Bio was a variable interest entity and not a business, we recognized a loss of $0.4 million for the nine months ended September 30, 2019.

Loss from PellePharm

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

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 September 30, 2019. There was no such liability subject to be recorded and remeasured as of and prior to September 30, 2018.

Other Expense

Other expense for the nine months ended September 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 September 30, 2019, we held 24,575,501 shares of common stock of Eidos. All cash and cash equivalents held by Eidos are restricted and can be applied solely to fund the operations of Eidos.

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

As of September 30, 2019, we had cash, cash equivalents and marketable securities of $611.9 million, of which $446.1 million was held at BridgeBio group of companies, excluding Eidos and $165.8 million at Eidos. The funds that were held by our wholly-owned subsidiaries and controlled entities are available for specific entity usage, except in limited circumstances.

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. 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. 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 agreements and amendments entered into with Hercules during June 2018 through May 2019 are collectively referred to as the Amended Hercules Term Loan.

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

Subsequent to our IPO, the interest rate under Amended Hercules Term Loan was established as follows: (1) Tranche I bears interest at a floating rate equal to the greater of: (i) the prime rate as reported in the Wall Street Journal plus 3.85% and (ii) 8.85% (8.85% as of September 30, 2019 based on the prime rate as of that date), payable monthly; (2) Tranche II bears interest at a floating rate equal to the greater of: (i) the prime rate as reported in the Wall Street Journal plus 2.85% and (ii) 8.60% (8.60% as of September 30, 2019), payable monthly; and (3) Tranche III bears interest at a floating rate equal to the greater of: (i) the prime rate as reported in the Wall Street Journal plus 3.10% and (ii) 9.10% (9.10% as of September 30, 2019), payable monthly.

The Amended Hercules Term Loan contains customary representations and warranties, events of default, and affirmative and negative covenants for a term loan facility of this size and type. However, Hercules 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

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 $366.2 million, net of underwriting discounts and commissions of $28.1 million and offering costs of $6.5 million. As of September 30, 2019, we had cash, cash equivalents and marketable securities of $611.9 million, of which $446.1 million was held at BridgeBio group of companies, excluding Eidos and $165.8 million at Eidos. 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 continue 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:

	Nine Months Ended September 30,	
	2019	2018
	(in thousands)	
Net cash used in operating activities	$ (177,384)	$ (90,229)
Net cash used in investing activities	(200,352)	(17,437)
Net cash provided by financing activities	355,888	227,374
Net increase (decrease) in cash and cash equivalents and restricted cash	$ (21,848)	$ 119,708

Net Cash Flows from Operating Activities

Net cash used in operating activities for the nine months ended September 30, 2019 was $177.4 million, which included $15.1 million of net cash used in operating activities by Eidos and $162.3 million of net cash used by other entities in BridgeBio group. It primarily consisted of our net loss of $204.4 million and changes in net operating assets and liabilities of $7.0 million, which were partially offset by non-cash charges of $34.0 million.

The net change in operating assets and liabilities was primarily due to an increase of $12.5 million in prepaid expenses and other assets and of $1.7 million in other assets, both increases were primarily due to the advance payments made for research due to increased activities at CROs and CMOs. Such increase in prepaid expenses and other assets was offset by changes in liabilities, including an increase in accrued compensation and benefits of $3.5 million, an increase of $4.3 million in accrued research and development liabilities and an increase of $2.7 million in other accrued liabilities, and reduced by a decrease in accounts payable of $3.2 million, which was primarily related to the timing of payments.

Our non-cash charges primarily consisted primarily of a $16.1 million loss from PellePharm, $11.4 million for equity-based compensation expense, $3.6 million for acquired in-process research and development assets and $1.0 million of expense related to the revaluation of the LEO Call Option liability.

Net cash used in operating activities for the nine months ended September 30, 2018 was $90.2 million, which included $23.7 million of net cash used in operating activities by Eidos and $66.5 million of net cash used by other entities in BridgeBio group. It primarily consisted of our net loss of $120.2 million, which was partially offset by non-cash charges of $22.8 million and a change in net operating assets and liabilities of $7.2 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, $3.0 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 $9.0 million in accounts payable, increase of $6.1 million in accrued research and development liabilities, and increase in other accrued liabilities of $1.2 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. Additionally, there was an increase of $2.4 million in accrued compensation and benefits related to increased staffing and related activities of our subsidiaries. These amounts were partially offset by an increase of $11.7 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 nine months ended September 30, 2019 was $200.4 million, which consisted primarily of $197.7 million used to purchase marketable securities, $2.5 million paid for in-progress research and development assets acquired in connection with asset acquisitions and $0.9 million related to purchase of property and equipment.

Net cash used in investing activities for the nine months ended September 30, 2018 was $17.4 million, which consisted of $16.0 million paid for in-progress research and development assets acquired in connection with asset acquisitions and $1.4 million related to purchase of property and equipment.

Net Cash Flows from Financing Activities

Net cash provided by financing activities of $355.9 million for the nine months ended September 30, 2019 was primarily to the proceeds from our IPO of $366.2 million, proceeds from issuance of noncontrolling interest in Eidos to Alexion of $23.3 million, proceeds from Hercules term loan of $19.8 million and proceeds from issuance of redeemable convertible noncontrolling interest in ML Bio of $1.5 million, offset by $55.0 million payment in relation to repurchase of common stock of Eidos from a noncontrolling interest holder.

Net cash provided by financing activities of $227.4 million for the nine months ended September 30, 2018 was primarily related to net proceeds of $95.5 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 equity financing received by BBP LLC 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

In March 2019, Eidos entered into an amendment to its office lease. The amended lease commenced in August 2019 and Eidos increased its rentable facilities to 10,552 square feet. The amended lease is for 87 months and has $6.4 million of payments under this lease.

In July 2019, the completion of our IPO triggered certain provisions of the Amended Hercules Term Loan. The outstanding balance of the Amended Hercules Term Loan is to be repaid by us monthly beginning on July 1, 2021 and extending through January 1, 2023. Immediately prior to completion of our IPO, these dates were January 1, 2021 and July 1, 2022, respectively.

The following table summarizes our contractual obligations as of September 30, 2019:

	Payments Due by Period				
	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years	Total
Operating lease obligations	$ 2,375	$ 3,864	$ 2,181	$ 2,057	$ 10,477
Hercules term loans debt	—	58,329	16,671	—	75,000
Interest on term loans debt and final end of term payment	6,753	10,378	309	—	17,440
Total contractual obligations	$ 9,128	$ 72,571	$ 19,161	$ 2,057	$ 102,917

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.

We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate sensitivities. The primary objective of our investment activities is to preserve our capital to fund our operations. We also seek to maximize income from our investments without assuming significant risk. To achieve our objectives, we maintain a portfolio of cash equivalents and investments in a variety of marketable securities of high credit quality.

We held cash, cash equivalents and marketable securities of $611.9 million as of September 30, 2019, including $446.1 million was held at BridgeBio group of companies, excluding Eidos and $165.8 million at Eidos. Our cash equivalents consist of amounts invested in money market accounts, such as money market funds and overnight repurchase agreements collateralized with securities issued by the U.S. government or its agencies. Our marketable securities consisted of commercial paper, corporate debt securities and U.S. government agency securities. We do not enter into investments for trading or speculative purposes and have not used any derivative financial instruments to manage our interest rate risk exposure. We have not been exposed nor do we anticipate being exposed to material risks due to changes in interest rates. A hypothetical 100 basis point change in interest rate during any of the periods presented would not have had a material impact on our financial statements. We do not believe that our cash, cash equivalents or marketable securities have a significant risk of default or illiquidity.

As of September 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 3.85% and (ii) 8.85% (8.85% as of September 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 2.85% and (ii) 8.60% (8.60% as of September 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 September 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 September 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 yet 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 February 13, 2019, Children Hospital Research Center at Oakland, or 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 Superior Court of the State of California, County of San Francisco. CHRCO asserted 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). In September 2019, CHRCO, PellePharm and Dr. Epstein reached a mutually agreeable and confidential settlement of their differences, and CHRCO voluntarily dismissed its lawsuit against PellePharm and Dr. Epstein with prejudice.

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 any such matters or the ultimate legal and financial liability, and at this time cannot reasonably estimate the possible loss or range of loss and accordingly have 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 nine months ended September 30, 2019 and the years ended December 31, 2018 and 2017 were $204.4 million, $169.5 million and $43.8 million, respectively. As of September 30, 2019, we had an accumulated deficit of $366.6 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 September 30, 2019, we had working capital of $518.3 million and cash, cash equivalents and marketable securities of $611.9 million. 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.

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. For instance, in August 2019, we announced a non-binding proposal to acquire all of the outstanding shares of common stock of Eidos that were not then owned by us or our subsidiaries, or the Eidos Buyout Offer. Although discussions between a special committee comprised of Eidos' disinterested and independent directors and us with respect to the proposed transaction have terminated, the attention of certain members of each company's management and each company's resources may have focused on completion of the Eidos Buyout Offer and been diverted from day-to-day business operations, which may disrupt each company's ongoing business.

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.

Other third parties may assert that we are employing their proprietary technology without authorization. There may be other third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of BBP-265, BBP-831, BBP-454, BBP-631 or other product candidates that we may identify. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that BBP-265, BBP-831, BBP-454, BBP-631 or other product candidates that we may identify may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of BBP-265, BBP-831, BBP-454, BBP-631 or other product candidates that we may identify, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire.

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

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize BBP-265, BBP-831, BBP-454, BBP-631 or other product candidates that we may identify. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys’ fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

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

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

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

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

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

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

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

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

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

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

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

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

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential collaborators or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. We may license our trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names. Our efforts to enforce or protect our proprietary rights related to trademarks, trade names, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our competitive position, business, financial condition, results of operations and prospects.

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

Competitors may infringe our patents or other intellectual property. If we were to initiate legal proceedings against a third party to enforce a patent covering one or more of our product candidates, the defendant could counterclaim that the patent covering our product candidate is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including novelty, nonobviousness, written description or enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. The outcome following legal assertions of invalidity and unenforceability is unpredictable. Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms or at all, or if a non-exclusive license is offered and our competitors gain access to the same technology. Our defense of litigation or interference or derivation proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue clinical trials, continue research programs, license necessary technology from third parties, or enter into development partnerships that would help us bring product candidates to market. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions, or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock.

We may be subject to claims challenging the inventorship of our patents and other intellectual property.

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

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

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

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

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

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

As is common in the biotechnology and pharmaceutical industry, we employ individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and independent contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of any of our employee's former employer or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely impact our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

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

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

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

Filing, prosecuting and defending patents on our product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may also export infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology and pharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

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

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

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

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

Risks Related to Commercialization

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

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

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

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

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

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

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

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

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

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

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

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

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

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

There is also significant uncertainty related to the insurance coverage and reimbursement of newly approved products and coverage may be more limited than the purposes for which the medicine is approved by the FDA or comparable foreign regulatory authorities. In the United States, the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. No uniform policy of coverage and reimbursement for products exists among third-party payors and coverage and reimbursement levels for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time consuming and costly process that may require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. It is difficult to predict what CMS will decide with respect to reimbursement for fundamentally novel products such as ours, as there is no body of established practices and precedents for these new products. Reimbursement agencies in Europe may be more conservative than CMS. For example, a number of cancer drugs have been approved for reimbursement in the United States and have not been approved for reimbursement in certain European countries. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale, and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved products we may develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize product candidates, and our overall financial condition.

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

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

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

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

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

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Violations are subject to civil and criminal fines and penalties 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. 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. On July 9, 2019, the Fifth Circuit US Court of Appeals held a hearing to determine whether certain states and the House of Representatives have standing to appeal the lower court decision, but 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 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. 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 or other competitors, including competitors for our other product candidates, receive FDA approval before we do, our product candidates would not be the first treatment on the market, and our market share may be limited. In addition to competition from other companies targeting our target indications, any products we may develop may also face competition from other types of therapies.

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

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

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

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

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

Risks related to our business and industry

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

We are highly dependent on the management, research and development, clinical, financial and business development expertise of our executive officers, our directors, our Management Committee as well as the other members of our scientific and clinical teams. However, some of these executive officers, directors and other personnel split their time between BridgeBio and certain of our other subsidiaries. For instance, Neil Kumar serves as chief executive officer and a director both to us and Eidos; Uma Sinha serves as chief scientific officer to us and Eidos; 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 September 30, 2019, we had 28 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 September 30, 2019, we had 210 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 IPO, we were a private company with limited accounting personnel to adequately execute our accounting processes and other supervisory resources with which to address our internal control over financial reporting and, as a result, we may experience difficulty in meeting these reporting requirements in a timely manner. To date, we have never conducted a review of our internal 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 September 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 IPO, 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 IPO, (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 IPO will be able to be sold in the public market beginning 180 days after the date of our IPO. 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 September 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 49.5% 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.

(a) 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.

(b) 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 $366.2 million, net of underwriting discounts and commissions of $28.1 million and 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.

(c) Issuer Purchases of Company Equity Securities

None.

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
10.1†	License Agreement, by and between the Registrant and Alexion Pharma International Operations Unlimited Company, dated September 9, 2019	—	—	—	Filed herewith
10.2#	Offer Letter, between BridgeBio Pharma, Inc. and Brian Stolz, dated September 19, 2019	—	—	—	Filed herewith
10.3#	Offer Letter, between and BridgeBio Services, Inc. and Yi Ching Yau, dated September 9, 2019	—	—	—	Filed herewith
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	—	—	—	Filed herewith
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	—	—	—	Filed herewith
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	—	—	—	Filed herewith
32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	—	—	—	Filed herewith
101.INS	XBRL Instance Document	—	—	—	Filed herewith
101.SCH	XBRL Taxonomy Extension Schema Document	—	—	—	Filed herewith
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document	—	—	—	Filed herewith
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document	—	—	—	Filed herewith
101.LAB	XBRL Taxonomy Extension Label Linkbase Document	—	—	—	Filed herewith
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document	—	—	—	Filed herewith

* This certification will not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent specifically incorporated by reference into such filing.

# Indicates a management contract or any compensatory plan, contract or arrangement.

† Certain confidential portions (indicated by brackets and asterisks) have been omitted from this exhibit in accordance with the rules of the Securities and Exchange Commission.

SIGNATURES

Pursuant to the requirements of 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: November 8, 2019

By: /s/ Neil Kumar

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

Date: November 8, 2019

By: /s/ Brian Stephenson

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

Exhibit 10.1

CONFIDENTIAL
Execution Version

LICENSE AGREEMENT

between

Alexion Pharma International Operations Unlimited Company

and

Eidos Therapeutics, Inc.

DATED

September 9, 2019

[***] Certain information in this exhibit has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the registrant if publicly disclosed.

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LICENSE AGREEMENT

This **License Agreement** (this "***Agreement***") is made as of September 9, 2019 (the "***Effective Date***"), by and between **Eidos Therapeutics, Inc.**, a Delaware corporation ("***Eidos***"), having a place of business at 101 Montgomery Street, Suite 2550, San Francisco, California 94104, USA, and **Alexion Pharma International Operations Unlimited Company**, an Irish unlimited company ("***Alexion***"), having a place of business at College Business & Technology Park, Blanchardstown, Dublin 15, Ireland. Eidos and Alexion are referred to in this Agreement individually as a "***Party***" and collectively as the "***Parties***."

Recitals

Whereas, Alexion is a global pharmaceutical company with experience and expertise in the research, development and commercialization of pharmaceutical products;

Whereas, Eidos is a clinical stage biopharmaceutical company that Controls (as defined below) the intellectual property and other rights related to the pharmaceutical compound known as AG10; and

Whereas, Alexion is interested in obtaining an exclusive license under such intellectual property and other rights to Develop and Commercialize Licensed Product in the Field in the Territory (each capitalized term as defined below), and Eidos is willing to grant such an exclusive license to Alexion, subject to the terms and conditions set forth herein.

Agreement

Now, Therefore, in consideration of the foregoing premises and the covenants contained herein, the Parties hereby agree as follows:

ARTICLE 1
DEFINITIONS

Unless specifically set forth to the contrary herein, the following terms, whether used in the singular or plural, shall have the respective meanings set forth below:

1.1 "***Acquiring Entity***" means a Third Party (the "***Acquiror***") that acquires a Party (and is therefore deemed to be an Affiliate of such Party) through a Change of Control, together with any Affiliates of such Acquiror existing immediately prior to the consummation of the Change of Control. For purposes of clarity, an "Acquiring Entity" of a Party shall exclude (a) the Party and all of its Affiliates existing immediately prior to the consummation of the Change of Control and (b) any Person that becomes an Affiliate of the Acquiror following the consummation of the Change of Control, and not as a result of the Change of Control.

1.2 "***Acquiror***" has the meaning set forth in Section 1.1.

1.3 "***Additional Cure Period***" has the meaning set forth in Section 12.2(b)(ii).

1.4 "***Additional Trial***" has the meaning set forth in Section 4.2(b).

1.5 "***Affiliate***" means, (a) with respect to Alexion, any Person controlling, controlled by or under common control with Alexion, at the time that the determination of affiliation is made and for as long as such control exists, (b) with respect to Eidos, any entity that is controlled by Eidos at the time that the determination of affiliation is made and for as long as such control exists, and (c) with respect to any other Person, any entity controlling, controlled by or under common control with such first Person, at the time that the determination of affiliation is made and for as long as such control exists. For the purpose of this definition only, "control" (including, with correlative meaning, the terms "controlled by" and "under the common control") means (a) direct or indirect ownership of fifty percent (50%) or more of the stock or shares having the right to vote for the election of directors of such Person (or if the jurisdiction where such Person is domiciled prohibits foreign ownership of such entity, the maximum foreign ownership interest permitted under such Applicable Laws; provided, however, that such ownership interest provides actual control over such Person), (b) status as a general partner in any partnership, or (c) the possession, directly or indirectly, of the power to direct, or cause the direction of, the management or policies of such Person, whether through the ownership of voting securities, by contract or otherwise. For the avoidance of doubt, [***] shall not be deemed to be an Affiliate of [***] and any company in which [***] has a direct or indirect controlling financial interest shall not be deemed to be an Affiliate of [***] solely due to such controlling financial interest.

1.6 "***Alexion Indemnitees***" has the meaning set forth in Section 10.2.

1.7 "***Alexion Technology***" means the Patent Rights and Know-How Controlled by Alexion or its Affiliates as of the Effective Date or any time during the Term that are necessary for the Development, Manufacture, or Commercialization of the Licensed Products in the Territory.

1.8 "***Alliance Manager***" has the meaning set forth in Section 3.1.

1.9 "***Applicable Laws***" means collectively all laws, regulations, ordinances, decrees, judicial and administrative orders, notices and guidelines (and any license, franchise, permit or similar right granted under any of the foregoing) and any policies and other requirements of any applicable Governmental Authority that govern or otherwise apply to a Party's activities in connection with this Agreement.

1.10 "***Applicable Territory***" means (a) with respect to Alexion, the Territory, and (b) with respect to Eidos, the ROW Territory.

1.11 "***Arbitration Commencement Date***" has the meaning set forth in Exhibit 12.3(b)(i).

1.12 "***ATTRibute Clinical Trial***" means each of the ATTRibute-CM Clinical Trial and ATTRibute-PN Clinical Trial, collectively, the "***ATTRibute Clinical Trials***".

1.13 "***ATTRibute-CM Clinical Trial***" means the Clinical Trial with the Protocol No. Eidos AG10-301.

1.14 "***ATTRibute-PN Clinical Trial***" means the Clinical Trial with the Protocol No. Eidos AG10-333.

1.15 "***Auditor***" has the meaning set forth in Section 7.6(a).

1.16 "***Bankruptcy Code***" means Title 11 of the United States Code.

1.17 "***Business Day***" means a day other than a Saturday, Sunday or a day on which banking institutions in New York, New York or San Francisco, CA are required by Applicable Laws to remain closed.

1.18 "***Calendar Quarter***" means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31.

1.19 "***Calendar Year***" means each twelve (12) month period commencing on January 1.

1.20 "***cGMP***" means all applicable current Good Manufacturing Practices, including, as applicable, (a) the principles detailed in the U.S. Current Good Manufacturing Practices, 21 C.F.R. Parts 4, 210, 211, 601, 610 and 820, (b) European Directive 2003/94/EC and Eudralex 4, (c) the principles detailed in the ICH Q7 of ICH Guidelines, and (d) the equivalent Applicable Laws in the Territory, each as may be amended and applicable from time to time.

1.21 "***Change of Control***" means, with respect to a Party, any of the following: (a) the sale or disposition of all or substantially all of the assets of such Party or its direct or indirect controlling Affiliate to a Third Party, other than to a Person of which more than fifty percent (50%) of the voting capital stock are owned after such sale or disposition by the Persons that were shareholders of such Party or its direct or indirect controlling Affiliate (in either case, whether directly or indirectly through any other Person) immediately prior to such transaction; or (b) (i) the acquisition by a Third Party, alone or together with any of its Affiliates, other than an employee benefit plan (or related trust) sponsored or maintained by such Party or any of its Affiliates, of more than fifty percent (50%) of the outstanding shares of voting capital stock of such Party or its direct or indirect controlling Affiliate, or (ii) the acquisition, merger or consolidation of such Party or its direct or indirect controlling Affiliate with or into another Person, other than, in the case of this clause (b), an acquisition or a merger or consolidation of such Party or its controlling Affiliate in which the holders of shares of voting capital stock of such Party or its controlling Affiliate, as the case may be, immediately prior to such acquisition, merger or consolidation will beneficially own, directly or indirectly, at least fifty percent (50%) of the shares of voting capital stock of the acquiring Third Party or the surviving corporation in such acquisition, merger or consolidation, as the case may be, immediately after such acquisition, merger or consolidation. Notwithstanding the foregoing, any transaction or series of transactions effected for the sole purpose of changing the form or jurisdiction of organization of such Party will not be deemed a "Change of Control" for purposes of this Agreement.

1.22 "***Clinical Supply Agreement***" has the meaning set forth in Section 5.1.

1.23 "***Clinical Trial***" means any clinical trial in humans of a pharmaceutical compound or product.

1.24 "***CMO***" means a contract manufacturing organization.

1.25 "***Combination Product***" has the meaning set forth in Section 1.79.

1.26 "***Commercial Supply Agreement***" has the meaning set forth in Section 5.2.

1.27 "***Commercialize***" or "***Commercialization***" means to market, promote, advertise, exhibit, distribute (including storage for distribution or inventory), detail, sell (including to offer for sale or contract to sell) or otherwise commercially exploit (including to conduct pricing and reimbursement activities) a pharmaceutical compound or product, or to conduct any activities directed to any of the foregoing (including importing and exporting activities in connection therewith).

1.28 "***Commercially Reasonable Efforts***" means, with respect to a Party and a Licensed Product, that level of efforts and resources commonly devoted by such Party to [***] Commercially Reasonable Efforts shall be determined [***].

1.29 "***Confidential Information***" has the meaning set forth in Section 8.1.

1.30 "***Control***" or "***Controlled***" means, with respect to a Party and any Patent Rights, Know-How or other intellectual property rights, the possession by such Party or its Affiliates (whether by ownership, license or otherwise) of, (a) with respect to any tangible Know-How, the legal authority or right to physical possession of such tangible Know-How, with the right to provide such tangible Know-How to the other Party on the terms and conditions set forth herein, or (b) with respect to Patent Rights, intangible Know-How or other intellectual property rights, the legal authority or right to grant a license, sublicense, access or right to use (as applicable) under such Patent Rights, intangible Know-How or other intellectual property rights to the other Party on the terms and conditions set forth herein, in each case of (a) and (b), without (i) breaching the terms of any agreement with a Third Party in existence as of the time such Party or its Affiliates would first be required hereunder to grant the other Party such access, right to use or (sub)license or (ii) paying any consideration to any Third Party under an agreement between such Party (or its Affiliates) and such Third Party under which such Patent Rights, Know-How or other intellectual property rights are in-licensed to such Party or its Affiliates, [***]. Notwithstanding the foregoing, a Party will be deemed not to Control any intellectual property (including Patent Rights or Know-How), compounds, physical, biological or chemical materials or Confidential Information that are owned or in-licensed by an Acquiring Entity except (1) with respect to any such intellectual property (including Patent Rights or Know-How) arising as a result of activities of employees or consultants of the Acquiring Entity who participate in activities or have access to Confidential Information of either Party under this Agreement after a Change of Control; (2) to the extent that any such intellectual property (including Patent Rights or Know-How) is included in or used in furtherance of a Party's activities under this Agreement by the Acquiring Entity or its Affiliates after a Change of Control; or (3) to the extent that any such intellectual property (including Patent Rights or Know-How) is used by the acquired Party or the Acquiring Entity or their respective Affiliates to Exploit the Licensed Compound or Licensed Products. Notwithstanding anything to the contrary herein, if Eidos Controls any Patent Rights or Know-How that constitute Eidos IP through any of its Affiliates as of the Effective Date or at any time during the Term, such Patent Rights or Know-How will be deemed to be Controlled by Eidos (and therefore subject to the License) for the remainder of the Term, notwithstanding any change in the Affiliate status of the applicable Affiliate.

1.31 "***Cover***" means, with respect to a product, technology, process, method or mode of administration that, in the absence of ownership of or a license granted under a particular Patent Right, the Manufacture use, offer for sale, sale or importation of such product or composition of matter or the practice of such technology, process, method or mode of administration would infringe a claim of such Patent Right or, in the case of a claim of a Patent Right that has not yet issued, would infringe such claim if it were to issue without change.

1.32 "***CRO***" means a contract research organization.

1.33 "***Defaulting Party***" has the meaning set forth in Section 12.2(b)(ii).

1.34 "***Develop***" or "***Development***" means to conduct any non-clinical or clinical drug research or development activities, whether before or after Regulatory Approval, including drug metabolism and pharmacokinetics, translational research, toxicology, pharmacology, test method development and stability testing, process and packaging development and improvement, process validation, process scale-up, formulation development, delivery system development, quality assurance and quality control development, statistical analysis, conduct of Clinical Trials, regulatory affairs, the preparation and submission of regulatory filings, Clinical Trial regulatory activities, or any other activities directed towards obtaining or maintaining Regulatory Approval of any pharmaceutical compound or product. Development includes use and importation of the relevant compound or product to conduct such Development activities. Development does not include Commercialization activities.

1.35 "***Direct Competitor***" means any Third Party that is Exploiting in the Field in the Territory any pharmaceutical compound or product that is intended to treat any Exclusive Indication.

1.36 "***Disclosing Party***" has the meaning set forth in Section 8.1.

1.37 "***Dollar***" or "**$**" means the U.S. dollar, and "$" shall be interpreted accordingly.

1.38 "***Eidos Indemnitees***" has the meaning set forth in Section 10.1.

1.39 "***Eidos IP***" means the Eidos Know-How and the Eidos Patents.

1.40 "***Eidos Know-How***" means all Know-How Controlled by Eidos or its Affiliates as of the Effective Date or that comes into the Control of Eidos or its Affiliates at any time during the Term that is necessary or useful to Exploit the Licensed Compound or Licensed Products in the Field.

1.41 "***Eidos Patents***" means all Patent Rights Controlled by Eidos or its Affiliates as of the Effective Date or that come into the Control of Eidos or its Affiliates at any time during the Term that Cover the Licensed Compound or any Licensed Product in the Field (including composition of matter and methods of using or making the Licensed Compound or a Licensed Product), or are otherwise necessary or useful to Exploit the Licensed Compound or Licensed Products in the Field. The Eidos Patents as of the Effective Date are set forth in Exhibit 1.41, provided that any Patent Right that satisfies this definition shall constitute an Eidos Patent notwithstanding any failure to list such Patent Right on Exhibit 1.41.

1.42 "***Exclusive Indication***" means (a) transthyretin amyloidosis, (b) any Indication for the treatment of which a Licensed Product has received Regulatory Approval in the Territory or the ROW Territory, or (c) any Indication for the treatment of which a Licensed Product is being Developed in the Territory or the ROW Territory (*e.g.*, for which pre-clinical studies or Clinical Trials of a Licensed Product are being conducted).

1.43 "***Executive Officers***" means the Chief Executive Officer of Eidos and the Chief Executive Officer of Alexion, or their respective designees.

1.44 "***Existing Confidentiality Agreement***" means that certain Confidential Disclosure Agreement, dated May 28, 2019, between Eidos and Alexion.

1.45 "***Expert***" has the meaning set forth in Exhibit 12.3(b)(i).

1.46 "***Exploit***" means, with respect to any pharmaceutical compound or product, to Develop, Manufacture, have Manufactured, use, Commercialize, import, export, obtain and maintain Regulatory Approvals and applicable pricing or reimbursement approvals, and otherwise exploit or have exploited such pharmaceutical compound or product.

1.47 "***Field***" means the treatment, prevention, control or diagnosis of any and all diseases or conditions.

1.48 "***First Commercial Sale***" means, with respect to a given Licensed Product in the Territory, the first sale by Alexion, its Affiliates or Sublicensees in an arm's length transaction of such Licensed Product to a Third Party other than a Sublicensee in such country in exchange for cash (or some equivalent to which value can be assigned) after Regulatory Approval for such Licensed Product has been granted in the Territory. For the avoidance of doubt, supply of Licensed Product as samples or to patients for compassionate use, named patient use, clinical trials or other similar purposes shall not be considered a First Commercial Sale.

1.49 "***FTE***" means a qualified full time person, or more than one person working the equivalent of a full-time person, where "full time" is based upon a total of [***] working hours per [***] of scientific or technical work carried out by a duly qualified employee of Eidos. Overtime and work on weekends, holidays and the like shall not be counted with any multiplier (*e.g.*, time-and-a-half or double time) toward the number of hours that are used to calculate the FTE contribution.

1.50 "***FTE Costs***" means the product of (a) the number of FTEs (proportionately, on per-FTE basis) used by a Party or its Affiliates in directly performing activities assigned to such Party under this Agreement multiplied by (b) the FTE Rate.

1.51 "***FTE Rate***" means [***] U.S. Dollars ($[***]) per FTE for the [***], subject to annual increases beginning on [***] to reflect any year to year percentage increase in the Consumer Price Index – Urban Wage Earners and Clerical Workers, US City Average, All Items, 1982-84 = 100, published by the United States Department of Labor, Bureau of Labor Statistics (or its successor equivalent index) over the twelve (12)-month period preceding each such January 1.

1.52 "***GAAP***" means generally accepted accounting principles in the United States, consistently applied.

1.53 "***GCP***" means all applicable Good Clinical Practice standards for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of clinical trials, including, as applicable (a) as set forth in the ICH E6 of the ICH Guideline and any other guidelines for good clinical practice for clinical trials on medicinal products in the Territory, (b) the Declaration of Helsinki (2004) as last amended at the 64th World Medical Association in October 2013 and any further amendments or clarifications thereto, (c) U.S. Code of Federal Regulations Title 21, Parts 50 (Protection of Human Subjects), 56 (Institutional Review Boards) and 312 (Investigational New Drug Application), and (d) the equivalent Applicable Laws in the Territory, each as may be amended and applicable from time to time and in each case, that provide for, among other things, assurance that the clinical data and reported results are credible and accurate and protect the rights, integrity, and confidentiality of trial subjects.

1.54 "***Generic Competition Percentage***" means, on a Licensed Product-by-Licensed Product and Calendar-Quarter-by-Calendar Quarter basis in the Territory, the total aggregate units of the applicable Generic Products sold in a Calendar Quarter in the Territory divided by the sum of: (a) total aggregate units of a Licensed Product sold in such Calendar Quarter in the Territory, and (b) total aggregate units of each Generic Product sold in such Calendar Quarter in the Territory, where, in each case ((a) and (b)), the total aggregate units of a Licensed Product and each Generic Product will be based on the monthly data provided by IMS or another independent source mutually agreed upon by the Parties.

1.55 "***Generic Product***" means, with respect to a Licensed Product in the Territory, a product sold by a Third Party that [***].

1.56 "***Global Brand Plan***" means a global brand plan that sets forth a high-level global marketing and branding strategy for the Licensed Products, including a life cycle plan, brand vision, key messaging, concept and imagery, and supporting market research.

1.57 "***GLP***" means all applicable Good Laboratory Practice standards, including, as applicable, as set forth in the then-current good laboratory practice standards promulgated or endorsed by the U.S. Food and Drug Administration, as defined in 21 C.F.R. Part 58, and the equivalent Applicable Laws in the Territory, each as may be amended and applicable from time to time.

1.58 "***Governmental Authority***" means any federal, state, national, state, provincial or local government, or political subdivision thereof, or any multinational organization or any authority, agency or commission entitled to exercise any administrative, executive, judicial, legislative, police, regulatory or taxing authority or power, or any court or tribunal (or any department, bureau or division thereof, or any governmental arbitrator or arbitral body).

1.59 "***ICH Guidelines***" mean the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use Harmonized Tripartite Guideline.

1.60 "***Indemnification Claim Notice***" has the meaning set forth in Section 10.3.

1.61 "***Indemnified Party***" has the meaning set forth in Section 10.3.

1.62 "***Indemnifying Party***" has the meaning set forth in Section 10.3.

1.63 "***Indication***" means a disease, condition, disorder or syndrome.

1.64 "***Insolvency Event***" has the meaning set forth in Section 12.2(e).

1.65 "***Invoice***" means an original invoice sent by Eidos to Alexion with respect to any payment due hereunder meeting the reasonable requirements provided by Alexion to Eidos.

1.66 "***JAMS***" has the meaning set forth in Exhibit 12.3(b)(i).

1.67 "***Joint Commercialization Committee***" has the meaning set forth in Section 3.2(b).

1.68 "***Joint Development Committee***" has the meaning set forth in Section 3.2(a).

1.69 "***Know-How***" means any and all information or materials, including discoveries, improvements, modifications, processes, methods, assays, designs, protocols (including Clinical Trial protocols), formulas, data, inventions, algorithms, forecasts, profiles, strategies, plans, results, know-how and trade secrets (in each case, regardless of whether patentable, copyrightable or otherwise), but excluding any Patent Rights. For the avoidance of doubt, "Know-How" shall include Product Data and Regulatory Documents.

1.70 "***License***" means the licenses granted by Eidos to Alexion pursuant to Section 2.1.

1.71 "***Licensed Compound***" means the compound known by the name AG10, as described on Exhibit 1.71, [***].

1.72 "***Licensed Product***" means any pharmaceutical product that contains the Licensed Compound, either alone or in combination with one or more other active pharmaceutical ingredients, delivery systems or devices.

1.73 "***Licensed Product Trademarks***" means the Trademark(s) used or anticipated to be used by a Party or its Affiliates or its Third Parties Licensees (in the case of Eidos) or Sublicensees (in the case of Alexion) for the Exploitation of Licensed Products in such Party's Applicable Territory, and any registrations thereof or any pending applications relating thereto with any Governmental Authority.

1.74 "***Licensed Product-Specific Trademarks***" has the meaning set forth in Section 6.3(b).

1.75 "***Losses***" has the meaning set forth in Section 10.1.

1.76 "***LP Generic Competition Percentage***" means, on a Licensed Product-by-Licensed Product and Calendar-Quarter-by-Calendar Quarter basis in the Territory, the total aggregate units of the applicable LP Generic Products sold in a Calendar Quarter in the Territory divided by the sum of: (a) total aggregate units of a Licensed Product sold in such Calendar Quarter in the Territory, and (b) total aggregate units of each LP Generic Product sold in such Calendar Quarter in the Territory, where, in each case ((a) and (b)), the total aggregate units of a Licensed Product and each LP Generic Product will be based on the monthly data provided by IMS or another independent source mutually agreed upon by the Parties.

1.77 "***LP Generic Product***" means, with respect to a Licensed Product in the Territory, a product sold by a Third Party that [***].

1.78 "***Manufacture***" or "***Manufacturing***" means to conduct or have conducted any activities directed to producing, manufacturing, scaling up, processing, filling, finishing, packaging, labeling, quality assurance testing and release, shipping, and storage at manufacturing facilities of any pharmaceutical compound or product, or any component thereof (including production of drug substance and drug product, in bulk form, whether for Development or Commercialization).

1.79 "***Net Sales***" means, with respect to a Licensed Product in the Territory in a particular period, the sum of (a) and (b):

(a) net sales amounts recorded by Alexion or its Affiliates for sales of such Licensed Product to Third Parties calculated in a manner consistent with Alexion's calculations of net product sales in externally published audited financial statements with respect to such Licensed Products for that period ([***]) for Licensed Products sold in the Territory (provided that if for any reason Alexion does not have externally published audited financial statements for such Licensed Product, then net sales amounts for any period that would not be covered by an externally published audited financial statement shall be calculated as specified in this clause (a)), this amount reflecting the [***] at which such Licensed Products were sold [***] by Alexion and its Affiliates ([***]) to Third Parties in that period reduced by [***], taken in accordance with GAAP; and

(b) net sales amounts received by each Sublicensee for sales of such Licensed Product to Third Parties determined in accordance with GAAP.

The calculations described in clauses (a) and (b) above shall exclude [***]. For the avoidance of doubt, the supply of Licensed Product [***].

If a Licensed Product (x) is sold as part of a combination product containing both the Licensed Compound and one or more active pharmaceutical ingredient(s) as separate molecular entity(ies) that are not Licensed Compounds; (y) is sold as part of a combination of a Licensed Product and another pharmaceutical product that contains at least one other active pharmaceutical ingredient that is not a Licensed Compound, where such products are not formulated together but are sold together (*i.e.*, bundled) as a single product and invoiced as one product or (z) is sold in combination with one or more other components or products (such as devices or delivery systems) or services for a single invoice price (in any case ((x), (y) or (z)), a "***Combination Product***", and such other active pharmaceutical ingredient(s), component(s), product(s) or services, the "***Other Component(s)***"), then the Net Sales of such Licensed Product for the purpose of calculating payments owed under this Agreement for sales of such Licensed Product, shall be determined as described below.

In the event a Licensed Product is sold as part of a Combination Product, Net Sales of the Combination Product will be calculated as follows:

(i) If the Licensed Product and the Other Component(s) contained in the Combination Product are sold separately in the same respective dosages in the applicable country in the Territory, Net Sales will be calculated by multiplying the total Net Sales of the Combination Product by the fraction A/(A+B), where A is the average gross selling price in the applicable country in the Territory of the Licensed Product sold separately, and B is the sum of the average gross selling prices in the applicable country in the Territory of the Other Component(s) sold separately, during the applicable Calendar Quarter.

(ii) If the Combination Product and the Licensed Product in the same dosage are sold separately in the applicable country in the Territory, but the average gross selling price of the Other Component(s) in the same dosage(s) in the applicable country in the Territory cannot be determined, Net Sales of the Combination Product shall be equal to the Net Sales of the Combination Product multiplied by the fraction A/C wherein A is the average gross selling price in the applicable country in the Territory of the Licensed Product sold separately and C is the average gross selling price of the Combination Product in the applicable country in the Territory, during the applicable Calendar Quarter.

(iii) If the Combination Product and the Other Component(s) in the same dosage(s) are sold separately, but the average gross selling price of the Licensed Product in the same dosage in the applicable country in the Territory cannot be determined, Net Sales of the Combination Product shall be equal to the Net Sales of the Combination Product multiplied by the following formula: one (1) minus B/C wherein B is the average gross selling price in the applicable country in the Territory of the Other Component(s) sold separately and C is the average gross selling price of the Combination Product in the applicable country in the Territory, during the applicable Calendar Quarter.

(iv) If neither the Licensed Product nor the Other Component(s) contained in the Combination Product are sold separately in the same respective dosages in the applicable country in the Territory, Alexion shall make a good faith reasonable determination of the relative value of the Licensed Product and the Other Component(s) for the purpose of calculating Net Sales of such Combination Product, and shall calculate Net Sales based on such good faith determination; provided, however, that if Eidos disputes that such determination by Alexion represents a reasonable determination of the relative value of the Licensed Product and the Other Component(s) for the purpose of calculating Net Sales of such Combination Product, then such dispute shall be resolved in accordance with Exhibit 12.3(b)(i).

The average gross selling price for the Other Component(s) in the same dosage(s) contained in the Combination Product shall be calculated for a Calendar Quarter by dividing the sales such Other Component(s) in the same dosage(s) in the applicable country in the Territory in such Calendar Quarter by the units of such Other Component(s) in the same dosage(s) in the applicable country in the Territory in such Calendar Quarter, as published by IMS or another mutually agreed independent source.

1.80 "***New In-License Agreement***" has the meaning set forth in Section 11.8(c).

1.81 "***Non-Defaulting Party***" has the meaning set forth in Section 12.2(b)(ii).

1.82 "***Other Component***" has the meaning set forth in Section 1.79.

1.83 "***Out-of-Pocket Costs***" means amounts paid by a Party or any of its Affiliates to a Third Party for goods or services, but shall not include such Party's, or any of its Affiliates', internal or general overhead costs or expenses.

1.84 "***Patent Challenge***" has the meaning set forth in Section 12.2(d).

1.85 "***Patent Prosecution***" means activities directed to (a) preparing, filing and prosecuting applications (of all types) for any Patent Right, (b) managing any interference, opposition, re-issue, reexamination, supplemental examination, invalidation proceedings (including *inter partes* or post-grant review proceedings), revocation, nullification, or cancellation proceeding relating to the foregoing Patent Rights, (c) maintaining issued Patent Right(s), (d) listing in regulatory publications such as the Orange Book and its equivalents (as applicable), (e) obtaining patent term extensions, supplementary protection certificates and the like for issued Patent Right(s), and maintenance thereof, and (f) managing, including settling, any interference, opposition, reexamination, invalidation, revocation, nullification or cancellation proceeding relating to issued Patent Right(s).

1.86 "***Patent Right***" means (a) all patents and patent applications in any country or supranational jurisdiction in the Territory, (b) any substitutions, divisionals, continuations, continuations-in-part, provisional applications, reissues, renewals, registrations, confirmations, re-examinations, extensions, supplementary protection certificates and the like of any such patents or patent applications, (c) foreign counterparts of any of the foregoing, (d) all applications claiming priority to any of the foregoing and (e) any patents issuing on any patent application identified in clauses (a) through (d).

1.87 "***Person***" means any individual, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, incorporated association, joint venture, unincorporated organization or association, or Governmental Authority.

1.88 "***Pharmacovigilance Agreement***" has the meaning set forth in Section 4.8.

1.89 "***PMDA***" means the Japanese Pharmaceuticals and Medical Devices Agency, and local counterparts thereto, and any successor agency(ies) or authority thereto having substantially the same function.

1.90 "***Product Data***" means any and all data relating to or arising out of the Development or Manufacture of the Licensed Compound or Licensed Products, or that is otherwise necessary or useful for the Exploitation of the Licensed Compound or Licensed Products in the Field in the Territory, including data collected or resulting from pre-clinical studies or Clinical Trials, CMC data, Manufacturing records and information, and supporting documentation (*e.g.*, protocols, format of case report forms, analysis plans) relating to pre-clinical studies, Clinical Trials or other Development or Manufacturing activities with respect to the Licensed Compound or Licensed Products.

1.91 "***Product Infringement***" has the meaning set forth in Section 11.3(b)(i).

1.92 "***Publishing Party***" has the meaning set forth in Section 8.8.

1.93 "***Quality Agreement***" has the meaning set forth in Section 5.4.

1.94 "***Rebuttal***" has the meaning set forth in Exhibit 12.3(b)(i).

1.95 "***Receiving Party***" has the meaning set forth in Section 8.1.

1.96 "***Regulatory Approval***" means, with respect to a pharmaceutical product in a country, (a) any and all licenses, registrations, authorizations and approvals of the applicable Governmental Authority, including NDAs or any foreign equivalent thereof, as applicable, and (b) if applicable, any and all pricing or reimbursement authorizations and approvals in regulatory jurisdictions where the applicable Governmental Authorities approve or determine the price or reimbursement of pharmaceutical products, in each case ((a) and (b)), that are necessary to Commercialize such pharmaceutical product in such country. Without limiting any of the foregoing, with respect to a Licensed Product, Regulatory Approval for a Licensed Product in the Territory will include pricing approval from the National Health Insurance in the Territory.

1.97 "***Regulatory Authority***" means any Governmental Authority responsible for granting Regulatory Approvals. "Regulatory Authority" includes the USFDA, PMDA and any corresponding national or regional regulatory authorities, and any successor agency of the foregoing.

1.98 "***Regulatory Documents***" means any filing, application or submission with any Regulatory Authority, including authorizations, approvals or clearances arising from the foregoing, including Regulatory Approvals and Investigational New Drug Applications or their equivalents in any jurisdiction, and all written correspondence or written communication with or from the relevant Regulatory Authority, as well as minutes of any material meetings, telephone conferences or discussions with the relevant Regulatory Authority, in each case, with respect to the Licensed Compound or the Licensed Product.

1.99 "***Reversion License***" has the meaning set forth in Section 12.3(b)(i).

1.100 "***ROW Territory***" means all countries of the world outside of the Territory.

1.101 "***Royalty Term***" means, with respect to a given Licensed Product in the Territory, the period commencing on the First Commercial Sale of such Licensed Product in the Territory and ending upon the later to occur of (a) the expiration of the last-to-expire Valid Claim of the Eidos Patents that Covers such Licensed Product in the Territory, or (b) the tenth (10^{th}) anniversary of such First Commercial Sale.

1.102 "***Securitization Transaction***" has the meaning set forth in Section 13.2(b).

1.103 "***Selected Agreement***" has the meaning set forth in Exhibit 12.3(b)(i).

1.104 "***Stanford***" has the meaning set forth in Section 2.4(a)(i).

1.105 "***Stanford Agreement***" has the meaning set forth in Section 2.4(a)(i).

1.106 [***].

1.107 "***Subcontractor***" has the meaning set forth in Section 2.3.

1.108 "***Sublicensee***" means any Third Party, including a co-development, co-promotion or co-marketing partner, to whom Alexion or any of its Affiliates grants a sublicense of the License, or any further sublicensee of such rights (regardless of the number of tiers, layers or levels of sublicenses of such rights), but excluding service providers, CROs, manufacturers, wholesalers, distributors or other Subcontractors.

1.109 "***Supporting Memorandum***" has the meaning set forth in Exhibit 12.3(b)(i).

1.110 "***Tax***" or "***Taxes***" means all forms of preliminary or finally imposed taxation, domestic and foreign taxes, fees, levies, duties and other assessments or charges of whatever kind (including sales, use, excise, stamp, transfer, property, value added, goods and services, withholding and franchise taxes) together with any interest, penalties or additions payable in connection with such taxes, fees, levies duties and other assessments or charges.

1.111 "***Technology Transfer***" has the meaning set forth in Section 5.3(b).

1.112 "***Term***" has the meaning set forth in Section 12.1.

1.113 "***Territory***" means Japan and its territories and possessions.

1.114 "***Third Party***" means any Person other than a Party or an Affiliate of a Party.

1.115 "***Third Party Claims***" has the meaning set forth in Section 10.1.

1.116 "***Third Party Licensee***" means any Third Party holding a license (whether exclusive or non-exclusive) under the Eidos IP in the Field in the ROW Territory.

1.117 "***Trademark***" means any word, name, symbol, color, designation or device or any combination thereof that functions as a source identifier, including any trademark, trade dress, brand mark, service mark, trade name, brand name, logo, business symbol or domain names, whether or not registered.

1.118 [***].

1.119 [***].

1.120 "***U.S. Prime Rate***" has the meaning set forth in Section 7.4(g).

1.121 "***United States***" means the United States of America.

1.122 "***Upstream Licenses***" means the Stanford Agreement and any New In-License Agreements.

1.123 "***Upstream Licensor***" means any Third Party licensor that is a party to an Upstream License.

1.124 "***USFDA***" means the United States Food and Drug Administration or any successor agency(ies) or authority thereto having substantially the same function.

1.125 "***Valid Claim***" means either (a) a claim of an issued and unexpired patent or a supplementary protection certificate, which has not been held permanently revoked, unenforceable or invalid by a decision of a court, patent office or other forum of competent jurisdiction, unappealable or unappealed within the time allowed for appeal and that is not admitted to be invalid or unenforceable through reissue, disclaimer or otherwise (*i.e.*, only to the extent the subject matter is disclaimed or is sought to be deleted or amended through reissue), dedicated to the public or abandoned, or (b) a claim of a pending patent application being prosecuted in good faith (*i.e.*, it is reasonably believed that there is a *bona fide* chance that such pending application will be issued) that has not been abandoned, finally rejected or expired without the possibility of appeal or refiling, provided that "Valid Claim" shall exclude any such claim in such a pending application that has not been granted within [***] following the earliest priority filing date for such claim (unless and until such claim is granted).

ARTICLE 2
LICENSE

2.1 License Grants to Alexion.

(a) **Exclusive License Grant to Alexion**. Eidos hereby grants to Alexion an exclusive (even as to Eidos, except as necessary for Eidos to perform its obligations under this Agreement, including the conduct of any ATTRibute Clinical Trial or Additional Clinical Trial in the Territory following a [***] in accordance with Section 4.2(b), or to exercise the retained rights expressly set forth in this Section 2.1(a)), royalty-bearing, non-transferable (except in accordance with Section 13.2) license, with the right to grant sublicenses through multiple tiers (in accordance with Section 2.2), under the Eidos IP to Exploit the Licensed Compound and Licensed Products in the Field in the Territory. For clarity, Eidos retains a right under the Eidos IP, with the right to grant licenses through multiple tiers, to Develop, Manufacture, have Manufactured, use, import, and export Licensed Products anywhere in the world for the purpose of Exploiting the Licensed Products in the ROW Territory, including, notwithstanding the foregoing exclusive license grant, the non-exclusive right to Develop, Manufacture and have Manufactured Licensed Compound and Licensed Product in the Territory (including importing and exporting activities in connection therewith) for Exploiting Licensed Products in the ROW Territory, but excluding, for the avoidance of doubt, any right to Commercialize Licensed Products in the Territory. Notwithstanding anything contained herein to the contrary, except for the ATTRibute-CM Clinical Trial and ATTRibute-PN Clinical Trial in accordance with Section 4.2(b), Eidos may not conduct clinical Development for the Licensed Product in the Territory without the prior written consent of Alexion.

(b) **Non-Exclusive License Grant to Alexion**. Eidos hereby grants to Alexion a non-exclusive, royalty-free, non-transferable (except in accordance with Section 13.2) license, with the right to grant sublicenses through multiple tiers (in accordance with Section 2.2), under the Eidos IP to Develop, Manufacture, have Manufactured, use, import and export the Licensed Compound and Licensed Products in the Field in the ROW Territory, solely for the purpose of Exploiting the Licensed Compound and Licensed Products in the Field in the Territory. Notwithstanding the foregoing, Alexion may not conduct clinical Development for the Licensed Product in the ROW Territory without Eidos' prior written consent.

2.2 Right to Sublicense.

(a) Alexion shall have the right to grant sublicenses of the License to its Affiliates to fulfill any of its obligations or exercise any of its rights under this Agreement. Each sublicense granted pursuant to this Section 2.2(a) shall be consistent with the terms and conditions of this Agreement. Notwithstanding any such sublicense, Alexion shall remain directly responsible for all of its obligations under this Agreement.

(b) Alexion shall have the right to grant sublicenses of the License to Sublicensees pursuant to this Section 2.2(b). Each sublicense granted pursuant to this Section 2.2(b) shall be subject to a written agreement that is consistent with the terms and conditions of this Agreement. Each such sublicense shall contain a requirement that the Sublicensee comply with all provisions of the applicable Upstream Licenses that are applicable to Alexion and its Sublicensees, and a requirement that the Sublicensee perform and take such actions as may be reasonably required to allow Eidos and Alexion to comply with their obligations thereunder. Further, Alexion shall use commercially reasonable efforts to include in each such sublicense a requirement that the Sublicensee (i) [***] and (ii) provide the following to Alexion if the sublicense agreement terminates: [***]. Alexion shall provide Eidos with a copy of any sublicense it enters into with a Third Party, within [***] after the execution thereof, which copy may be disclosed to the Upstream Licensors, provided that such copy may be subject to redaction as Alexion reasonably believes appropriate to protect confidential business information, including financial provisions and other sensitive information as applicable. Notwithstanding any such sublicense, Alexion will remain directly responsible for all of its obligations under this Agreement.

2.3 Right to Subcontract. Alexion shall have the right to engage CROs, contract manufacturing organizations, distributors and other Third Parties to perform its activities under this Agreement (each, a "***Subcontractor***"), and to grant sublicenses of the License to any such Subcontractor, provided that (i) Alexion shall cause its Subcontractors to be bound by written obligations of confidentiality and non-use at least as restrictive as those set forth in this Agreement, (ii) Alexion shall remain directly responsible for any obligations that have been subcontracted to a Subcontractor as if the Subcontractor were a party hereto, and (iii) for any subcontract entered into after the Effective Date, Alexion will use commercially reasonable efforts to include in such subcontract [***].

2.4 Stanford Agreement.

(a) Alexion acknowledges and agrees that:

(i) Eidos obtained the rights to certain Eidos IP from Leland Stanford Junior University ("***Stanford***") under that certain Exclusive (Equity) Agreement, dated April 1, 2016, as amended, by and between Stanford and Eidos, as may be amended from time to time (the "***Stanford Agreement***");

(ii) the License constitutes a sublicense under the Stanford Agreement and, [***], to the extent required under Section 4.3(A) of the Stanford Agreement, Alexion is subject to and will comply with its obligations under the Stanford Agreement as a sublicensee thereunder;

(iii) [***], Alexion acknowledges and agrees that it shall comply with Sections 4.4 (Litigation by Sublicensee), 8.4 (Accounting), 8.5 (Audit by Stanford), 8.6 (Paying for Audit), and Articles 9 (Exclusions and Negation of Warranties) and 10 (Indemnity) of the Stanford Agreement as such relate to Alexion as a sublicensee under the Stanford Agreement, which, as required by Section 4.3(D) and (E) of the Stanford Agreement, shall be deemed included in this Agreement for the benefit of Stanford, and these Sections and Articles are attached hereto in Exhibit 2.4; and

(iv) notwithstanding any provision of this Agreement to the contrary, (i) Eidos may provide a copy of this Agreement, and any amendment to this Agreement, to Stanford, and (ii) Eidos may provide to Stanford any information required to be provided in accordance with the Stanford Agreement subject to Stanford's obligations of confidentiality thereunder.

(b) Eidos acknowledges and agrees that:

(i) it has provided Alexion with a true and complete copy of the Stanford Agreement as it exists as of the Effective Date;

(ii) it is solely responsible for making all payments due under the Stanford Agreement; and

(iii) notwithstanding the foregoing, following the Effective Date, Eidos shall use commercially reasonable efforts [***].

2.5 Disclosure of the Eidos IP.

(a) Within [***] after the Effective Date, Eidos shall furnish to Alexion, in its then-current format, copies or reasonable access thereto of all documentation or other embodiments of any Eidos Know-How (including Regulatory Documents and Product Data) in the Control of Eidos or any of its Affiliates or Subcontractors as of the Effective Date.

(b) Following the initial transfer described in Section 2.5(a), Eidos shall provide prompt high-level updates to Alexion regarding any newly acquired or generated Eidos Know-How (including Regulatory Documents and Product Data) that comes into the Control of Eidos or any of its Affiliates or Subcontractors during the Term that has not been previously provided or made accessible to Alexion, and, upon Alexion's reasonable request, promptly transfer to Alexion, in its then-current format, copies, or reasonable access thereto, of such documentation or other embodiments of such Eidos Know-How.

(c) [***] shall be responsible for the cost and expense of the disclosure of Eidos Know-How as set forth in this Section 2.5; provided, however, in the event [***].

2.6 No Implied Licenses. Except as expressly set forth herein, neither Party shall acquire any license or other intellectual property interest, by implication or otherwise, under any Patent Rights, Know-How, Trademarks, or other intellectual property rights of the other Party.

2.7 Non-Compete.

(a) Except for the rights retained by Eidos as set forth in Section 2.1(a), during the Term, Eidos and its Affiliates shall not, independently or for or with any Third Party, including by grant of any rights to any Third Party, Exploit in the Field in the Territory any pharmaceutical compound or product that is intended to treat any Exclusive Indication.

(b) The restrictions placed on Eidos and its Affiliates in Section 2.7(a) will not apply to the Exploitation by any Acquiring Entity of any pharmaceutical compound or product that is intended to treat any Exclusive Indication, provided that such Exploitation occurs without any access to any Confidential Information of either Party relating to the Licensed Products or any Eidos IP; and provided, further, that a "firewall" of reasonable safeguards is put in place between individuals with access to any such Confidential Information or Eidos IP, on the one hand, and the personnel responsible for the Exploitation of such other pharmaceutical compound or product, on the other hand.

2.8 Control of Know-How and Patent Rights by Third Party Licensees. Eidos shall use commercially reasonable efforts to include in each agreement with any Third Party Licensees, CROs, contract manufacturing organizations, distributors and other similar Third Parties that such Third Party will provide the following to Eidos on commercially reasonable terms: (i) the assignment and transfer of ownership and possession of all Regulatory Documents and Regulatory Approvals owned or controlled by such Third Party to the extent such relate solely and exclusively to any Licensed Compound or Licensed Product, (ii) a sublicensable right of reference to all Regulatory Documents and Regulatory Approvals owned or controlled by such Third Party to the extent pertaining to any Licensed Compound or Licensed Product in the Field in the ROW Territory (and not otherwise assigned and transferred to Eidos under clause (i)), (iii) a freely sublicensable non-exclusive license to all Know-How and Patent Rights owned or controlled by such Third Party that are necessary for the Exploitation of Licensed Products in the Field in the Territory and were conceived, discovered, developed or otherwise made by or on behalf of such Third Party Licensee during the exercise of its rights or fulfillment of its obligations pursuant to such agreement, and (iv) the right to disclose to Alexion under this Agreement the Development activities of its Third Party Licensees as contemplated by Section 4.4.

2.9 Other Alexion Programs. Eidos understands and acknowledges that Alexion may have present or future initiatives or opportunities, including initiatives or opportunities with its Affiliates or Third Parties, involving products, programs, technologies or processes that are similar to, and in some instances may compete with, the Licensed Compound or Licensed Products, program, technology or process covered by this Agreement. Eidos acknowledges and agrees that nothing in this Agreement will be construed as a representation, warranty or covenant that Alexion will not itself Develop, Manufacture or Commercialize or enter into business relationships with one (1) or more of its Affiliates or Third Parties to Develop, Manufacture or Commercialize, products, programs, technologies or processes that are similar to or that may compete with any product, program, technology or process covered by this Agreement, provided that, for clarity, Alexion will not use Eidos' Confidential Information or Eidos IP in breach of this Agreement. Nothing set forth in this Section 2.9 shall limit Alexion's diligence obligations set forth in Section 4.1 and Section 6.1.

ARTICLE 3
GOVERNANCE

3.1 Alliance Managers. Each Party shall appoint an individual to act as its alliance manager under this Agreement as soon as practicable after the Effective Date (each Party's appointed individual, its "***Alliance Manager***"). The Alliance Managers shall: (a) serve as the primary points of contact between the Parties for the purpose of providing the other Party with information on the progress of a Party's activities under this Agreement; (b) be responsible for facilitating the flow of information and otherwise promoting communication, coordination and collaboration between the Parties; and (c) facilitate the prompt resolution of any disputes. Each Party may replace its Alliance Manager at any time upon [***] prior written notice to the other Party.

3.2 Committees.

(a) **Joint Development Committee**. As soon as practicable but no later than [***] after the Effective Date, the Parties shall establish a joint development committee (the "***Joint Development Committee***") to monitor and facilitate the Development of Licensed Products in the Field in the Territory and the ROW Territory.

(b) **Joint Commercialization Committee**. At either Party's request, the Parties shall establish a joint commercialization committee (the "***Joint Commercialization Committee***") to monitor and facilitate the Commercialization of Licensed Products in the Field in the Territory and the ROW Territory, including the review and discussion of the parameters of a Global Brand Plan for the Licensed Products on an annual basis. The Parties may, in each of their sole discretions, seek to align on aspects of implementation of the Global Brand Plan in their Applicable Territory, including trademarks (names and logos), color and marketing strategy, and promotional campaigns and marketing messages based on the approved labeling of the Licensed Products in each Party's Applicable Territory, in each case, subject to Applicable Law in each Party's Applicable Territory.

(c) **Role and Purpose**. Each such committee (i.e. the Joint Development Committee and Joint Commercialization Committee) shall be composed of an equal number of representatives from each Party with appropriate experience and expertise. Each such committee shall be a forum for information-sharing and discussion between the Parties and shall not have any decision-making authority, and shall meet [***] for [***] and [***] for [***] or at times and frequencies as otherwise mutually agreed by the Parties. Solely to the extent consistent with a Party's reporting and information sharing obligations elsewhere in this Agreement, each Party will provide such information to the applicable committee as the other Party may reasonably request with respect to Development, Manufacture or Commercialization of Licensed Compounds and Licensed Products in the Field in its Applicable Territory and will keep such committee reasonably informed of such Party's activities with respect to the Licensed Compounds and Licensed Products in the Applicable Territory.

ARTICLE 4
DEVELOPMENT AND REGULATORY MATTERS

4.1 Development Diligence. Alexion shall use Commercially Reasonable Efforts to Develop and seek Regulatory Approval for at least [***]. Alexion will have no other diligence obligations under this Agreement with respect to the Development of Licensed Products.

4.2 Development Activities.

(a) Alexion shall have the sole right and responsibility to conduct Development activities with respect to the Licensed Compound and the Licensed Products in the Field in the Territory in its sole discretion, except as necessary for Eidos to conduct the ATTRibute-CM Clinical Trial, the ATTRibute-PN Clinical Trial or any Additional Clinical Trial in the Territory following a [***] in accordance with Section 4.2(b).

(b) Except as otherwise expressly set forth herein, Eidos shall have the sole right, and will have sole discretion and control over the Development of the Licensed Compound and Licensed Product for the purpose of obtaining and maintaining Regulatory Approval for the Commercialization of such Licensed Products in the Field in the ROW Territory. Notwithstanding the foregoing, Eidos shall use Commercially Reasonable Efforts to manage, conduct and complete the ATTRibute-CM Clinical Trial and the ATTRibute-PN Clinical Trial through the final dosing of the final subject in such Clinical Trials and completion of the final clinical study report for such Clinical Trials. Eidos shall keep Alexion reasonably informed, on at least [***] basis, as to the status and results of the ATTRibute-CM Clinical Trial and the ATTRibute-PN Clinical Trial. In addition, Eidos shall consider in good faith any comments provided by Alexion with respect to the ATTRibute-CM Clinical Trial and the ATTRibute-PN Clinical Trial, including comments on the design and any potential protocol amendments. Without limiting the foregoing, Alexion shall have the right to (i) require, in its sole discretion, that Eidos [***], or request such [***] at any time thereafter with Eidos' written consent, not to be unreasonably withheld, conditioned or delayed, (ii) request that Eidos [***] subject to Eidos' written consent, not to be unreasonably withheld, conditioned or delayed; and (iii) require that Eidos [***]. If Alexion wishes to initiate a [***] pursuant to this Section 4.2(b), Alexion shall provide written notice thereof to Eidos. If Alexion is requesting (rather than requiring) [***], within [***] of Eidos' receipt of such notice, Eidos shall inform Alexion in writing whether Eidos agrees to the requested [***]. Additionally, if Eidos

intends to initiate an additional Clinical Trial in the ROW Territory (each such Clinical Trial, an "***Additional Trial***"), Eidos shall provide prompt written notice thereof to Alexion. Upon Alexion's written request [***]. The Parties shall decide by mutual agreement all matters relating to the conduct of the ATTRibute-CM Clinical Trial, ATTRibute-PN Clinical Trial and the Additional Trial in the Territory, including the choice of Clinical Trial sites, and the Parties shall conduct the ATTRibute-CM Clinical Trial, ATTRibute-PN Clinical Trial or the Additional Trial, as applicable, in the Territory in accordance with such decisions.

4.3 Development Costs.

(a) As between the Parties, Alexion shall be responsible all costs and expenses of any Development activities conducted by Alexion, its Affiliates, its Sublicensees or its Subcontractors hereunder, and Eidos shall be responsible all costs and expenses of any Development activities conducted by Eidos, its Affiliates or its subcontractors hereunder, except as set forth in this Section 4.3.

(b) If a [***] has been initiated pursuant to Section 4.2(b), [***] shall be responsible for all Out-of-Pocket Costs and FTE Costs, incurred by [***] directly and solely allocable to such [***]. With respect to any [***] to be initiated pursuant to Section 4.2(b), then (i) the Parties will agree upon a reasonably detailed budget for the conduct of the applicable Clinical Trial in the Territory and (ii) [***] shall submit to [***] an Invoice on [***] basis in arrears for all costs, including Out-of-Pocket Costs and FTE Costs, incurred by [***] allocable to such [***] and in accordance with such budget, and [***] shall pay the undisputed amount of any such Invoice within [***] of the receipt of such Invoice.

(c) Upon Alexion's reasonable request, whether or not a [***] has occurred, Eidos will, [***], cooperate with Alexion to provide Alexion with such reasonable assistance as may be reasonably necessary for Alexion to Develop the Licensed Compound and the Licensed Products in the Field in the Territory, including by making its applicable personnel reasonably available for discussion of such Development.

4.4 Development Reports. No less frequently than once per [***] during the Term, each Party shall provide the other Party with a written report summarizing its, its Affiliates' and its Third Party Licensees' (with respect to Eidos, and subject to Section 2.8) or Sublicensees' (with respect to Alexion) Development of Licensed Products, including a summary of the data, timelines and results of such Development, and an overview of future Development activities reasonably contemplated by such Party, the delivery of which shall be provided by the Alliance Managers of each Party; provided that, notwithstanding anything to the contrary in this Agreement, with respect to any Third Party Licensee of Eidos that, despite Eidos' efforts pursuant to Section 2.8, does not agree to disclose information to Alexion to satisfy the reporting requirements in this Section 4.4, Eidos will ensure that no Confidential Information of Alexion, its Affiliates or Sublicensees is disclosed to such Third Party Licensee, including the information of Alexion, its Affiliates and Sublicensees disclosed to Eidos under this Section 4.4. Each Party shall also establish a secure link that includes adequate encryption safeguards to provide the other Party with electronic access to such information. Such reports shall be the Confidential Information of the Party providing the reports pursuant to Section 8.1.

4.5 Regulatory Activities.

(a) Except for the performance of [***] or an Additional Clinical Trial, Alexion shall have the sole right and responsibility, [***], for all regulatory activities leading up to and including the obtaining, holding and maintaining of Regulatory Approvals for Licensed Products from Regulatory Authorities in the Field in the Territory. Notwithstanding the foregoing, Eidos shall have the right to have [***] of Eidos accompany Alexion to each meeting with Regulatory Authorities in the Territory pertaining solely to the Licensed Products in an observational capacity only, and solely to the extent such attendance is permitted by the applicable Regulatory Authorities in the Territory.

(b) At any time following the Effective Date upon Alexion's request, Eidos shall promptly transfer to Alexion ownership of all Regulatory Approvals and Regulatory Documents in the Field in the Territory in Eidos' Control. Notwithstanding the foregoing, if [***], Eidos shall obtain, hold and maintain all Regulatory Documents in the Territory [***], and shall thereafter promptly transfer to Alexion ownership of such Regulatory Documents. Notwithstanding anything to the contrary in this Agreement, Alexion or its designee shall own all Regulatory Approvals and, except as expressly set forth in the preceding sentence, all other Regulatory Documents, with respect to the Licensed Products in the Field in the Territory.

(c) Eidos shall in good faith cooperate with Alexion in obtaining, holding and maintaining any Regulatory Approvals, for a Licensed Product in the Field in the Territory by providing, to the extent Controlled by Eidos and not already transferred to Alexion pursuant to Section 2.5 or Section 4.5(b), reasonable access to Regulatory Approvals and Regulatory Documents for the Licensed Compound and Licensed Products in the Field in the Territory or the ROW Territory and reasonable access to and a copy of any and all Product Data (including raw data and records) with respect to the Licensed Compound and Licensed Products.

(d) At Alexion's reasonable request, Eidos shall, [***], reasonably assist Alexion with the preparation and filing of (i) any regulatory filings and associated documents or (ii) any specific technical documents required for Regulatory Approval.

4.6 Right of Reference and Use. Eidos hereby grants to Alexion (and any Affiliate or Sublicensee of Alexion) a right of reference to all Regulatory Documents pertaining to Licensed Products in the Field submitted by or on behalf of Eidos, its Affiliates or, subject to Section 2.8, Third Party Licensees, for the purpose of seeking, obtaining and maintaining Regulatory Approval of Licensed Products in the Field in the Territory (or to seek any approvals from a Regulatory Authority required for the Development or Manufacturing of the Licensed Product in the ROW Territory in accordance with the scope of the license granted to Alexion in Section 2.1(b)). If requested by Alexion, Eidos will, and will cause its Affiliates and, subject to Section 2.8, Third Party Licensees, to provide a signed statement to this effect in accordance with Applicable Laws. Alexion hereby grants to Eidos (and any Affiliate or Third Party Licensee of Eidos) a right of reference to all Regulatory Documents pertaining to Licensed Products submitted by or on behalf of Alexion, its Affiliates or, subject to Section 2.2(b), Sublicensees, for the purpose of seeking, obtaining and maintaining Regulatory Approval as applicable, of Licensed Products in the ROW Territory (or to seek any approvals from a Regulatory Authority required for the Development or Manufacturing of the Licensed Product in the Territory in accordance with Eidos' retained rights). If requested by Eidos, Alexion will, and will cause its Affiliates and, subject to Section 2.2(b), its Sublicensees, to provide a signed statement to this effect in accordance with Applicable Laws.

4.7 Data Exchange and Use.

(a) **For the ROW Territory**. During the Term, Alexion shall provide prompt high-level updates to Eidos through the Joint Development Committee described in Section 3.2(a) regarding any newly generated Regulatory Document and Product Data that (i) Alexion Controls, (ii) has been generated and finalized by or on behalf of Alexion or its Affiliates or Sublicensees with respect to the Licensed Products in the Field, (iii) is reasonably necessary or useful for Exploitation of the Licensed Product in the Field in the ROW Territory during the Term and (iv) that has not been previously provided or made accessible to Eidos and, upon Eidos' reasonable request, Alexion shall promptly provide Eidos with copies of, in its then-current format and language, or reasonable access to, such Regulatory Document and Product Data, in each case solely to support the exercise of the right of reference granted to Eidos under Section 4.6 and the rights granted to Eidos under the following sentence. With respect to any Product Data disclosed by Alexion to Eidos that is not available for use in Eidos' Regulatory Documents through exercise of the right of reference granted under Section 4.6, Eidos shall have the right, subject in each case to Alexion's prior written consent, not to be unreasonably withheld, conditioned or delayed, to use such Product Data solely to the extent necessary or useful to obtain or maintain Regulatory Approvals of the Licensed Products in the Field in the ROW Territory.

(b) **For the Territory**. During the Term, Eidos shall provide prompt high-level updates to Alexion through the Joint Development Committee described in Section 3.2(a) regarding any newly generated Product Data that (i) Eidos Controls (ii) has been generated and finalized by or on behalf of Eidos or its Affiliates or Third Party Licensees with respect to the Licensed Compound or Licensed Products, (iii) is reasonably necessary or useful for Exploitation of the Licensed Product in the Field in the Territory during the Term and (iv) that has not been previously provided or made accessible to Alexion and, upon Alexion's reasonable request, Eidos shall promptly provide Alexion with copies of, in its then-current format and language, any such Product Data. Upon Alexion's reasonable request, Eidos shall, subject to Section 2.5 and to the extent not already provided to Alexion under this Agreement, transfer to Alexion copies of, or reasonable access to, records relating to Eidos' and its Affiliates' and Third Party Licensees' Development activities (including access to relevant databases and Product Data and copies of study reports), to the extent that such records are (A) Controlled by Eidos and (B) reasonably necessary or useful to Exploit the Licensed Products in the Field in the Territory.

4.8 Adverse Events Reporting. Promptly following the Effective Date, but in no event later than [***] thereafter, Alexion and Eidos shall develop and agree in a written agreement to worldwide safety and pharmacovigilance procedures for the Parties with respect to Licensed Products, such as safety data sharing and exchange, adverse events reporting and prescription events monitoring (the "***Pharmacovigilance Agreement***"). Such Pharmacovigilance Agreement shall describe the obligations of both Parties with respect to the coordination of collection, investigation, reporting and exchange of information between the Parties concerning adverse events or any other safety issue of any significance and product quality and product complaints involving adverse events, in each case with respect to Licensed Products and sufficient to permit each Party and its Affiliates, Third Party Licensees and Sublicensees to comply with its legal obligations with respect thereto. The Pharmacovigilance Agreement shall be promptly updated if required by changes in Applicable Law. Each Party hereby agrees to comply with its respective obligations under the Pharmacovigilance Agreement and to cause its Affiliates, Third Party Licensees and Sublicensees to comply with such obligations. Without limiting the foregoing, Eidos will be responsible for maintaining a global adverse event database for all Clinical Trials conducted in the Territory and the ROW Territory, [***].

4.9 No Harmful Actions. Each Party shall not, and shall use commercially reasonable efforts to cause its Affiliates, Sublicensees (with respect to Alexion), Third Party Licensees (with respect to Eidos) and Subcontractors not to, take any action with respect to the Licensed Compound or a Licensed Product that could reasonably be expected to have an adverse impact upon the other Party's Regulatory Approval status of the Licensed Compound or any Licensed Product in the other Party's Applicable Territory. If a Party believes that the other Party is (or any of its Affiliates, Sublicensees (with respect to Alexion), Third Party Licensees (with respect to Eidos) or Subcontractors are) taking or intends to take any action with respect to the Licensed Compound or a Licensed Product that could have an adverse impact upon other Party's Regulatory Approval status of the Licensed Compound or any Licensed Product in such Party's Applicable Territory, then the Parties shall discuss in good faith a resolution of such concern.

4.10 Notice of Regulatory Action. Each Party shall promptly, but in any event within [***], notify the other Party of any information that it receives regarding any threatened or pending action, inspection or communication by or from a Third Party, including a Regulatory Authority, that would reasonably be expected to materially adversely affect the Exploitation of the Licensed Compound or Licensed Products in the Territory or the ROW Territory.

4.11 Eidos Support. In addition to the assistance Eidos has agreed to provide [***] under this Agreement, including under Section 4.3(c) and Section 4.5(d), the Parties understand and agree that it may be necessary for Alexion from time to time to seek additional guidance from Eidos, and Eidos hereby agrees to reasonably provide such additional guidance as a consultant upon the request of Alexion [***]. [***] shall invoice [***], and [***] shall pay [***] all amounts due under this Section 4.11 within [***] following receipt of the applicable Invoice.

ARTICLE 5
SUPPLY

5.1 Clinical Supply Agreement. Within [***] following the Effective Date, the Parties shall negotiate in good faith a clinical supply agreement containing supply terms and conditions consistent with the principles set forth on Exhibit 5.1 hereto (Supply Agreement Key Terms) and such other terms as are customary for such agreements, including provisions addressing technology transfer of the Eidos Know-How related to the Manufacture of the Licensed Compound and Licensed Products (the "***Clinical Supply Agreement***"), pursuant to which Eidos will Manufacture and supply to Alexion the Licensed Compound and Licensed Products for the Territory.

5.2 Commercial Supply Agreement. At a time specified by Alexion, but in any event as soon as practicable after either (a) [***] or (b) [***], the Parties shall negotiate in good faith a commercial supply agreement on commercially reasonable terms for the commercial supply of Licensed Product in the Territory by Eidos to Alexion (the "***Commercial Supply Agreement***").

5.3 Third Party Supply.

(a) **Eidos CMOs**. In the event that (i) the Parties fail to reach agreement on the Clinical Supply Agreement within [***], or such longer period as may be agreed by the Parties, (ii) the Parties fail to reach agreement on the Commercial Supply Agreement within [***], or such longer period as may be agreed by the Parties, or (iii) at any time during the term of the Commercial

Supply Agreement, Eidos commits a material breach of the Commercial Supply Agreement, then, in each case ((i) through (iii)), Alexion shall have the right to enter into direct supply agreements with Eidos' CMOs for the purchase of Licensed Product directly from Eidos' CMOs at all stages of the manufacturing supply chain and, upon Alexion's request, Eidos will use commercially reasonable efforts to facilitate Alexion's entry into such direct supply agreements with such CMOs.

(b) **Technology Transfer**. If, after using commercially reasonable efforts, Alexion is unable to timely negotiate and enter into direct supply agreements with Eidos' CMOs to allow for the direct purchase of the Licensed Product pursuant to Section 5.3(a), Alexion may require Eidos to conduct a technology transfer of the manufacturing process (including the transfer of the relevant QC methods) [***] from Eidos, its Affiliates and its CMOs to one or more CMOs of Alexion's choice, and will provide the assistance reasonably necessary to effectuate such transfer and secure licensure of such CMOs' facilities, such assistance to include providing to or securing for Alexion, [***], such reasonably sufficient access to data, other information and the personnel of Eidos, its Affiliates and CMOs, as may be necessary or useful for Alexion to enable its CMOs to Manufacture the Licensed Product (such transfer, a "***Technology Transfer***"); [***].

(c) **Eidos' CMO Agreements**. At least [***] prior to execution of any commercial supply agreement with a CMO, Eidos shall provide Alexion with a copy of the proposed terms of such commercial supply agreement. [***].

5.4 Quality Agreement. Within [***] following the Effective Date, the Parties shall enter into a separate quality agreement that describes the responsibilities of each Party in the area of technical cooperation and quality assurance with respect to the supply of the Licensed Compound and Licensed Products for the Territory and containing terms and conditions customary for such agreements (the "***Quality Agreement***").

ARTICLE 6
COMMERCIALIZATION

6.1 Commercialization Diligence. Following [***], Alexion shall use Commercially Reasonable Efforts to [***]. Alexion will have no other diligence obligations with respect to the Commercialization of Licensed Products under this Agreement.

6.2 Commercialization Activities. Each Party shall have the sole right and responsibility, at its sole cost and expense, to conduct Commercialization activities with respect to the Licensed Compound and the Licensed Products in such Party's Applicable Territory in its sole discretion. Alexion will provide Eidos with written notice of the First Commercial Sale of each Licensed Product in the Field in the Territory as soon as reasonably practicable after such event; provided, however, that, Alexion will inform Eidos of such event prior to public disclosure of such event by Alexion.

6.3 Licensed Product Trademarks.

(a) Each Party shall be solely responsible for developing, selecting, searching, registering and maintaining, and shall be the exclusive owner of, all Licensed Product Trademarks in such Party's Applicable Territory, except as expressly set forth in Section 6.3(b) and Section 6.3(c).

(b) Eidos hereby grants to Alexion and its Affiliates (i) an exclusive, royalty-free, non-transferable (except in accordance with Section 13.2) license, with the right to grant sublicenses solely in connection with a sublicense of Commercialization rights with respect to a Licensed Product in the Field in the Territory under any Licensed Product Trademarks other than any Trademarks that include any corporate name or logo of Eidos or its Affiliates (such Licensed Product Trademarks, the "***Licensed Product-Specific Trademarks")*** for all uses in the Field in the Territory and (ii) a non-exclusive, royalty-free, non-transferable (except in accordance with Section 13.2) license, with the right to grant sublicenses solely in connection with a sublicense of Commercialization rights with respect to a Licensed Product in the Field in the Territory under any Licensed Product-Specific Trademarks for use in the Field in the ROW Territory solely in connection with the exercise of Alexion's rights in the ROW Territory under Section 2.1(b). During the Term, Eidos and its Affiliates shall not use any Licensed Product-Specific Trademark or any other Trademark that is confusingly similar to any Licensed Product-Specific Trademark in the Territory (except the use of the Licensed Product-Specific Trademarks in the Territory solely in connection with the performance of Eidos' obligations or exercise of its retained rights in the Territory pursuant to Section 2.1(a)), or register or attempt to register any such Licensed Product-Specific Trademark or any other Trademark that is confusingly similar to any Licensed Product-Specific Trademark with any Governmental Authority in the Territory.

(c) Eidos hereby grants to Alexion and its Affiliates a non-exclusive, royalty-free, non-transferable (except in accordance with Section 13.2) license, with the right to grant sublicenses solely in connection with a sublicense of Commercialization rights with respect to a Licensed Product in the Field in the Territory under any Licensed Product Trademarks that include any corporate name or logo of Eidos or its Affiliates, for use solely in connection with the Exploitation of any Licensed Product in the Field in the Territory or, solely in connection with the exercise of Alexion's rights in the ROW Territory under Section 2.1(b), in the Field in the ROW Territory.

(d) Alexion agrees that any Licensed Product Commercialized in the Field in the Territory under this Agreement in connection with any Licensed Product Trademark shall meet quality standards substantially as high as those maintained by Eidos as of the Effective Date and during the Term with respect to the use of such Licensed Product Trademark. Upon Eidos' written request, Alexion shall provide samples of Alexion's use of the Licensed Product Trademark in the Field in the Territory in order for Eidos to confirm compliance with the foregoing quality standards. Notwithstanding anything in this Agreement to the contrary, Alexion shall have no obligation to use any Trademark licensed to Alexion under this Section 6.3 in any manner, including in connection with the Commercialization of any Licensed Products.

6.4 **No other Trademark Rights**. For the avoidance of doubt, except as expressly permitted by this Agreement or as otherwise agreed in writing by the Parties, neither Party will have any right to use the other Party's or the other Party's Affiliates' Trademarks, corporate names or logos in connection with Exploitation of Licensed Products, without first obtaining the other Party's written consent.

6.5 **Other Consultation**. Solely to the extent permitted by Applicable Law, the Parties may discuss [***].

6.6 **Diversion**. Subject to Applicable Law, each Party covenants and agrees that it shall not, and shall ensure that its Affiliates, Third Party Licensees (with respect to Eidos) and Sublicensees (with respect to Alexion) do not, either directly or indirectly, promote, market, distribute, import, sell or have sold any Licensed Products, including via the Internet or mail order, to any Third Party or to any address or Internet Protocol address or the like in the other Party's Applicable Territory; provided that each Party shall have the right to attend conferences and meetings of congresses in the other Party's Applicable Territory and to promote and market, for their Applicable Territory, Licensed Products to Third Party attendees at such conferences and meetings, subject to this Section 6.6. Neither Party shall engage, or shall permit its Affiliates, Third Party Licensees (with respect to Eidos) or Sublicensees (with respect to Alexion) to engage, in any advertising or promotional activities relating to any Licensed Products for use directed primarily to customers or users of Licensed Products located in any country, jurisdiction or region in the other Party's Applicable Territory, or solicit orders from any prospective purchaser that such Party has reason to believe intends to distribute such Licensed Product in any country, jurisdiction or region in the other Party's Applicable Territory. If a Party or any of its Affiliates, Third Party Licensees (with respect to Eidos) or Sublicensees (with respect to Alexion) receives any order for Licensed Products for use from a prospective purchaser that intends to distribute such Licensed Product in a country, jurisdiction or region in the other Party's Applicable Territory, then such Party shall promptly, but in any event within [***], refer that order to such other Party and shall not accept any such orders. Except as otherwise provided herein, neither Party shall, or shall permit its Affiliates, Third Party Licensees (with respect to Eidos) or Sublicensees (with respect to Alexion) to, deliver or tender (or cause or knowingly permit to be delivered or tendered) any Licensed Products for use in the other Party's Applicable Territory.

ARTICLE 7
PAYMENTS

7.1 **Upfront Payment**. Alexion shall pay to Eidos a one-time, non-refundable, non-creditable upfront payment of Twenty-Five Million U.S. Dollars ($25,000,000) within [***] of the Effective Date.

7.2 **Equity Investment**. As of the Effective Date, the Parties have entered into a Stock Purchase Agreement, pursuant to which Alexion will purchase shares of Eidos' Common Stock.

7.3 [***] Milestone Payment. Alexion shall notify Eidos in writing promptly (but in no event later than [***] following achievement thereof) following the [***]. Alexion shall pay to Eidos a one-time, non-refundable, non-creditable milestone payment in the amount of Thirty Million U.S. Dollars ($30,000,000) within [***] after receipt of an Invoice therefor from Eidos. For clarity, the milestone payment set forth in this Section 7.3 shall be [***].

7.4 Royalty Payments to Eidos.

(a) **Royalty Payments and Rates**. Subject to the provisions of Section 7.4(c), Alexion shall, on a Licensed Product-by-Licensed Product basis during the applicable Royalty Term, make royalty payments to Eidos on a [***] basis of [***] percent ([***]%) of the Net Sales of each Licensed Product sold in the Territory.

(b) **Royalty Termination Date**. Following expiration of the Royalty Term for a given Licensed Product in the Territory: (i) no further royalties shall be payable in respect of sales of such Licensed Product in the Territory and (ii) the License granted to Alexion hereunder with respect to such Licensed Product in the Territory shall automatically become fully paid-up, perpetual, irrevocable and royalty-free.

(c) **Royalty Reductions**.

(i) **Third Party Payments**. If Alexion (A) enters into any agreement with a Third Party (including any settlement agreement) to obtain rights under any Know-How or Patent Rights that are [***], (B) agrees pursuant to Section 11.8 to be responsible for payments under any New In-License Agreement pursuant to which Eidos has in-licensed any rights under any Know-How or Patent Rights that are [***], or (C) is subject to a final court or other binding order or ruling that the Exploitation of any Licensed Product by or on behalf of Alexion, its Affiliates or its Sublicensees under this Agreement infringes, misappropriates or otherwise violates any Third Party rights in Know-How or Patent Rights (each of (A), (B) and (C), a "***Third Party Obligation***"), then Alexion may offset against any royalty payments payable to Eidos under Section 7.4(a) (as reduced under Section 7.4(c)(ii) or Section 7.4(c)(iii)) in a given Calendar Quarter [***] of the amount of any upfront payments, milestone payments, royalties or other amounts paid by Alexion or its Affiliates pursuant to any Third Party Obligations in or prior to such Calendar Quarter, provided that in no event shall any amount payable to Eidos under Section 7.4(a) in a given [***] be reduced by more than [***] as a result of this Section 7.4(c)(i); [***].

(ii) **Generic Entry**. If (A) a Generic Product is sold by a Third Party in the Territory in any Calendar Quarter during the Royalty Term for a Licensed Product and the Generic Competition Percentage in the Territory for such Calendar Quarter is greater than or equal to [***] or (B) a LP Generic Product is sold by a Third Party in the Territory in any Calendar Quarter during the Royalty Term for a Licensed Product and the LP Generic Competition Percentage in the Territory for such Calendar Quarter is greater than or equal to [***], then the royalty rate under Section 7.4(a) shall be reduced by [***] in such Calendar Quarter.

(iii) **Valid Claim Expiration**. If, in any Calendar Quarter during the Royalty Term for a Licensed Product, there are no Valid Claims remaining within the Eidos Patents that Cover the composition of matter or method of use of such Licensed Product in the Territory, then the royalty rate under Section 7.4(a) shall be reduced by [***] in such Calendar Quarter and all subsequent Calendar Quarters during the Royalty Term.

(iv) **Cumulative Reductions Floor**. In no event will the royalty rate under Section 7.4(a) in any given Calendar Quarter during the Royalty Term for any Licensed Product be reduced by more than [***] of the royalty rate that otherwise would have applied in such [***] for such Licensed Product but for the reductions set forth in Section 7.4(c)(i) through Section 7.4(c)(iii). [***].

(d) **Payments under Third Party Licenses as of or prior to the Effective Date**. Eidos shall be solely responsible for making all payments owed by it to Third Parties (including Stanford under the Stanford Agreement) under any agreement existing as of or prior to the Effective Date pursuant to which Eidos has obtained Control of any of the Eidos IP and Alexion shall not have any obligation to make any such payments on behalf of Eidos or as a sublicensee under any such agreement.

(e) **Royalty Reports and Payments**. Within [***] after the end of each Calendar Quarter, commencing with the Calendar Quarter of the First Commercial Sale of the first Licensed Product in the Territory, Alexion shall provide Eidos with a report that contains the following information for the applicable Calendar Quarter, on a Licensed Product-by-Licensed Product basis: (i) gross sales and Net Sales (including reasonable detail for deductions from gross sales to Net Sales) on a Licensed Product-by-Licensed Product basis, and (ii) the royalties payable under this Section 7.4 (including reasonable detail for any deductions to such royalties taken pursuant to Section 7.4(c)) for such Calendar Quarter. Concurrently with the delivery of such report, Alexion shall pay to Eidos the royalties payable under this Section 7.4 for such Calendar Quarter.

(f) **Payment Method, Currency, and Exchange Rate**. All payments to be made by Alexion to Eidos under this Agreement shall be made in Dollars by electronic funds transfer in immediately available funds to a bank account designated in writing by Eidos. For the purposes of calculating any sums due under this Agreement, Alexion shall convert any amount expressed in a foreign currency into Dollar equivalents, calculated using the applicable currency conversion rate as published by Bloomberg, (a) for sales, at the close of business on the date Alexion records net revenue from the applicable sale or (b) for all other payments payable under this Agreement, on the day the payment obligation accrued. In the event that the "applicable currency conversion rate" as published by Bloomberg is discontinued or no longer available, then the Parties shall mutually agree upon an alternate currency conversion index to be used for purposes of this Section 7.4.

(g) **Interest**. Any undisputed payments not made when due under this Agreement as provided herein will bear interest at the lower of (a) the Prime Rate published in the Wall Street Journal (the "***U.S. Prime Rate***") which applied on the first date on which such payment was delinquent plus [***] or (b) the maximum rate permitted by Applicable Law, in each case, compounded quarterly. If the U.S. Prime Rate is no longer published, the Parties will agree upon another nationally recognized rate which has historically been substantially equivalent to the U.S. Prime Rate and utilize such rate retroactively to such time as the U.S. Prime Rate was no longer available.

7.5 Taxes.

(a) **Responsibility**. All payments under or in connection with this Agreement shall be inclusive of any Taxes and each Party shall be responsible for and shall bear, pay or set-off its own Taxes assessed by a tax or other authority except as otherwise set forth in this Agreement.

(b) **Withholding Tax**. If Applicable Law requires withholding by Alexion or its Affiliates of any Taxes imposed upon Eidos or its Affiliates on account of any royalties and other payments paid under this Agreement for the benefit of Eidos or its Affiliates, such Taxes shall be retained by Alexion or its Affiliates as required by such Applicable Law from such remittable royalty and other payment and shall be timely remitted by Alexion or its Affiliates to the proper Tax authorities on behalf of Eidos or its Affiliates. Official receipts of the remittance by Alexion or its Affiliates of any such withholding Tax shall be reasonably promptly secured and sent by Alexion or its Affiliates to Eidos or its Affiliates as evidence of such payment. The Parties shall cooperate and exercise their reasonable best efforts to ensure that any withholding Taxes imposed on Eidos or its Affiliates are reduced as far as possible under the provisions of any Applicable Law, including that Alexion will cooperate with Eidos to permit the payments made under this Agreement to qualify for the 0% withholding tax rate applicable to "royalties" pursuant to Article 12 of the 1997 Income Tax Treaty between the United States and Ireland to the greatest extent allowable by Applicable Law, such as through the provision of any forms, certifications or other documents that would permit a payment made under this Agreement to so qualify. Notwithstanding the foregoing, the Parties acknowledge and agree that (i) under Applicable Law as of the date hereof, no amounts shall be withheld in respect of royalties or other amounts required to be paid by Alexion or its Affiliates to Eidos or its Affiliates pursuant to this Agreement and (ii) if a Party's redomiciliation to (or assignment of this Agreement to an entity resident for purposes of an applicable Tax treaty in) a jurisdiction other than the jurisdiction in which such Party is resident for such purposes as of the date of this Agreement (but not, for the avoidance of doubt, a change in Applicable Law) leads to the imposition of withholding Tax liability on the other Party that would not have been imposed in the absence of such action or in an increase in such liability above the liability that would have been imposed in the absence of such action, then such Party will reimburse the other Party for any such additional or increased withholding Tax liability (except to the extent that the other Party can reclaim it, provided that the other Party will be reimbursed for any reasonable out of pocket costs incurred in the reclaim).

(c) **Separate Transaction**. Eidos and Alexion agree that the transactions contemplated by this Agreement are separate and distinct from the acquisition of Eidos Common Stock pursuant to the Stock Purchase Agreement, and the payments by Alexion to Eidos under Section 7.1, Section 7.3 and Section 7.4 constitute consideration solely for the rights and obligations of this Agreement and not for the Eidos Common Stock acquired pursuant to the Stock Purchase Agreement.

7.6 Financial Audits.

(a) **By Eidos**. Alexion shall keep (and shall cause its Affiliates and Sublicensees to keep) complete and accurate records pertaining to the sale or other disposition of Licensed Products in reasonable detail to permit Eidos to confirm the accuracy of all royalty payments reported, for at least [***] following the end of the Calendar Year to which such records pertain. Eidos shall have the right to cause an independent, certified public accountant of nationally recognized standing and reasonably acceptable to Alexion (the "***Auditor***") to audit such records solely to confirm Net Sales and royalty payments for a period covering not more than the preceding [***], provided that such audits may not be performed more than [***]. Such audits shall be performed during normal business hours upon [***] prior written notice to Alexion. The Auditor will execute a written confidentiality agreement that is acceptable to Alexion with Alexion and will disclose to Eidos only such information as is reasonably necessary to provide Eidos and Upstream Licensors with information regarding any actual or potential discrepancies between amounts reported and amounts actually paid or payable under this Agreement. The report of the Auditor will include the methodology and calculations used to determine the results, will be delivered to Eidos and Alexion at the same time, and will be final [***] after delivery to both Parties, it being understood that either Party will have the right during [***] to discuss the report with the Auditor. Any disputes with respect to the findings of such Auditor may be referred by either Party to the dispute resolution procedure set forth in Article 13 within [***]. [***]. [***] Alexion shall pay the amount of any underpayment disclosed in any undisputed Auditor's report, together with any interest owed thereon within [***] after delivery to the Parties of the final Auditor's report. If such final Auditor's report discloses an overpayment by Alexion of the amounts payable hereunder, Alexion shall have the right to offset such overpayment against future payments owed to Eidos under this Agreement following the audit in question. Upon the expiration of [***] the calculation of royalty payments with respect to such [***] shall be binding [***]. Any disclosures or reports disclosed to Eidos under this Section 7.6(a) shall be Alexion's Confidential Information.

(b) **By Alexion**. Eidos shall keep (and shall cause its Affiliates and Sublicensees to keep) complete and accurate records pertaining to the FTE Costs and Out-of-Pocket Costs incurred by Eidos and its Affiliates in the conduct of (1) [***] and (2) if a [***] is initiated pursuant to Section 4.2(b), the applicable [***], for at least [***] following the end of the [***] to which such records pertain. Upon [***] prior notice from Alexion, Eidos shall permit an independent certified public accounting firm of nationally recognized standing selected by Alexion and reasonably acceptable to Eidos, to examine, at Alexion's sole expense, the relevant books and records of Eidos and its Affiliates as may be reasonably necessary to verify Eidos' and its Affiliates' FTE Costs and Out-of-Pocket Costs invoiced by Eidos under Section 4.11 or Section 4.3(b). An examination by Alexion under this Section 7.6(b) shall occur not more than once in any Calendar Year and shall be limited to the pertinent books and records for any Calendar Year ending not more than [***]. The accounting firm shall be provided access to such books and records at Eidos' or its Affiliates' facility(ies) where such books and records are normally kept and such examination shall be conducted during Eidos' normal business hours. The auditor will execute a written confidentiality agreement that is acceptable to Eidos with Eidos and will disclose to Alexion only such information as is reasonably necessary to provide Alexion with information regarding any actual or potential discrepancies between amounts invoiced and such costs and expenses actually incurred by Eidos and its Affiliates. Upon completion of the audit, the

accounting firm shall provide both Eidos and Alexion with a written report disclosing any discrepancies in the invoices submitted by Eidos and such costs and expenses actually incurred by Eidos and its Affiliates, and, in each case, the specific details concerning any discrepancies. [***]. Alexion shall pay the amount of any underpayment disclosed in any undisputed Auditor's report, together with any interest owed thereon within [***] after delivery to the Parties of the final Auditor's report. If such final Auditor's report discloses any overpayment by Alexion of the amounts payable hereunder, Alexion shall have the right to offset such overpayment against future payments owed to Eidos under this Agreement following the audit in question. Any disclosures or reports disclosed to Alexion under this Section 7.6(b) shall be Eidos' Confidential Information.

ARTICLE 8
CONFIDENTIALITY; PUBLICATION

8.1 Confidential Information. "***Confidential Information***" means all non-public Know-How or other confidential or proprietary information, including proprietary materials or information, ideas, inventions, discoveries, concepts, compounds, compositions, formulations, formulas, practices, procedures, processes, methods, knowledge, know-how, trade secrets, technology, inventories, machines, techniques, development, designs, drawings, computer programs, skill, experience, documents, apparatus, results, clinical and regulatory strategies, regulatory documentation, information and submissions pertaining to or made in association with Regulatory Documents, data (including pharmacological, toxicological, and clinical data, raw data, analytical and quality control data, manufacturing data and descriptions, patent and legal data, market data, financial data or descriptions), devices, assays, chemical formulations, specifications, material, product samples and other samples, physical, chemical and biological materials and compounds, and the like, transferred, disclosed or otherwise made available by or on behalf of a Party (the "***Disclosing Party***") to the other Party or its representatives (the "***Receiving Party***") prior to, on or after the Effective Date, whether or not patentable and whether or not disclosed in written, oral graphical, machine-readable, electronic or other form or otherwise observed by the Receiving Party, and whether or not such information is marked as confidential or proprietary. It is understood and agreed by the Parties that the terms and conditions of this Agreement will be considered Confidential Information of both Parties and kept confidential by each of the Parties as set forth in this Article 8. For clarity, the Eidos IP will be Confidential Information of Eidos.

8.2 Non-Disclosure and Non-Use Obligation. Except as otherwise expressly set forth herein, the Receiving Party shall keep the Confidential Information of the Disclosing Party confidential using at least the same degree of care with which the Receiving Party holds its own confidential information, but in no event less than a commercially reasonable degree of care, and shall not (i) disclose such Confidential Information to any person or entity without the prior written approval of the Disclosing Party, except, solely to the extent necessary to exercise its rights or perform its obligations under this Agreement, to its employees, Affiliates, Sublicensees (with respect to Alexion), Third Party Licensees (with respect to Eidos) and contractors, consultants or agents who have a need to know such Confidential Information, all of whom will be similarly bound by the provisions of this Article 8 and for whose compliance herewith the Disclosing Party will be responsible, or (ii) use such Confidential Information for any purpose other than for the purposes contemplated by this Agreement. The Receiving Party will use diligent efforts to cause the foregoing Persons to comply with the restrictions on use and disclosure of the Disclosing Party's Confidential Information set forth in this Section 8.2, and shall be responsible for ensuring that such Persons maintain the Disclosing Party's Confidential Information in accordance with this Article 8.

8.3 Return of Confidential Information. Upon the expiration or termination of this Agreement, the Receiving Party shall return to the Disclosing Party (or, as directed by the Disclosing Party, destroy) all Confidential Information of the Disclosing Party that is in the Receiving Party's possession or control, except, with respect to Alexion as the Receiving Party, to the extent Alexion has continuing rights to use any such Confidential Information of Eidos pursuant to Section 7.4(b); provided, however, that one (1) copy of any Confidential Information of the Disclosing Party may be retained and stored solely for the purpose of determining its obligations under this Agreement, provided that the non-disclosure and non-use obligation under this Article 8 shall continue to apply to any such copy. In addition, the Receiving Party shall not be required to return or destroy Confidential Information contained in any computer system back-up records made in the ordinary course of business, provided that such Confidential Information may not be accessed without the Disclosing Party's prior written consent or as required by Applicable Law, and that such Confidential Information remains subject to the non-disclosure and non-use obligations under this Article 8.

8.4 Exemption. The foregoing confidentiality and non-use obligations shall not apply to: (i) information already in the possession of the Receiving Party prior to its disclosure by the Disclosing Party as evidenced by contemporaneous written records; (ii) information that is already in the public domain as of the date of disclosure to the Receiving Party or that comes into the public domain thereafter by publication or otherwise through no breach of the obligations of confidentiality and non-use hereunder by the Receiving Party, including with respect to Section 8.8; (iii) information that has been disclosed to the Receiving Party from another source free from any obligation of confidentiality and that was not directly or indirectly obtained from the Disclosing Party; or (iv) information that is developed independently by employees, subcontractors, consultants or agents of the Receiving Party or any of its Affiliates without use of, access to, or reliance upon the Disclosing Party's Confidential Information, as evidenced by contemporaneous written records.

8.5 Permitted Disclosures. In addition to the exceptions contained in Section 8.2 and Section 8.4, the Receiving Party may disclose Confidential Information of the Disclosing Party to the extent (and solely to the extent) that such disclosure is reasonably necessary in the following instances:

(a) to comply with Applicable Law (including any securities law or regulation or the rules of a securities exchange pursuant to Section 8.6 below) or the order of a court of competent jurisdiction, provided that, where legally permissible, the Receiving Party promptly notifies the Disclosing Party of such obligation sufficiently prior to making such disclosure, so as to allow the Disclosing Party adequate time to take whatever action it may deem appropriate to protect the confidentiality of the information to be disclosed, and fully cooperates with the Disclosing Party, if so requested, in maintaining the confidentiality of such information by applying for a protective order or any similar legal instrument. In any event, the Receiving Party shall only disclose such Confidential Information to the extent required under Applicable Law and shall continue to treat such information as Confidential Information for all other purposes under this Agreement;

(b) to prosecute or defend litigation or to otherwise exercise its rights or perform its obligations in Section 11.4, to obtain or maintain Regulatory Approvals and other regulatory filings and communications, to file or prosecute patent applications as contemplated by this Agreement and to enforce Patent Rights in connection with the Receiving Party's rights and obligations pursuant to this Agreement; and

(c) to allow the Receiving Party to exercise its rights and perform its obligations under this Agreement, provided that such disclosure is covered by terms of confidentiality and non-use at least as restrictive as those set forth herein (but of duration customary in confidentiality agreements entered into for a similar purpose).

8.6 Disclosure of Agreement. Either Party may disclose the terms of this Agreement (a) to the extent required or advisable to comply with the rules and regulations promulgated by the United States Securities and Exchange Commission or any equivalent governmental agency in the Territory, [***]; (b) to actual acquirers, permitted assignees, merger partners, existing investment bankers, investors and lenders or financing sources, provided that such Third Party has executed with such Party, and such Party has provided to the other Party, a copy of a confidentiality agreement (redacted for name of party, economic terms or other competitive information) with terms at least as protective with respect to Confidential Information as those contained herein, in a form reasonably acceptable to the other Party (which acceptance shall not be unreasonably withheld, conditioned or delayed) (but of duration customary in confidentiality agreements entered into for similar purpose), (c) for customary discussions and other disclosures with and to *bona fide* prospective acquirers, permitted assignees or merger candidates or to *bona fide* potential investment bankers, investors and lenders, or financing sources in a redacted form of this Agreement or its terms which shall be redacted in respect of financial terms, including payment amounts, provided that either Party may disclose an unredacted form of this Agreement (including the foregoing information regarding payments) to such parties, but only at such time as such Third Party has executed with such Party, and such Party has provided to the other Party, a copy of a confidentiality agreement (redacted for name of party, economic terms or other competitive information) with terms at least as protective with respect to Confidential Information as those contained herein, in a form reasonably acceptable to the other Party (which acceptance shall not be unreasonably withheld, conditioned or delayed) (but of duration customary in confidentiality agreements entered into for similar purpose), [***]; and (d) to the extent necessary to perform such Party's obligations or exercise its rights under this Agreement, to any Upstream Licensor, or any actual or potential licensee, sublicensee or collaborator of such Party with respect to the Licensed Compound or Licensed Products, provided that (1) any such Upstream Licensor or actual or potential, licensee, sublicensee or collaborator agree in writing to be bound by obligations of confidentiality and non-use no less protective of the Disclosing Party than those set forth in this Article 8 [***].

8.7 Publicity; Use of Name and Logo. The Parties have agreed on a press release announcing this Agreement, which is attached hereto as Exhibit 8.7, to be issued by the Parties on such date and time as may be agreed by the Parties. Except to the extent expressly permitted under this Agreement or, if executed, the Clinical Supply Agreement, the Commercial Supply Agreement the Quality Agreement or the Pharmacovigilance Agreement, or as required by Applicable Laws, each Party will not use the other Party's or its Affiliates' name or logo in any label, press release or product advertising, or for any other promotional purpose, without first obtaining the other Party's written consent.

8.8 Publications. Except for disclosures permitted under this Article 8, neither Party shall have the right to make any publication or presentation that relates to the scientific or technical results of any Development activities with respect to the Licensed Products. If either Party (the "***Publishing Party***") wishes to publish or present in a public forum the scientific or technical results of any Development activities with respect to the Licensed Products, the Publishing Party shall provide the other Party the opportunity to review any proposed abstracts, manuscripts or scientific presentations (including verbal presentations) with respect thereto by delivering a copy thereof (if applicable) to the other Party at least [***] prior to their intended submission for publication. The other Party shall have [***] from its receipt of any such copy of the proposed disclosure in which to notify the Publishing Party in writing of approval of the disclosure, such approval not to be unreasonably withheld, conditioned or delayed. Each Party shall comply with (a) the other Party's internal publication policy as well as its own internal publication policy, if any, (b) the other Party's request to modify or delay the timing of any publication or presentation for patenting reasons, (c) the guidelines issued by the academic journals or scientific meetings applicable to the publication, and (d) guidelines by International Committee of Medical Journal Editors. Each Party also will have the right to require that its Confidential Information that would be disclosed in a publication of the other Party be deleted prior to such publication. Each Party will acknowledge the other Party's contributions in any such publication unless otherwise instructed by such other Party. In addition to the foregoing, with respect to any disclosures by Alexion, such disclosures will be subject at all times to any publicity or publication requirements set forth in any Upstream License of which Alexion is aware pursuant to Section 11.8.

8.9 Engaging Individuals. Each Party hereby agrees that all Persons engaged to perform any activities under this Agreement shall be contractually bound by confidentiality obligations at least as restrictive as the obligations of confidentiality and non-use set forth in this Article 8 prior to performing such activities.

8.10 Survival. This Article 8 shall survive the expiration or termination of this Agreement and shall remain in full force and effect for [***] after such expiration or termination.

ARTICLE 9
REPRESENTATIONS, WARRANTIES, AND COVENANTS

9.1 Representations, Warranties and Covenants of Each Party. Each Party represents and warrants to the other Party as of the Effective Date, and as applicable, covenants to the other Party, that:

(a) it is validly existing and in good standing under the Applicable Laws of the jurisdiction of its incorporation and has the full right, power and authority to enter into this Agreement, conduct the activities allocated to it under this Agreement, grant the licenses and grant and assign the rights under this Agreement and disclose such information and Know-How that is disclosed in performance of its obligations under this Agreement;

(b) this Agreement has been duly executed by it and is legally binding upon it, enforceable in accordance with its terms, and does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, nor violate any material Applicable Law of any court, governmental body or administrative or other agency having jurisdiction over it;

(c) neither it, nor any of its Affiliates are party to any agreements, oral or written, that conflict with its obligations under this Agreement; and

(d) neither it, nor any of its Affiliates, have been debarred, and during the Term, neither it, nor any of its Affiliates shall use, in any capacity in connection with the obligations to be performed under this Agreement, any Person who has been debarred. Each Party further covenants that if, during the Term of this Agreement, it becomes aware that it or any of its or its Affiliates' employees or agents performing under this Agreement is the subject of any investigation or proceeding that could lead to that Party becoming a debarred entity or individual, an excluded entity or individual or a convicted entity or individual, such Party will promptly notify the other Party.

9.2 Representations and Warranties of Eidos. Eidos represents and warrants to Alexion as of the Effective Date, and as applicable, covenants, that:

(a) all Eidos Patents existing as of the Effective Date are set forth on Exhibit 1.41 hereto, and all Eidos Patents included therein are (i) valid and enforceable, (ii) being diligently prosecuted in the respective patent offices in the Territory in accordance with Applicable Law, and (iii) have been filed and maintained properly and correctly and all applicable fees have been paid on or before the due date for such payments;

(b) except as set forth on Exhibit 9.2(b), Eidos is the sole and exclusive owner of the Eidos IP licensed by Eidos to Alexion under this Agreement except for that Eidos IP in-licensed under the Stanford Agreement, and Eidos exclusively Controls all right, title and interest in the Eidos IP licensed by Eidos and its Affiliates to Alexion under this Agreement;

(c) neither Eidos, nor any of its Affiliates, have previously assigned, transferred, conveyed or otherwise encumbered, and shall not assign, transfer, convey or other encumber during the Term, its right, title or interest in or to the Eidos IP in a manner that would prevent Alexion or its Affiliates, Subcontractors or Sublicensees from researching, Developing, Manufacturing or Commercializing Licensed Products or from otherwise exploiting its rights and licenses granted or assigned by Eidos hereunder;

(d) there are no claims, judgments or settlements against or pending, or amounts with respect thereto, owed by Eidos or any of its Affiliates, with respect to the Eidos IP and Eidos has not received written notice threatening any such claims, judgments or settlements;

(e) all information disclosed to Alexion by Eidos relating to the Eidos IP is, at the time of disclosure, accurate in all material respects;

(f) to Eidos' knowledge, no person is infringing or threatening to infringe or misappropriate or threatening to misappropriate the Eidos Patents;

(g) each person who has or has had any rights in or to any Eidos IP owned by Eidos or its Affiliates existing as of the Effective Date has assigned and has executed an agreement assigning its entire right, title and interest in and to such Eidos IP to Eidos or its applicable Affiliate, and, to Eidos' knowledge, each person who has or has had any rights in or to any Eidos IP that Eidos has in-licensed from a Third Party as of the Effective Date has assigned and has executed an agreement assigning its entire right, title and interest in and to such Eidos IP to such Third Party;

(h) it is entitled to grant the licenses and assign the rights according to Article 2 to Alexion, and that it has taken all appropriate measures under all Applicable Laws to grant such licenses and assign such rights; and

(i) to Eidos' knowledge, other than the Eidos IP, there are no Patent Rights (including any Patent Rights Controlled by a Third Party) that would be infringed, either by Alexion or by Eidos, in the course of Alexion's Exploitation of the Licensed Compound or any Licensed Product.

9.3 Representations, Warranties and Covenants of Eidos Concerning the Stanford Agreement. In addition to Section 9.2, Eidos represents and warrants to Alexion, as of the Effective Date that:

(a) the Stanford Agreement is in full force and effect and has not been materially modified or amended from that provided to Alexion as of the Effective Date;

(b) Eidos is in compliance, in all material respects, with the Stanford Agreement, and no circumstances exist which could reasonably be expected to result in a breach or default of the Stanford Agreement;

(c) Eidos has not waived any of its material rights under the Stanford Agreement, and, to its knowledge, no such material rights have lapsed or otherwise expired or been terminated;

(d) Eidos shall fulfill its obligations under the Stanford Agreement and shall not take any action or make any omission that would reasonably be expected to give rise to a termination right of Stanford under the Stanford Agreement;

(e) Eidos shall not terminate the Stanford Agreement either (i) in its entirety or (ii) in part in a manner that could reasonably be expect to adversely affect the License or any of Alexion's rights or obligations under this Agreement, in each case without Alexion's prior written consent;

(f) Eidos shall not modify or amend the Stanford Agreement, or waive any of its rights under the Stanford Agreement, in a manner that could reasonably be expected to adversely affect the License or any of Alexion's rights or obligations under this Agreement, without Alexion's prior written consent;

(g) Eidos shall furnish Alexion with copies of any breach notification that Eidos receives from Stanford in connection with the Stanford Agreement;

(h) Eidos shall furnish Alexion with copies of all notices and correspondence that Eidos receives from Stanford in connection with the Stanford Agreement relating to Alexion's rights or obligations under this Agreement or that could reasonably be expected to adversely affect the License, within a reasonable period following Eidos' receipt of the same; provided that Eidos may redact financial and confidential portions of any such notices and correspondence and any other information contained in such notices and correspondence that does not relate to or impact the License or any of Alexion's rights or obligations under this Agreement; and

(i) Alexion may provide to any Affiliate or Sublicensee a copy of the Stanford Agreement and this Agreement; provided that such Affiliate or Sublicensee is subject to confidentiality and non-use obligations no less stringent than those set forth in Article 8.

9.4 Covenant of Eidos. Eidos covenants to Alexion that:

(a) during the Term, Eidos will not make any commitment to any Third Party in conflict with the rights granted by it hereunder; and

(b) Neither Eidos, nor any of its Affiliates, shall assign, transfer, convey or otherwise encumber during the Term, its right, title or interest in or to the Eidos IP in a manner that would prevent (i) Eidos from performing the ATTRibute Clinical Trials in accordance with this Agreement or (ii) Alexion or its Affiliates, Subcontractors and Sublicensees from researching, Developing, Manufacturing or Commercializing Products or from otherwise exploiting its rights and licenses granted or assigned by Eidos hereunder.

9.5 Compliance with Law.

(a) Each Party hereby covenants to the other Party that, in the course of performing its obligations and exercising its rights under this Agreement, it shall comply with all Applicable Laws, including, as applicable, cGMP, GCP, and GLP standards, and will contractually obligate all Affiliates, permitted collaborators and Sublicensees (in the case of Alexion) to comply with such Applicable Laws in exercising their rights and fulfilling their obligations under this Agreement, and shall not knowingly employ or engage any Person who has been debarred by any Regulatory Authority, or, to its knowledge, is the subject of debarment proceedings by a Regulatory Authority.

(b) Eidos hereby covenants to Alexion that, in the course of Exploiting Licensed Compounds and Licensed Products, it shall comply with all Applicable Laws, including, as applicable, cGMP, GCP, and GLP standards, and will contractually obligate all Affiliates, permitted collaborators and Third Party Licensees to comply with such Applicable Laws in exercising their rights and fulfilling their obligations under this Agreement, and shall not knowingly employ or engage any Person who has been debarred by any Regulatory Authority, or, to its knowledge, is the subject of debarment proceedings by a Regulatory Authority.

(c) Without limiting the generality of Section 9.5(a), each Party will comply with all Applicable Laws concerning bribery, money laundering, or corrupt practices or which in any manner prohibit the giving of anything of value to any official, agent, or employee of any government, political party, or public international organization, candidate for public office, health care professional, or to any officer, director, employee, or representative of any other organization specifically including the U.S. Foreign Corrupt Practices Act, and the UK Bribery Act, in each case, in connection with the activities conducted pursuant to this Agreement. Each Party will contractually obligate any contractors, subcontractors, Sublicensees, Third Party Licensees or other Persons that provide services to such Party in connection with this Agreement to comply with the Parties' obligations under this Section 9.5(c).

9.6 NO OTHER WARRANTIES. EXCEPT AS EXPRESSLY STATED IN THIS ARTICLE 9, (A) NO REPRESENTATION, CONDITION OR WARRANTY WHATSOEVER IS MADE OR GIVEN BY OR ON BEHALF OF EIDOS OR ALEXION; AND (B) ALL OTHER CONDITIONS AND WARRANTIES WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE ARE EXPRESSLY DISCLAIMED, INCLUDING ANY CONDITIONS AND WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NON-INFRINGEMENT OR MISAPPROPRIATION OF THIRD PARTY INTELLECTUAL PROPERTY WITH RESPECT TO THE LICENSED COMPOUND OR LICENSED PRODUCT.

ARTICLE 10
INDEMNIFICATION

10.1 By Alexion. Alexion shall indemnify, defend and hold harmless Eidos, its Affiliates, and their directors, officers, employees and agents, and their respective successors, heirs and assigns (individually and collectively, the "***Eidos Indemnitee(s)***") from and against all losses, liabilities, damages, judgments, awards, costs and expenses (including reasonable attorneys' fees) (individually and collectively, "***Losses***") incurred in connection with any claims, demands, actions, suits or other proceedings by any Third Party (individually and collectively, "***Third Party Claims***") to the extent arising from: (a) the Exploitation of the Licensed Products by or on behalf of Alexion or any of its Affiliates, Sublicensees or Subcontractors (but excluding (1) [***] and (2) [***] (b) the gross negligence or willful misconduct of Alexion or its Affiliates, Sublicensees or Subcontractors, or any Alexion Indemnitees, (c) Alexion's breach of any of its representations or warranties made in or pursuant to this Agreement or any Alexion covenants or obligations set forth in or entered into pursuant to this Agreement, or (d) failure of Alexion or its Affiliates, Sublicensees or Subcontractors to abide by any Applicable Laws, in each case of clauses (a) through (d) above, except to the extent such Losses arise out of any matter for which Eidos has obligations of indemnification pursuant to Section 10.2, with respect to which each Party will indemnify the other in proportion to their respective liability for such Losses.

10.2 By Eidos. Eidos shall indemnify, defend and hold harmless Alexion, its Affiliates, and their directors, officers, employees and agents, and their respective successors, heirs and assigns (individually and collectively, the "***Alexion Indemnitee(s)***") from and against all Losses incurred in connection with any Third Party Claims to the extent arising from (a) the Exploitation of the Licensed Products by or on behalf of Eidos or any of its Affiliates, Third Party Licensees or Subcontractors, (b) the gross negligence or willful misconduct of Eidos or its Affiliates, Third Party Licensees or Subcontractors, or any Eidos Indemnitees, (c) Eidos' breach of any of its

representations or warranties made in or pursuant to this Agreement or any Eidos covenants or obligations set forth in or entered into pursuant to this Agreement, or (d) failure of Eidos or its Affiliates, Third Party Licensees or Subcontractors to abide by any Applicable Laws, in each case of clauses (a) through (d) above, except to the extent such Losses arise out of any matter for which Alexion has obligations of indemnification pursuant to Section 10.1, with respect to which each Party will indemnify the other in proportion to their respective liability for such Losses.

10.3 Indemnification Procedure. In the event that a Party seeks indemnification hereunder with respect to a Third Party Claim, the Party seeking indemnification (the "***Indemnified Party***") shall promptly notify the other Party (the "***Indemnifying Party***") in writing (an "***Indemnification Claim Notice***") of any Third Party Claim in respect of which it intends to claim indemnification under this Article 10 upon actual knowledge of any such claim or proceeding resulting in Losses, but in no event will the Indemnifying Party be liable for any Losses that result from any delay in providing such notice. The Indemnification Claim Notice must contain a description of the claim and the nature and amount of such Losses (to the extent that the nature and amount of such Losses is known at such time). The Indemnifying Party may, at its option, assume exclusive control of the defense and settlement of the Third Party Claim, subject to the limitations on settlement set forth below. If the Indemnifying Party assumes such defense, then such assumption by the Indemnifying Party will not be construed as an acknowledgement that the Indemnifying Party is liable to indemnify the Indemnified Party of any defenses it may assert against the Indemnified Party's claim for indemnification and the Indemnifying Party may appoint as lead counsel in the defense of the Third Party Claim any legal counsel selected by the Indemnifying Party (the Indemnifying Party will consult with the Indemnified Party with respect to a possible conflict of interest of such counsel retained by the Indemnifying Party). The Indemnified Party will have the right to participate in the defense thereof and to employ counsel, at its own expense, separate from the counsel employed by the Indemnifying Party. If the Indemnifying Party does not commence actions to assume control of the defense of a Third Party Claim within [***] after the receipt by the Indemnifying Party of the Indemnification Claim Notice required pursuant to this Section 10.3, the Indemnified Party will have the right to defend such claim in such manner as it may deem appropriate at the reasonable cost and expense of the Indemnifying Party. The Indemnified Party shall cooperate as may be reasonably requested by the Indemnifying Party (and at the Indemnifying Party's expense) in order to ensure the proper and adequate defense of any action, claim or liability covered by this indemnification. The Indemnifying Party may not settle or otherwise dispose of any Third Party Claim without the prior written consent of the Indemnified Party unless such settlement includes only the payment of monetary damages (which are fully paid by the Indemnifying Party), does not impose any injunctive or equitable relief upon the Indemnified Party, does not require any admission or acknowledgment of liability or fault of the Indemnified Party and contains an unconditional release of the Indemnified Party in respect of such Third Party Claim. Regardless of whether the Indemnifying Party chooses to defend or prosecute any Third Party Claim, no Indemnified Party will admit any liability with respect to or settle or otherwise dispose of any Third Party Claim for which the Indemnifying Party may be liable for Losses under this Agreement without the prior written consent of the Indemnifying Party, such consent not to be unreasonably withheld.

10.4 Mitigation of Loss. Each Indemnified Party shall take and shall procure that its Affiliates take all such reasonable steps and actions as are reasonably necessary or as the Indemnifying Party may reasonably require in order to mitigate any claims (or potential losses or damages) under this Article 10. Nothing in this Agreement shall or shall be deemed to relieve any Party of any common law or other duty to mitigate any losses incurred by it.

10.5 Limitation of Liability. NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES ARISING OUT OF THIS AGREEMENT OR THE EXERCISE OF ITS RIGHTS OR THE PERFORMANCE OF ITS OBLIGATIONS HEREUNDER, INCLUDING ANY LOST PROFITS ARISING OUT OF THIS AGREEMENT, IN EACH CASE, HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY WHETHER IN CONTRACT, TORT, NEGLIGENCE, BREACH OF STATUTORY DUTY OR OTHERWISE, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 10.5 IS INTENDED TO OR SHALL LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF EITHER PARTY UNDER SECTION 10.1 OR SECTION 10.2, OR DAMAGES AVAILABLE FOR A PARTY'S BREACH OF ITS OBLIGATIONS UNDER Article 8 OR, WITH RESPECT TO EIDOS, SECTION 2.7.

10.6 Insurance. Each Party shall procure and maintain insurance, including product liability insurance, with respect to its activities hereunder that is consistent with normal business practices of prudent companies similarly situated at all times during which any Licensed Product is being clinically tested in human subjects or commercially distributed or sold. Each Party shall provide the other Party with evidence of such insurance upon request and shall provide the other Party with written notice at least [***] prior to the cancellation, non-renewal or material changes in such insurance. Notwithstanding the foregoing, either Party may self-insure in whole or in part the insurance requirements described above, provided such Party continues to be investment grade determined by reputable and accepted financial rating agencies. Such insurance shall not be construed to create a limit of each Party's liability with respect to its indemnification obligations under this Article 10.

ARTICLE 11
INTELLECTUAL PROPERTY

11.1 Ownership. As between the Parties, each Party shall own and retain ownership of all Know-How and Patent Rights (a) owned by such Party as of the Effective Date or that come into the Control of such Party during the Term outside the scope of this Agreement, or (b) invented by the employees or representatives of such Party in the course of performance of activities pursuant to this Agreement. Inventorship of any inventions conceived or reduced to practice in the course of performance of activities pursuant to this Agreement shall be determined in accordance with U.S. patent laws.

11.2 Patent Prosecution.

(a) **Eidos Patents**.

(i) As between the Parties, Eidos shall have the first right to control, and shall use diligent, good faith efforts to conduct, in consultation with Alexion, the Patent Prosecution of all Eidos Patents in the Territory, [***]. Without limiting the foregoing, Eidos shall file Eidos Patents in the Territory claiming any Eidos Know-How identified by Alexion as suitable for patenting purposes, as reasonably requested by Alexion, provided, however, that if prosecuting such Know-How would materially harm Eidos, Eidos' Patent Rights strategy or Patents Rights with respect to other products, Eidos will notify Alexion of such circumstance and shall not be required to prosecute Patent Rights claiming such Know-How. If Eidos intends to abandon the Patent Prosecution of any Eidos Patent in the Territory, Eidos shall give Alexion prompt notice thereof (not less than [***] before any action is required to avoid abandonment or lapse), and Alexion shall have the right to continue such Patent Prosecution of such Eidos Patent in the Territory, [***]. To effect Alexion's right to assume Eidos' prosecution rights and obligations with respect to any Eidos Patent in the Territory pursuant to this Section 11.2(a)(i), Eidos shall reasonably cooperate with and assist Alexion in connection with its activities under this Section 11.2(a)(i), upon Alexion's reasonable request, including by making scientists and scientific records reasonably available and the execution of all such documents and instruments and the performance of such acts as may be reasonably necessary in order to permit Alexion to continue any Patent Prosecution of such Eidos Patent.

(ii) Eidos shall have the sole right to control, in its sole discretion, the Patent Prosecution of all Eidos Patents outside the Territory, [***].

(iii) The Party conducting Patent Prosecution of any Patent Right under Section 11.2(a) shall consult with the other Party and keep such other Party reasonably informed of the Patent Prosecution of the Patent Rights in the Territory. The prosecuting Party shall provide the other Party with copies of all material correspondence received from any patent authority in the Territory in connection therewith. In addition, the prosecuting Party shall provide the other Party with drafts of all proposed material filings and correspondence to any patent authority in the Territory in connection with the Patent Prosecution of the Patents Right at least [***] prior (or such shorter period prior if it is not reasonably practicable to provide such copies [***] prior) to filing to allow for review and comment by such other Party, and shall consider in good faith timely comments from such other Party thereon; [***]. The prosecuting Party shall also furnish the other Party with copies of all final filings and responses made to any patent authority in the Territory with respect to the Patent Rights being prosecuted by such Party in a timely manner following submission thereof.

(b) **Other Patents**. Except as expressly set forth in this Section 11.2, each Party shall have the sole right, in its sole discretion, to conduct Patent Prosecution with respect to any and all Patent Rights owned or Controlled by such Party, [***].

(c) **Cooperation**. Each Party shall provide the other Party all reasonable assistance and cooperation in the Patent Prosecution efforts under this Section 11.2, including providing any necessary powers of attorney and executing any other required documents or instruments for such prosecution.

11.3 Patent Enforcement.

(a) **Notice**. Each Party shall notify the other within [***] of becoming aware of any alleged or threatened infringement by a Third Party of any of the Eidos Patents or any related declaratory judgment or equivalent action alleging the invalidity, unenforceability or non-infringement of any Eidos Patents anywhere in the world.

(b) **Enforcement Rights**.

(i) Alexion shall have the first right, but not the obligation, in its sole discretion, to bring and control any legal action to enforce the Eidos Patents against any Third Party engaged in any infringement of the Eidos Patents related to a compound or product that competes with (or that would compete with if commercialized) a Licensed Compound or a Licensed Product in the Field in the Territory (a "***Product Infringement***"), [***]. For clarity, Product Infringement excludes any adversarial Patent Prosecution proceedings. Alexion shall give Eidos advance notice of Alexion's intent to file any such suit or take any such action and the reasons therefor, and shall provide Eidos with an opportunity to make suggestions or comments regarding such suit or action. Thereafter, Alexion shall keep Eidos promptly informed, and shall from time to time consult with Eidos regarding the status of any such suit or action. In the event Alexion does not bring any such legal action within [***] (or settle or otherwise secure the abatement of such Product Infringement action) or ceases to diligently pursue such Product Infringement action, Eidos may bring and control any legal action to enforce the Eidos Patents against such Product Infringement, [***].

(ii) Eidos shall have the sole right, but not the obligation, in its sole discretion, to bring and control any legal action to enforce Eidos Patents against any infringement in the ROW Territory, [***], provided that Eidos notifies Alexion of any such legal action reasonably in advance, and considers in good faith Alexion's comments with respect thereto.

(c) **Other Patents**. Except as expressly set forth in this Section 11.3, each Party shall have the sole right, in its sole discretion, to enforce against any infringement any and all Patent Rights owned or Controlled by such Party, [***].

(d) **Cooperation**. At the request of the Party bringing an action under Section 11.3(b), the other Party shall provide reasonable assistance in connection therewith, including by executing reasonably appropriate documents, cooperating in discovery, facilitating registration of licenses and joining as a party to the action if required by Applicable Law to pursue such action, [***].

(e) **Recoveries**. Any recoveries resulting from any action under Section 11.3(b)(i) in the Territory shall be first applied against payment of each Party's costs and expenses in connection therewith. [***].

11.4 Infringement of Third Party Rights.

(a) **Notice**. If (i) any Licensed Compound or Licensed Product used or sold by Alexion, its Affiliates or Sublicensees in the Territory becomes the subject of a Third Party's claim or assertion of infringement of a Patent Right or other rights in the Territory that are owned or controlled by such Third Party or (ii) any Licensed Compound or Licensed Product used or sold by Eidos, its Affiliates or Third Party Licensees in the ROW Territory becomes the subject of a Third Party's claim or assertion of infringement of a Patent Right or other rights in the ROW Territory, then the Party becoming aware of such claim or assertion shall promptly notify the other Party within [***] after receipt of such claim or assertion and such notice shall include a copy of any summons or complaint (or the equivalent thereof) received regarding the foregoing. The Parties shall assert and not waive the joint defense privilege with respect to any communications between the Parties in connection with the defense of such claim or assertion.

(b) **Defense by Alexion**. As between the Parties, Alexion shall be solely responsible for the defense of any such infringement claims in the Field in the Territory with respect to the activities of Alexion, its Affiliates or Sublicensees, [***], and Eidos shall provide reasonable assistance to Alexion [***]; provided that Alexion shall not agree to any settlement, consent to judgment or other voluntary final disposition in connection with such defense action without Eidos' consent (such consent not to be unreasonably withheld, conditioned or delayed) if such settlement, consent to judgment or other voluntary final disposition would (i) result in the admission of any liability or fault on behalf of Eidos, (ii) result in or impose any payment obligations upon Eidos, or (iii) subject Eidos to an injunction or otherwise limit Eidos' ability to take any actions or refrain from taking any actions under this Agreement or with respect to any Licensed Compound or Licensed Product. Alexion shall keep Eidos informed on the status of such defense action, and Eidos shall, at its own expense, (A) provide reasonable support to Alexion upon Alexion's reasonable request; and (B) have the right, but not the obligation, to participate or be separately represented in such defense action at its sole option and expense.

(c) **Defense by Eidos**. As between the Parties, Eidos shall be solely responsible for the defense of any such infringement claims with respect to Eidos' activities, including any such infringement claim in the Territory or in the ROW Territory, [***], and Alexion shall provide reasonable assistance to Eidos [***]; provided that Eidos shall not agree to any settlement, consent to judgment or other voluntary final disposition in connection with such defense action without Alexion's consent (such consent not to be unreasonably withheld, conditioned or delayed) if such settlement, consent to judgment or other voluntary final disposition would (i) result in the admission of any liability or fault on behalf of Alexion, (ii) result in or impose any payment obligations upon Alexion, or (iii) subject Alexion to an injunction or otherwise limit Alexion's ability to take any actions or refrain from taking any actions under this Agreement or with respect to any Licensed Compound or Licensed Product. Eidos shall keep Alexion informed on the status of such defense action, and Alexion shall, at its own expense, (A) provide reasonable support to Eidos upon Eidos' reasonable request; and (B) have the right, but not the obligation, to participate or be separately represented in such defense action at its sole option and expense.

11.5 Upstream License. To the extent that an Upstream Licensor of Eidos has retained any right to prosecute or enforce any Eidos Patents or otherwise be involved in such activities pursuant to the Upstream License granting Eidos a license thereto (including pursuant to the Stanford Agreement), [***]. Notwithstanding anything to the contrary in this Agreement, this Section 11.5 shall only be in effect to the extent that Eidos has notified Alexion of the relevant rights and obligations under the Upstream License pursuant to Section 11.8.

11.6 Licensed Product-Specific Trademarks.

(a) **Ownership and Prosecution of Licensed Product-Specific Trademarks**. Eidos shall own all right, title, and interest to the Licensed Product-Specific Trademarks (including relevant registrations and applications) in the ROW Territory and the Territory, and shall be responsible for the registration, prosecution, maintenance and renewal thereof; provided that Alexion shall have the right to provide input on the overall strategy for such registration, prosecution, maintenance and renewal in the Territory, and Eidos shall consider such input in good faith. All costs and expenses of registration, prosecuting, maintaining and renewing the Licensed Product-Specific Trademarks shall be borne solely by [***]. If Eidos intends to abandon the prosecution of (including any decision to not renew) any Licensed Product-Specific Trademark in the Territory, Eidos shall give Alexion prompt notice thereof (not less than [***] before any action is required to avoid abandonment or lapse), and Alexion shall have the right to continue such prosecution of such Licensed Product-Specific Trademark in the Territory, [***].

(b) **Enforcement of Licensed Product-Specific Trademarks**. Eidos shall have the sole right and responsibility for taking such action as Eidos, after consultation with Alexion, deems necessary against a Third Party based on any alleged, threatened, or actual infringement, dilution, or other violation of, or unfair trade practices or any other like offense relating to, the Licensed Product-Specific Trademarks by a Third Party in the Territory. [***] shall bear the costs and expenses relating to any enforcement action commenced pursuant to this Section 11.6(b) and any settlements and judgments with respect thereof, and shall retain any damages or other amounts collected in connection therewith. Subject to the foregoing, Alexion may elect at its expense to participate in the enforcement of the Licensed Product-Specific Trademarks in the Territory. In the event that Eidos fails to assume responsibility for such enforcement, Alexion shall have the sole right and responsibility for such action, in which case [***] shall bear all costs and expenses and shall retain any damages or other amounts collected in connection therewith.

(c) **Third Party Claims**.

(i) **Defense by Alexion**. Alexion shall have the sole right and responsibility for defending against any alleged, threatened, or actual claim by a Third Party that the use or registration of the Licensed Product-Specific Trademarks by Alexion, its Affiliates or Sublicensees in the Territory infringes, dilutes or otherwise violates any Trademark or other right of that Third Party or constitutes unfair trade practices or any other like offense, or any other claims as may be brought by a Third Party against a Party in connection with the use or registration of the Licensed Product-Specific Trademarks by Alexion, its Affiliates or Sublicensees in the Territory. [***] shall bear the costs and expenses relating to any defense commenced pursuant to this Section 11.6(c)(i) and any settlements and judgments with respect thereto, and shall retain any damages or other amounts collected in connection therewith.

(ii) **Defense by Eidos**. Eidos shall have the sole right and responsibility for defending against any alleged, threatened, or actual claim by a Third Party that Eidos' use or registration of the Licensed Product-Specific Trademarks in the Territory in accordance with this Agreement infringes, dilutes or otherwise violates any Trademark or other right of that Third Party or constitutes unfair trade practices or any other like offense, or any other claims as may be brought by a Third Party against a Party in connection with Eidos' use of any Licensed Product-Specific Trademark in the Territory in accordance with this Agreement; provided that Eidos shall not agree to any settlement, consent to judgment or other voluntary final disposition in connection with such defense action without Alexion's consent (such consent not to be unreasonably withheld, conditioned or delayed) if such settlement, consent to judgment or other voluntary final disposition would (i) result in the admission of any liability or fault on behalf of Alexion, (ii) result in or impose any payment obligations upon Alexion, or (iii) subject Alexion to an injunction or otherwise limit Alexion's ability to take any actions or refrain from taking any actions under this Agreement or with respect to any Licensed Compound or Licensed Product. [***] shall bear the costs and expenses relating to any defense commenced pursuant to this Section 11.6(c)(ii) and any settlements and judgments with respect thereto, and shall retain any damages or other amounts collected in connection therewith.

(d) **Notice and Cooperation**. Each Party shall provide to the other Party prompt written notice of any actual or threatened infringement of the Licensed Product-Specific Trademarks in the Territory and of any actual or threatened claim that the use of the Licensed Product-Specific Trademarks in the Territory violates the rights of any Third Party. Each Party agrees to cooperate fully with the other Party with respect to any enforcement action or defense commenced pursuant to this Section 11.6(d), including cooperation required to permit required registration of trademark licenses within the Territory.

11.7 Common Interest Agreement. All information exchanged between the Parties regarding the prosecution and maintenance, and enforcement and defense, of Eidos Patents under this Article 11 will be deemed Confidential Information of the disclosing Party. In addition, the Parties acknowledge and agree that, with regard to such prosecution and maintenance, and enforcement and defense, the interests of the Parties as collaborators and licensor and licensee are to obtain the strongest patent protection possible, and as such, are aligned and are legal in nature. The Parties agree and acknowledge that they have not waived, and nothing in this Agreement constitutes a waiver of, any legal privilege concerning the Patent Rights under this Article 11, including privilege under the common interest doctrine and similar or related doctrines. Notwithstanding anything to the contrary contained herein, to the extent a Party has a good faith belief that any information required to be disclosed by such Party to the other Party under this Article 11 is protected by attorney-client privilege or any other applicable legal privilege or immunity, such Party will not be required to disclose such information, and the Parties will in good faith cooperate to agree upon a procedure (including entering into a specific common interest agreement, disclosing such information on a "for counsel eyes only" basis or similar procedure) under which such information may be disclosed without waiving or breaching such privilege or immunity.

11.8 New In-License Agreements.

(a) If Eidos or its Affiliate is planning to enter into an agreement during the Term with a Third Party (other than a Third Party Licensee) under which Eidos or its Affiliate obtains a license or rights to Patent Rights or Know-How that are necessary or useful for the Exploitation of the Licensed Compound or Licensed Product in the Field in the Territory [***].

(b) Subject to Section 11.8(a), if Eidos or its Affiliate enters into an agreement during the Term with a Third Party under which Eidos or its Affiliate obtains a license or rights to Patent Rights or Know-How that are necessary or useful for the Exploitation of the Licensed Compound or Licensed Product in the Field in the Territory, Eidos shall provide Alexion with prompt written notice thereof, as well as (i) [***], and (iii) a copy of such Third Party agreement, including references to the applicable provisions of such Third Party agreement with which Alexion must agree to comply with as a sublicensee of the rights; [***].

(c) If Alexion notifies Eidos in writing that such Patent Rights or Know-How licensed under such agreement should be included within the Eidos IP and agrees that it will comply with all applicable provisions of such New In-License Agreement, then (a) such agreement will be deemed to be a "**New In-License Agreement**" hereunder, (b) the Patent Rights and Know-How in-licensed under such New In-License Agreement will be deemed "Controlled" by Eidos (or its Affiliate, as applicable) and included within Eidos IP except for the purposes of determining the Royalty Term and whether a Licensed Product is Covered by a Valid Claim under Section 7.4(c)(iii) (i.e. a Patent Right in-licensed under such New In-License Agreement will not be deemed an Eidos Patent for those purposes), (c) any Third Party payments under such New In-License Agreement will be allocated between the Parties as provided above and (d) the provisions of Section 9.3(d) through Section 9.3(i) shall apply, *mutatis mutandis*, to such New In-License Agreement. If Alexion does not elect to include such Patent Rights or Know-How in-licensed under such agreement as Eidos IP hereunder, then (A) such agreement will not be deemed to be a New In-License Agreement hereunder and (B) the Patent Rights and Know-How in-licensed under such agreement will not be deemed to be "Controlled" by Eidos (or its Affiliate, as applicable) or included within the Eidos IP, and Alexion will have no license or rights to such Patent Rights or Know-How.

ARTICLE 12
TERMS AND TERMINATION

12.1 Term. This Agreement shall be effective as of the Effective Date, and shall continue, unless terminated earlier in accordance with this Article 12, until expiration of the last Royalty Term for the last Licensed Product in the Field in the Territory (the "***Term***").

12.2 Termination.

(a) **Termination by Alexion for Convenience**. At any time, Alexion may terminate this Agreement in its entirety for convenience by providing written notice of termination to Eidos, which notice includes an effective date of termination at least [***] after the date of the notice.

(b) **Termination for Material Breach**.

(i) If either Party believes in good faith that the other is in material breach of this Agreement, then the non-breaching Party may deliver written notice of such breach to the other Party. For any such alleged material breach, the allegedly breaching Party shall have [***] (or, in the case of a payment breach, [***]) from the receipt of the initial notice to cure such breach. If the Party receiving notice of material breach fails to cure the breach within such [***] (or [***]) day period, then the non-breaching Party may terminate this Agreement in its entirety effective on written notice of termination to the other Party. Notwithstanding the foregoing, if such material breach (other than a payment breach), by its nature, is curable, but is not reasonably curable within the [***] period, then such period shall be extended if the breaching Party provides a written plan for curing such breach to the non-breaching Party and uses commercially reasonable efforts to cure such breach in accordance with such written plan; provided, that no such extension shall exceed an additional [***] without the consent of the non-breaching Party.

(ii) In case the Party alleged under Section 12.2(b)(i) to have committed a material breach of this Agreement (the "***Defaulting Party***") by the other Party (the "***Non-Defaulting Party***") disputes the existence or materiality of such material breach, then the issue of whether the Non-Defaulting Party may properly terminate this Agreement on expiration of the applicable cure period shall be resolved in accordance with Section 13.6. If, as a result of such dispute resolution proceeding, it is determined that the Defaulting Party committed a material breach and the Defaulting Party does not cure such material breach within [***] after the date of such determination (the "***Additional Cure Period***"), then such termination shall be effective as of the expiration of the Additional Cure Period. If the Parties dispute whether such material breach was so cured, such dispute shall also be determined in accordance with Section 13.6. This Agreement shall remain in full force and effect while any such dispute resolution proceeding is pending, such proceeding shall not suspend any obligations of either Party hereunder, and each Party shall use reasonable efforts to mitigate any damage. If, as a result of such dispute resolution proceeding, it is determined that (A) the Defaulting Party did not commit such breach, (B) such breach was not material or (C) such breach was cured in accordance with this Section 12.2(b), then no termination shall be effective, and this Agreement shall continue in full force and effect.

(c) **Termination by Eidos for [***]**. If Alexion, its Affiliates and Sublicensees do not [***], then Eidos may terminate this Agreement in its entirety with [***] written notice to Alexion, unless within such [***] period Alexion provides to Eidos reasonable documentation evidencing [***].

(d) **Termination by Eidos for Patent Challenges**. Eidos has the right, in its sole discretion, to terminate this Agreement in its entirety upon written notice to Alexion, in the event that Alexion or any of its Affiliates or Sublicensees directly or indirectly commences any interference or opposition proceeding, challenges the validity or enforceability of, or opposes any extension of or the grant of a supplementary protection certificate with respect to, any Eidos Patents ("***Patent Challenge***"), provided that, Eidos will not have the right to terminate this Agreement under this Section 12.2(d) if (i) Alexion causes such Patent Challenge to be terminated or dismissed (or in the case of ex-parte proceedings, multi-party proceedings, or other Patent Challenges in which the challenging party does not have the power to unilaterally cause the Patent Challenge to be withdrawn, withdraws or causes its Affiliate or Sublicensee to withdraw as a party

from such Patent Challenge and to cease actively assisting any other party to such Patent Challenge), (ii) Alexion, with respect to a Sublicensee, terminates such Sublicensee's sublicense to the Patent Rights being challenged by the Sublicensee (or if Alexion has provided such Sublicensee with written notice of such termination and is enforcing such termination in accordance with the applicable sublicense agreement), in each case (i) and (ii), within [***] of Eidos' notice to Alexion under this Section 12.2(d), (iii) the Patent Challenge is in defense of any claim first brought by Eidos, its Affiliates or Third Party Licensees or (iv) the activities constituting the Patent Challenge are required under a court order or subpoena.

(e) **Termination for Insolvency**. Each Party shall have the right to terminate this Agreement upon delivery of written notice to the other Party in the event that (i) such other Party files in any court or agency pursuant to any statute or regulation of any jurisdiction a petition in bankruptcy or insolvency or for reorganization or similar arrangement for the benefit of creditors or for the appointment of a receiver or trustee of such other Party or its assets, (ii) such other Party is served with an involuntary petition against it in any insolvency proceeding and such involuntary petition has not been stayed or dismissed within [***] of its filing, or (iii) such other Party makes an assignment of substantially all of its assets for the benefit of its creditors (each of (i) through (iii), an "***Insolvency Event***").

12.3 Effect of Termination. In the event of any termination of this Agreement for any reason:

(a) Except as expressly set forth in this Agreement (including Section 12.7), all rights and obligations of the Parties shall immediately terminate, including the License; provided, however, that any Sublicensee will, as of the effective date of termination of this Agreement, automatically and without any additional consideration become a direct licensee of Eidos with respect to the rights sublicensed to the Sublicensee by Alexion under this Agreement, so long as (i) such Sublicensee is not in breach of its sublicense agreement with Alexion, (ii) such Sublicensee agrees in writing to comply with all of the terms of this Agreement to the extent applicable to the rights originally sublicensed to it by Alexion, and (iii) such Sublicensee agrees to pay directly to Eidos such Sublicensee's payments under this Agreement to the extent applicable to the rights sublicensed to it by Alexion. The foregoing shall not apply if a Sublicensee provides written notice to Eidos that it does not wish to receive and retain the rights afforded to it pursuant to this Section 12.3. At Alexion's request, Eidos will enter into a standby license with any Sublicensee confirming the benefits conferred on such Sublicensee by this Section 12.3.

(b) Upon Eidos' written request to Alexion, which notice may only be delivered within [***] following the [***], Alexion will promptly, subject to the terms and conditions of this Agreement (including the rights of a Sublicensee under Section 12.3(a)):

(i) grant, and hereby does grant, and will cause its Affiliates and its Sublicensees (subject to Section 2.2(b)) to grant, subject to the terms of this Section 12.3(b)(i), to Eidos and its Affiliates an [***] (the "***Reversion License***"); provided that (A) Eidos shall be responsible for (1) making any payments (including royalties, milestones and other amounts) payable by Alexion to Third Parties under any Third Party agreements with respect to the Alexion Technology that is the subject of the Reversion License by making such payments directly to Alexion and, in each case, Eidos shall make the requisite payments to Alexion and provide the necessary reporting information to Alexion in sufficient time to enable Alexion to comply with its obligations under such Third Party agreements, and (2) complying with any other obligations included in any such Third Party agreements that are applicable to the grant to Eidos of such Reversion License or the exercise of such Reversion License by Eidos or any of its Affiliates or Third Party Sublicensees and (B) Alexion can terminate the Reversion License with respect to any Patent Right or Know-How that is in-licensed under a Third Party agreement if Eidos does not comply with the obligations under such Third Party agreement as described in clause (A) of this proviso, provided that Eidos shall not be responsible for such payments, and Alexion may not be able to terminate the Reversion License, if Eidos is not aware of the relevant rights and obligations under such Third Party agreement. The Reversion License will be fully paid-up and royalty-free except in the event this Agreement is terminated by Alexion pursuant to Section 12.2(b) or by Eidos pursuant to Section 12.2(c), in which case, the Reversion License will be royalty-bearing. If such termination is by Alexion pursuant to Section 12.2(b) or by Eidos pursuant to Section 12.2(c), the Parties will negotiate in good faith on a commercially reasonable royalty rate for such Reversion License. If the Parties are unable to agree on the financial terms of such license agreement, the matter shall be resolved in accordance with Exhibit 12.3(b)(i);

(ii) [***]; and

(iii) grant, and hereby does grant, to Eidos and its Affiliates a royalty-free, fully paid-up, perpetual, irrevocable, non-exclusive license, with the right to sublicense through multiple tiers, to use the Trademarks owned by Alexion or its Affiliates solely identifying each Licensed Product for the purpose of Commercializing the Licensed Product in the Territory (for clarity, such Trademarks described in this Section 12.3(b)(iii) shall not include any Trademarks that include any corporate name or logo of Alexion, its Affiliates or Sublicensees or the name (including a common prefix or suffix) of any other product Exploited by Alexion, its Affiliates or Sublicensees).

(c) [***].

12.4 Alternative Remedy in Lieu of Termination. If Eidos has breached Section 2.7, Article 5, Article 11 or Section 13.2 and Alexion has the right to terminate this Agreement pursuant to Section 12.2(b) (*i.e.*, such breach constitutes a material breach and is not cured within the applicable cure period) as a result of such breach, then Alexion may, in its sole discretion, in lieu of terminating this Agreement [***] with respect to such breach of Section 2.7, Article 5, Article 11 or Section 13.2, exercise an alternative remedy as follows:

(a) Alexion may retain the License and other rights granted under this Agreement, subject to all of its payment and other obligations; [***]

(b) any Alexion Confidential Information provided to Eidos pursuant to this Agreement will be promptly returned to Alexion or destroyed, and Alexion shall be released from its ongoing disclosure and information exchange obligations with respect to activities following the date of such election, provided that (i) Alexion shall disclose directly to the applicable Upstream Licensors any such information required to be disclosed pursuant to the Upstream Licenses and (ii) Eidos may retain, and Alexion shall continue to disclose, any such information necessary for Eidos to perform its obligations under this Agreement.

12.5 Rights in Insolvency. All rights and licenses now or hereafter granted by Eidos to Alexion under or pursuant to this Agreement are, for all purposes of Section 365(n) of the Bankruptcy Code, licenses of rights to "intellectual property" as defined in the Bankruptcy Code. Upon an Insolvency Event, Eidos agrees that Alexion, as licensee of such rights under this Agreement, will retain and may fully exercise all of its rights and elections under the Bankruptcy Code. Eidos will, during the Term, create and maintain current copies or, if not amenable to copying, detailed descriptions or other appropriate embodiments, to the extent feasible, of all intellectual property licensed under this Agreement. Each Party acknowledges and agrees that "embodiments" of intellectual property within the meaning of Section 365(n) include laboratory notebooks, cell lines, product samples and inventory, research studies and data, all Regulatory Approvals (and all applications for Regulatory Approval) and rights of reference therein, the Eidos IP and all information related to the Eidos IP.

(a) If (x) a case under the Bankruptcy Code is commenced by or against Eidos, (y) this Agreement is rejected as provided in section 365 of the Bankruptcy Code and (z) Alexion elects to retain its rights hereunder as provided in Section 365(n) of the Bankruptcy Code, Eidos (in any capacity, including debtor-in-possession) and its successors and assigns (including a trustee) will:

(i) provide Alexion with embodiments of all Eidos IP held by Eidos and such successors and assigns, or otherwise available to them, immediately upon Alexion's written request, and Alexion will have the right to perform Eidos' obligations hereunder and exercise all of the rights of a licensee of intellectual property under section 365(n) of the Bankruptcy Code, provided that neither such provision nor such performance by Alexion will release Eidos from liability resulting from rejection of the license or the failure to perform such obligations; and

(ii) not interfere with Alexion's rights under this Agreement, or any agreement supplemental hereto, to such intellectual property (including such embodiments), including any right to obtain such intellectual property (or such embodiments) from any other Person, to the extent provided in Section 365(n) of the Bankruptcy Code.

(b) All rights, powers and remedies of Alexion provided herein are in addition to and not in substitution for any other rights, powers and remedies now or hereafter existing at law or in equity (including the Bankruptcy Code) in the event of the commencement of a case under the Bankruptcy Code with respect to Eidos. The Parties intend the following rights to extend to the maximum extent permitted by Applicable Law, and to be enforceable under Bankruptcy Code Section 365(n):

(i) the right of access to the Eidos IP, or any Third Party with whom Eidos contracts to perform an obligation of Eidos under this Agreement; and

(ii) the right to contract directly with any Third Party to complete the contracted work.

12.6 Accrued Rights. Expiration or termination of this Agreement for any reason shall be without prejudice to any right which shall have accrued to the benefit of either Party prior to such termination, including damages arising from any breach under this Agreement.

12.7 Survival. The provisions of Article 1 (Definitions) (to the extent necessary to give effect to the other surviving provisions), Section 2.6 (No Implied Licenses), Section 2.9 (Other Alexion Programs), Section 7.4(e) (Royalty Reports and Payments) through (g) (Interest) and Section 7.5 (Taxes) (each solely with respect to payment obligations accruing prior to the effective date of expiration or termination), Section 7.6 (Financial Audits), Article 8 (Confidentiality; Publication) (for the time period set forth therein), Section 9.6 (No Other Warranties), Article 10 (Indemnification), Section 11.1 (Ownership), Section 12.3 (Effect of Termination), Section 12.6 (Accrued Rights), this Section 12.7 (Survival) and Article 13 (Miscellaneous), together with any other provisions of this Agreement that by their terms are expressly stated to survive, shall survive the expiration or termination of this Agreement.

12.8 Termination of Stanford or Upstream License Agreements. Without limiting anything set forth in the [***], upon any termination of the Stanford Agreement or any other agreement pursuant to which Eidos Controls any of the Eidos IP, Eidos shall facilitate Alexion's negotiations with Stanford or the applicable licensor for a direct license in the Field in the Territory.

ARTICLE 13
MISCELLANEOUS

13.1 Force Majeure. Neither Party shall be held liable to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in performing any obligation under this Agreement to the extent such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party, including embargoes, war, acts of war (whether war be declared or not), acts of terrorism, insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances (except for a strike, lockout or labor disturbance with respect to the non-performing Party's respective employees or agents), fire, floods, earthquakes or other acts of God, or any generally applicable action or inaction by any governmental authority (but excluding any government action or inaction that is specific to such Party or its Affiliates, such as revocation or non-renewal of such Party's or its Affiliate's license to conduct business), or omissions or delays in acting by the other Party. The affected Party shall notify the other Party in writing of such force majeure circumstances as soon as reasonably practicable (in any event, within [***]), and shall promptly undertake and continue diligently all reasonable efforts necessary to cure such force majeure circumstances or to perform its obligations despite the ongoing circumstances.

13.2 Assignment.

(a) This Agreement may not be assigned or otherwise transferred by a Party, nor may any right or obligation hereunder be assigned or transferred by a Party (except as expressly permitted under this Agreement), without the prior written consent of the other Party, such consent not to be unreasonably withheld, conditioned or delayed. Notwithstanding the foregoing, either Party may, without the consent of the other Party, assign this Agreement (i) in whole or in part to any of its Affiliates or (ii) in whole, but not in part, to a purchaser of all or substantially all of its assets to which this Agreement relates (whether by merger, stock purchase, consolidation, asset purchase, or otherwise) or to any successor resulting from a Change of Control of such Party, provided that (A) the applicable assignee agrees in writing to assume all rights and obligations of the assignor Party under this Agreement, and (B) a copy of such writing is provided to the non-assigning Party within [***] of such assignment. Any attempted assignment not in accordance with this Section 13.2 shall be null and void and of no legal effect. The terms and conditions of this Agreement shall be binding upon, and shall inure to the benefit of, the Parties and their respected successors and permitted assigns.

(b) [***]

13.3 Severability. If any one (1) or more of the provisions contained in this Agreement is held invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions contained herein shall not in any way be affected or impaired thereby, unless the absence of the invalidated provision(s) adversely affects the substantive rights of the Parties. The Parties shall in such an instance use their commercially reasonable efforts to replace the invalid, illegal or unenforceable provision(s) with valid, legal and enforceable provision(s) that, insofar as practicable, implement the purposes of this Agreement.

13.4 Notices. All notices that are required or permitted hereunder shall be in writing and sufficient if delivered personally, sent by facsimile or electronic mail (and promptly confirmed by personal delivery, registered or certified mail or overnight courier), sent by nationally-recognized overnight courier or sent by registered or certified mail, postage prepaid, return receipt requested, addressed as follows:

If to Eidos:

Eidos Therapeutics, Inc.
101 Montgomery Street, Suite 2550
San Francisco, CA 94104
Attention: Cameron Turtle

If to Alexion:

Alexion Pharma International Operations Unlimited Company
c/o Alexion Pharmaceuticals, Inc.
121 Seaport Boulevard
Boston, MA 02210
Attention: General Counsel

or to such other address as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith**.** Any such notice shall be deemed to have been given: (i) when delivered if personally delivered or sent by electronic mail or facsimile on a Business Day (or if delivered or sent on a non-Business Day, then on the next Business Day); (ii) on the Business Day after dispatch if sent by nationally-recognized overnight courier; or (iii) on the fifth Business Day following the date of mailing if sent by mail.

13.5 Governing Law. This Agreement, and all claims or causes of action (whether in contract, tort or statute) that may be based upon, arise out of or relate to this Agreement, or the negotiation, execution or performance of this Agreement or the breach thereof (including any claim or cause of action based upon, arising out of or related to any representation or warranty made in or in connection with this Agreement or as an inducement to enter into this Agreement), shall be governed by, and enforced in accordance with, the internal laws of the State of Delaware, without reference to its conflicts of law principles.

13.6 Dispute Resolution; Escalation. Any dispute arising out of or in connection with this Agreement shall be settled, if possible, through good faith negotiations between the Parties. If the Parties are unable to settle such dispute within [***] of first considering such dispute, such dispute shall be referred to the Alliance Managers for resolution. The Alliance Managers of both Parties shall meet to attempt to resolve such dispute. If the Alliance Managers are unable to settle such dispute within [***] of first considering such dispute, such dispute shall be referred to the Executive Officers for resolution. The Executive Officers of both Parties shall meet to attempt to resolve such dispute. Such resolution, if any, of a referred issue shall be final and binding on the Parties. All negotiations pursuant to this Section 13.6 are confidential and shall be treated as compromise and settlement negotiations for purposes of applicable rules of evidence. If the Executive Officers cannot resolve such dispute within [***] after either Party requests such a meeting in writing, then either Party shall have the right to pursue any and all remedies available at law or equity.

13.7 Entire Agreement; Amendments. This Agreement, together with the Exhibits hereto, contains the entire understanding of the Parties with respect to the subject matter hereof. Any other express or implied agreements and understandings, negotiations, writings and commitments, either oral or written, in respect to such subject matter are superseded by the terms of this Agreement. The Exhibits to this Agreement are incorporated herein by reference and shall be deemed a part of this Agreement. This Agreement may be amended, or any term hereof modified, only by a written instrument duly executed by authorized representative(s) of both Parties. The Parties agree that, effective as of the Effective Date, that the Existing Confidentiality Agreement shall be superseded by this Agreement, and that disclosures made prior to the Effective Date pursuant to the Confidentiality Agreement shall be subject to the confidentiality and non-use provisions of this Agreement. The foregoing shall not be interpreted as a waiver of any remedies available to either Party or its Affiliates as a result of any breach, prior to the Effective Date, by the other Party or its Affiliates of such Party's or its Affiliate's obligations pursuant to the Confidentiality Agreement.

13.8 Headings. The captions to the several Articles, Sections, subsections and Exhibits hereof are not a part of this Agreement, but are merely for convenience to assist in locating and reading the several Articles, Sections and Exhibits of this Agreement.

13.9 Independent Contractors. It is expressly agreed that Eidos and Alexion shall be independent contractors and that the relationship between the two (2) Parties shall not constitute a partnership, joint venture or agency. Neither Eidos nor Alexion shall have the authority to make any statements, representations or commitments of any kind, or to take any action that is binding on the other Party without the prior written consent of the other Party.

13.10 Waiver. Any waiver of any provision of this Agreement shall be effective only if in writing and signed by Eidos and Alexion. No express or implied waiver by a Party of any default under this Agreement will be a waiver of a future or subsequent default. The failure or delay of any Party in exercising any rights under this Agreement will not constitute a waiver of any such right, and any single or partial exercise of any particular right by any Party will not exhaust the same or constitute a waiver of any other right provided in this Agreement.

13.11 Waiver of Rule of Construction. Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, the rule of construction that any ambiguity in this Agreement shall be construed against the drafting Party shall not apply.

13.12 Cumulative Remedies; Recovery of Damages. Except as expressly set forth in this Agreement, no remedy referred to in this Agreement is intended to be exclusive, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under Applicable Laws. If Alexion seeks direct damages from Eidos arising from any breach of this Agreement, then Alexion shall be entitled to seek damages including, without limitation, any and all amounts paid by Alexion to Eidos under this Agreement, including without limitation any payment described as nonrefundable or non-creditable; provided that, nothing in this Section 13.12 shall be construed to change any legal obligation under Applicable Law for Alexion to prove its damages for such breach.

13.13 Business Day Requirements. In the event that any notice or other action or omission is required to be taken by a Party under this Agreement on a day that is not a Business Day then such notice or other action or omission shall be deemed to be required to be taken on the next occurring Business Day.

13.14 Further Actions. Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as necessary or appropriate in order to carry out the purposes and intent of this Agreement.

13.15 Construction. Except where the context expressly requires otherwise, (a) the use of any gender herein shall be deemed to encompass references to either or both genders, and the use of the singular shall be deemed to include the plural (and vice versa), (b) the words "include", "includes" and "including" shall be deemed to be followed by the phrase "without limitation", (c) the word "will" shall be construed to have the same meaning and effect as the word "shall", (d) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein), (e) any reference herein to any person shall be construed to include the person's successors and assigns, (f) the words "herein", "hereof" and "hereunder", and words of similar import, shall be construed to refer to this Agreement in its entirety and not to any particular provision hereof, (g) all references herein to Sections, Schedules, or Exhibits shall be construed to refer to Sections, Schedules or Exhibits of this Agreement unless otherwise specified, and references to this Agreement include all Schedules and Exhibits hereto, (h) the word "notice" means notice in writing (whether or not specifically stated) and shall include notices, consents, approvals and other written communications contemplated under this Agreement, (i) provisions that require that a Party, the Parties or any committee hereunder "agree", "consent" or "approve" or the like shall require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise (but excluding e-mail and instant messaging), (j) references to any specific law, rule or regulation, or Section, section or other division thereof, shall be deemed to include the then-current amendments thereto or any replacement or successor law, rule or regulation thereof, and (k) the term "or" shall be interpreted in the inclusive sense commonly associated with the term "and/or."

13.16 Counterparts. This Agreement may be executed in two (2) counterparts, each of which shall be deemed an original, but both of which together shall constitute one and the same instrument. Each Party shall be entitled to rely on the delivery of executed digital (*e.g.*, PDF) copies of counterpart execution pages of this Agreement and such digital copies shall be legally effective to create a valid and binding agreement among the Parties.

{Signature Page Follows}

In Witness Whereof, the Parties intending to be bound have caused this License Agreement to be executed by their duly authorized representatives as of the Effective Date.

EIDOS THERAPEUTICS, INC.

By: /s/ Christine Siu
Name: Christine Siu
Title: Chief Financial Officer

ALEXION PHARMA INTERNATIONAL OPERATIONS UNLIMITED COMPANY

By: /s/ Shane Doyle
Name: Shane Doyle
Title: Director

[*Signature Page to License Agreement*]

List of Exhibits

Exhibit 1.41: Eidos Patents
Exhibit 1.71: Licensed Compound
Exhibit 2.4: Certain Provisions of the Stanford Agreement
Exhibit 5.1: Clinical Supply Agreement Key Terms
Exhibit 8.7: Joint Press Release
Exhibit 9.2(b): Disclosure
Exhibit 12.3(b)(i): Select Arbitration Provisions

Exhibit 1.41
Eidos Patents

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Exhibit 1.71
Licensed Compound

[***]

Exhibit 2.4
Certain Provisions of the Stanford Agreement

[***]

Exhibit 5.1
Clinical Supply Agreement Key Terms

[***]

Exhibit 8.7
Joint Press Release

Alexion and BridgeBio Announce Japanese License Agreement for Eidos' Transthyretin Amyloidosis (ATTR) Investigational Medicine

- Eidos grants Alexion exclusive license to develop and commercialize AG10 in Japan -

- Phase 3 study of AG10 in ATTR cardiomyopathy underway in U.S. & Europe; Phase 3 trial in ATTR polyneuropathy planned to initiate in second half of 2019 -

- Agreement expands Alexion's amyloidosis portfolio -

- Eidos to receive upfront payment of $25 million and equity investment of $25 million, with potential for additional Japanese-based milestone- & royalty-dependent payments -

BOSTON & SAN FRANCISCO – SEPTEMBER 9, 2019 - Alexion Pharmaceuticals, Inc. (NASDAQ:ALXN) and BridgeBio Pharma, Inc.'s (NASDAQ:BBIO) subsidiary Eidos Therapeutics, Inc. (NASDAQ:EIDX) today announced an agreement that grants Alexion an exclusive license to develop and commercialize AG10 in Japan. AG10 is a small molecule designed to treat the root cause of transthyretin amyloidosis (ATTR) – destabilized and misfolded transthyretin (TTR) protein – by binding and stabilizing TTR in the blood. Eidos is currently evaluating AG10 in a Phase 3 study in the U.S. and Europe for ATTR cardiomyopathy (ATTR-CM) – a progressive, fatal disease caused by the accumulation of misfolded TTR amyloid in the heart – and plans to begin a Phase 3 study in ATTR polyneuropathy (ATTR-PN) – a progressive, fatal disease caused by the accumulation of misfolded TTR amyloid in the peripheral nervous system.

"There is a significant need for new treatments for TTR amyloidosis. We believe AG10 holds promise in its ability to stabilize TTR and halt disease progression," said John Orloff, M.D., Executive Vice President and Head of Research & Development at Alexion. "We are excited by the potential to grow our amyloidosis portfolio by partnering with Eidos to expand the development of AG10 to Japan. Alexion has more than 10 years of experience operating there, and we look forward to applying our expertise to bring AG10 to Japanese patients."

"The Phase 2 study in ATTR-CM suggested that AG10 has the potential to become an important treatment option for the underserved ATTR-CM population. The trial showed that AG10 was generally well-tolerated and resulted in near-complete stabilization of TTR, which is known to be correlated with disease severity in ATTR-CM. In the study, AG10 also normalized serum TTR levels, a prognostic indicator of survival in ATTR patients," said Jonathan Fox, M.D., Ph.D., President and Chief Medical Officer of Eidos. "We have now begun our Phase 3 program to evaluate the safety and efficacy of AG10 in larger studies. This agreement provides the potential opportunity to help even more patients globally by leveraging Alexion's significant development and commercial experience to expand the AG10 program into Japan."

Under the terms of the agreement, Alexion will acquire an exclusive license for the clinical development and commercialization of AG10 in Japan. Eidos will receive an upfront payment of $25 million and an equity investment of $25 million at a premium to the market price upon deal execution, with the potential for additional Japanese-based milestone- and royalty-dependent payments.

About AG10

AG10 is an investigational, orally-administered small molecule designed to potently stabilize tetrameric transthyretin, or TTR, thereby halting at its outset the series of molecular events that give rise to TTR amyloidosis, or ATTR. In a Phase 2 clinical trial in patients with symptomatic ATTR-CM, AG10 was generally well tolerated, demonstrated greater than 90 percent average TTR stabilization at Day 28, and increased serum TTR concentrations, a prognostic indicator of survival in a retrospective study of ATTR-CM patients, in a dose-dependent manner.

AG10 was designed to mimic a naturally-occurring variant of the TTR gene (T119M) that is considered a rescue mutation because co-inheritance has been shown to prevent or ameliorate ATTR in individuals also inheriting a pathogenic, or disease-causing, mutation in the TTR gene. To our knowledge, AG10 is the only TTR stabilizer in development that has been observed to mimic the stabilizing structure of this rescue mutation.

The Phase 3 ATTRibute-CM study of AG10 in patients with ATTR-CM is underway in the United States and Europe. Part A of the study will assess the change from baseline in 6-minute walk distance (6MWD) at 12 months. Part B of the study will evaluate reduction in all-cause mortality and frequency of cardiovascular-related hospitalizations will be evaluated at 30 months. In addition, Eidos plans to initiate a Phase 3 study of AG10 in ATTR polyneuropathy (ATTR-PN) in the second half of 2019.

About Transthyretin Amyloidosis (ATTR)

There is significant medical need in transthyretin amyloidosis (ATTR) given the large patient population and an inadequate current standard of care. ATTR is caused by the destabilization of TTR due to inherited mutations or aging and is commonly divided into three distinct categories: wild-type ATTR cardiomyopathy (ATTRwt-CM), mutant ATTR cardiomyopathy (ATTRm-CM), and ATTR polyneuropathy (ATTR-PN). The worldwide prevalence of each disease is approximately 400,000 patients, 40,000 patients and 10,000 patients, respectively.

All three forms of ATTR are progressive and fatal. For patients with untreated ATTRwt-CM and ATTRm-CM, symptoms usually manifest later in life (age 50+), with median survival of three to five years from diagnosis. ATTR-PN either presents in a patient's early 30s or later (age 50+), and results in a median life expectancy of five to ten years from diagnosis for untreated patients. Progression of all forms of ATTR causes significant morbidity, impacts productivity and quality of life, and creates a significant economic burden due to the costs associated with progressively greater patient needs for supportive care.

About Alexion

Alexion is a global biopharmaceutical company focused on serving patients and families affected by rare diseases through the discovery, development and commercialization of life-changing therapies. As the global leader in complement biology and inhibition for more than 20 years, Alexion has developed and commercializes two approved complement inhibitors to treat patients with paroxysmal nocturnal hemoglobinuria (PNH) as well as the first and only approved complement inhibitor to treat atypical hemolytic

uremic syndrome (aHUS), anti-acetylcholine receptor (AchR) antibody-positive generalized myasthenia gravis (gMG) and neuromyelitis optica spectrum disorder (NMOSD). Alexion also has two highly innovative enzyme replacement therapies for patients with life-threatening and ultra-rare metabolic disorders, hypophosphatasia (HPP) and lysosomal acid lipase deficiency (LAL-D). In addition, the company is developing several mid-to-late-stage therapies, including a second complement inhibitor, a copper-binding agent for Wilson disease and an anti-neonatal Fc receptor (FcRn) antibody for rare Immunoglobulin G (IgG)-mediated diseases as well as several early-stage therapies, including one for light chain (AL) amyloidosis and a second anti-FcRn therapy. Alexion focuses its research efforts on novel molecules and targets in the complement cascade and its development efforts on the core therapeutic areas of hematology, nephrology, neurology, and metabolic disorders. Alexion has been named to the *Forbes'* list of the World's Most Innovative Companies seven years in a row and is headquartered in Boston, Massachusetts' Innovation District. The company also has offices around the globe and serves patients in more than 50 countries. This press release and further information about Alexion can be found at: www.alexion.com.

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About BridgeBio and Eidos

BridgeBio is a team of experienced drug discoverers, developers and innovators working to create life-altering medicines that target well-characterized genetic diseases at their source. BridgeBio was founded 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. BridgeBio's pipeline of over 15 development programs includes product candidates ranging from early discovery to late-stage development. For more information, please visit www.bridgebio.com.

Eidos is a BridgeBio Pharma subsidiary focused on addressing the large and growing unmet need in diseases caused by transthyretin (TTR) amyloidosis (ATTR). Eidos is developing AG10, a potentially disease-modifying therapy for the treatment of ATTR. For more information, please visit www.eidostx.com.

Forward-Looking Statements

This press release includes forward-looking statements. Such forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied in such statements. Examples of forward-looking statements include, among others, statements we make regarding: (i) the therapeutic benefits and commercial potential of AG10 in Japan and elsewhere; (ii) development plans and clinical trial plans related to AG10; (iii) the potential of AG10 for the treatment of ATTR cardiomyopathy, ATTR polyneuropathy and other conditions; (iv) that the rights of Alexion under the license agreement will result in growth of Alexion's amyloidosis portfolio by partnering with Eidos to expand the development of AG10 to Japan; and (v) the likelihood that AG10 will be approved for commercial sale in Japan. The process by which products such as AG10 could potentially be developed and approved for commercial sale is long and subject to highly significant risks. Applicable risks and uncertainties include: results in early stage clinical trials may not be indicative of full results or results from later stage or larger clinical trials (or in broader patient populations) and do not ensure regulatory approval; the possibility that results of clinical trials are not predictive of safety and efficacy and potency of products (or the failure to adequately operate or manage our clinical trials) which could cause the halt of trials, delays or prevention from making regulatory approval filings or result in denial of regulatory approval of product candidates; unexpected delays in clinical trials; unexpected concerns that may arise from additional data or analysis

obtained during clinical trials; delays or failure of product candidates to obtain regulatory approval due to clinical trial results, issues with clinical trial products, unexpected expense or otherwise; as well as those additional risks relating to product development and approval and other risks identified under the heading "Risk Factors" included in Alexion's, BridgeBio's and Eidos' most recent Form 10-Q filings and in their respective other future filings with the SEC. The forward-looking statements contained in this press release reflect Alexion's, BridgeBio's and Eidos' current views with respect to future events. Alexion, BridgeBio and Eidos do not undertake and each specifically disclaims any obligation to update any forward-looking statements, except as required by law.

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Exhibit 9.2(b)
Disclosure

[***]

Exhibit 12.3(b)(i)
Select Arbitration Provisions

[***]

Exhibit 10.2

September 19, 2019

Brian Stolz
via Email

Dear Brian:

BridgeBio Pharma, Inc. is pleased to offer you employment on the following terms:

1. **Position**. Your title shall be Chief Operating Officer of the Company. You shall report to the Company's Chief Executive Officer (the "CEO") and you shall have such powers, duties, responsibilities and accountabilities as may from time to time be prescribed by the CEO or the Board of Directors of the Company (the "Board"), provided that such duties are consistent with your position as the Chief Operating Officer of the Company. You may work remotely and travel to the Company's locations as requested by the Company. During your employment with the Company, you shall not engage in any other outside employment, consulting or other business activity whether full-time or part-time without the Company's written consent, which shall not be unreasonably withheld. By signing this letter agreement, you confirm to the Company that you have no contractual commitments or other legal obligations that would prohibit you from performing your duties for the Company. As used in this letter agreement, the "Company" shall refer to BridgeBio Pharma, Inc. and its subsidiaries, including without limitation BridgeBio Services, Inc.; provided, that your direct employer will be BridgeBio Services, Inc.

2. **Salary**. The Company shall pay you a starting salary at the annual rate of $625,000, payable in accordance with the Company's standard payroll schedule and subject to tax-related deductions and withholdings. This salary shall be subject to adjustment pursuant to the Company's employee compensation policies in effect from time to time.

3. **Employee Benefits**. You shall be eligible to participate in any and all benefit programs that the Company establishes and makes available to its similarly situated employees from time to time, including healthcare insurance, paid time off, and a 401(k) plan.

4. **Bonus.** Compensation for this position also includes participation in the Company's bonus plan with an annual target bonus of 60% of your annual salary. Your bonus shall be based on the Company's overall goals as well as your individual goals. For each year during your employment, you shall be eligible to receive a bonus (pro-rated in the case of the first year during which you were employed by the Company) based on a determination by the Board or its Compensation Committee (the "Compensation Committee") regarding the Company's achievement of its goals and your own successful performance of your duties through the end of the applicable year. Within sixty (60) days of your Start Date and within sixty (60) days of the beginning of each calendar year thereafter, the Company will, in consultation with you, communicate in writing all such goals and milestones and the amount of the bonus that is tied to each such goal and milestone. Except as otherwise specified in Section 8 (Severance) below, you must be continuously employed by the Company or one of its subsidiaries through the last day of the calendar year in order to receive the bonus applicable for such calendar year. Your bonus shall be paid no later than March 15th of the calendar year following the calendar year to which the bonus relates.

5. **Signing Bonus Equity**. Subject to approval by the Board or the Compensation Committee by such date that is no later than the next regularly scheduled meeting thereof following your Start Date, you shall be granted $600,000 worth of fully vested common stock of the Company, with the number of shares to be determined by dividing $600,000 by the closing price of a share of Company common stock as reported on the Nasdaq Global Select Market (or any successor exchange upon which the Company's common stock is traded) on the date you sign this agreement (the "Signing Bonus Stock"). The Signing Bonus Stock shall be subject to the terms and conditions of the Company's 2019 Stock Option and Incentive Plan (as amended from time to time, the "Plan") and the applicable stock issuance agreement thereunder, which you shall be required to sign as a condition to receiving your Signing Bonus Stock and which shall reflect the relevant terms set forth in this letter. In the event (A) your employment is terminated by the Company (or its acquirer or successor) for Cause (as defined below) or (B) you resign other than for Good Reason (as defined below) or other than as a result of your death or disability, in each case within 24 months following your Start Date, you will promptly pay the Company an amount equal to $600,000, less applicable taxes and withholding on the Signing Bonus Stock, multiplied by a fraction, the numerator of which is equal to the number of months remaining in the two (2) year period as measured from the date of termination, and the denominator of which is equal to 24.

6. **Stock Options**. Subject to approval by the Board or the Compensation Committee, by such date that is no later than the next regularly scheduled meeting thereof following your Start Date, you shall be granted an option worth $1.045M to purchase a number of shares of the Company's common stock equal to $1.045M divided by the Black-Scholes value of an option to purchase one share of Company common stock on the date of grant (the "Option"), at an exercise price per share equal to the fair market value of a share of the Company's common stock (being the closing price of a share of Company common stock as reported on the Nasdaq Global Select Market (or any successor exchange upon which the Company's common stock is traded) on the date that your Option is granted. Twenty-five percent (25%) of the Option shall vest on the first anniversary of your Start Date and the remaining portion of the Option shall vest in equal monthly installments over the following three years, subject to your continued service with the Company or any of its subsidiaries through each applicable vesting date. In addition to any acceleration set forth in Section 9 and notwithstanding anything to the contrary in the Plan or applicable stock option agreement, the vested portion of the Option will remain exercisable until the earlier of (i) one year from your termination date or (ii) the expiration date of the Option if your employment is terminated by the Company (or its acquirer or successor) without Cause (including by reason of your death or disability) or you terminate your employment for Good Reason. The Option shall be subject to the terms and conditions of the Plan and the stock option agreement thereunder, which you shall be required to sign as a condition to receiving your Option and which shall reflect the relevant terms set forth in this letter.

7. **Restricted Stock Units.**

A. Subject to approval by the Board or the Compensation Committee, by such date that is no later than the next regularly scheduled meeting thereof following your Start Date, you shall be granted $2.090M worth of time-based restricted stock units, with the number of restricted stock units to be determined by dividing $2.090M by the closing price of a share of Company common stock as reported on the Nasdaq Global Select Market (or any successor exchange upon which the Company's common stock is traded) on your Start Date (the "Time-Based RSUs"). Each Time-Based RSU entitles you to one share of Company common stock if and when the Time-Based RSU vests. The RSUs will vest over approximately four years. In general, 25% of the RSUs will vest on the first anniversary of the vesting commencement date (as set forth in the applicable RSU award agreement), and the balance will vest in quarterly installments over the next three years, subject to your continued service with BridgeBio Pharma, Inc. or any of its subsidiaries through each applicable vesting date. The RSUs will be subject to the terms and conditions of BridgeBio Pharma, Inc.'s 2019 Stock Option and Incentive Plan (as amended from time to time, the "Plan") and the RSU agreement thereunder, which you will be required to sign as a condition to receiving your RSUs.

B. Subject to approval by the Board or the Compensation Committee, by such date that is no later than the next regularly scheduled meeting thereof following your Start Date, you shall be granted a target number of performance-based restricted stock units worth $1.045M, with the number of performance-based restricted stock units to be determined by dividing $1.045M by the closing price of a share of Company common stock as reported on the Nasdaq Global Select Market (or any successor exchange upon which the Company's common stock is traded) on your Start Date (the "Performance-Based RSUs"). Each Performance-Based RSU entitles you to one share of Company common stock if and when the Performance-Based RSU vests. In addition to any acceleration set forth in Section 9, the number of Performance-Based RSUs that may be earned shall be based on the Company's total shareholder return percentile ranking relative to the Nasdaq Biotech Index for a three-year cumulative performance period commencing on the date you execute this letter agreement and ending on the date three (3) years thereafter or such shorter period in accordance with Section 9 (the "Performance Measurement Period"). All earned Performance-Based RSUs shall vest at the end of the Performance Measurement Period, subject to your continued service with the Company or any of its subsidiaries through the vesting date. The Performance-Based RSUs shall be subject to the terms and conditions of the Plan and the Performance-Based RSU agreement thereunder, which you shall be required to sign as a condition to receiving your Performance-Based RSUs and which shall reflect the relevant terms set forth in this letter.

8. **Severance.** In the event that (A) your employment is terminated by the Company (or its acquirer or successor) without Cause (including due to death or disability) or (B) you resign for Good Reason, subject to you signing a customary general release of claims in favor of the Company that becomes irrevocable within sixty (60) days following the termination date, you shall be entitled to be paid (i) (Y) if such termination in (A) or (B) occurs on or before the three (3) year anniversary of your Start Date, an amount equal to twenty-four (24) months of your then-current base salary, payable in substantially equal installments in accordance with the Company's regular payroll cycle over twelve (12) months or (Z) if such termination in (A) or (B) occurs after the three (3) year anniversary of your Start Date, an amount equal to twelve (12) months of your then-current base salary, payable in substantially equal installments in accordance with the Company's regular payroll cycle over twelve (12) months, PLUS (ii) an amount equal to 100% of your target annual bonus, as determined in accordance with Section 4 above, payable in substantially equal installments in accordance with the Company's regular payroll cycle over twelve (12) months, PLUS (iii) an amount equal to your bonus for the calendar year of termination, calculated as 100% of the target bonus amount multiplied by a fraction, the numerator of which is the number of days during the calendar year of termination that you were employed and the denominator of which is the total number of days during the calendar year of termination; provided, that the pro-rated bonus shall be payable when annual bonuses are paid to other senior executives of the Company, but in no event later than March 15th of the calendar year following the calendar year in which the bonus relates, PLUS (iv) provided that you timely elect continuation coverage pursuant to COBRA for you and your eligible dependents, reimbursement from the Company for the COBRA premiums for such coverage (at the coverage levels in effect immediately prior to such termination) until the earlier of (a) twelve (12) months following the termination date or (b) the date on which you obtain other employment; provided, however, that if the Company determines that reimbursed COBRA premiums would be deemed to be discriminatory or to otherwise violate the then-applicable provisions of the Patient Protection and Affordable Care Act or the Health Care and Education Reconciliation Act of 2010, and the guidance and regulations issued thereunder, the Company shall, in lieu thereof, provide to you a taxable monthly payment, payable on the last day of a given month, in an amount equal to the monthly COBRA premium that you would be required to pay to continue your group health coverage in effect on the date of termination (which amount shall be based on the premium for the first month of COBRA coverage). Such COBRA payments, if any, shall commence on the month following your termination of employment and shall end on the earlier of (I) the date upon which you obtain other employment or (II) the date the Company has paid an amount equal to twelve (12) payments (clauses (i), (iii) and (iv), the "Severance Benefits"). The Severance Benefits shall commence to be paid within sixty (60) days after the date of termination; provided, however, that if the 60-day period begins in one calendar year and ends in a second calendar year, the

Severance Benefits, to the extent they qualify as "non-qualified deferred compensation" within the meaning of Section 409A of the Internal Revenue Code of 1986, as amended (the "Code"), shall begin to be paid in the second calendar year by the last day of such 60-day period; provided further, that the initial payment shall include a catch-up payment to cover amounts retroactive to the day immediately following the date of termination. Each payment pursuant to this letter agreement is intended to constitute a separate payment for purposes of Treasury Regulation Section 1.409A-2(b)(2).

9. **Change of Control Acceleration**. In the event your employment is terminated by the Company (or its acquirer or successor) without Cause (including due to death or disability) or you resign for Good Reason, in each case in connection with or within twelve (12) months following a Sale Event (as defined in the Plan), subject to you signing a customary general release of claims in favor of the Company (or its acquirer or successor) that becomes irrevocable within sixty (60) days following the termination date, any outstanding unvested shares underlying the Option and any outstanding unvested Time-Based RSUs shall vest and become exercisable (as applicable) as of such termination date. In the event of a Sale Event, if Performance-Based RSUs are assumed, continued or substituted by the acquirer in a Sale Event, the Performance Measurement Period shall be measured through the date of the Sale Event and a number of Performance-Based RSUs will be earned based on the Company's total shareholder return percentile ranking relative to the Nasdaq Biotech Index through the date of the Sale Event, however such earned Performance-Based RSUs shall not vest until the third anniversary of the date you execute this letter agreement, subject to your continued service relationship with the Company (or its acquirer or successor) through such date; provided, that in the event your employment is terminated by the Company (or its acquirer or successor) without Cause (including due to death or disability) or you resign for Good Reason, in each case in connection with or within twelve (12) months following the Sale Event, subject to you signing a customary general release of claims in favor of the Company (or its acquirer or successor) that becomes irrevocable within sixty (60) days following the termination date, all of your earned Performance-Based RSUs will vest on the date of your termination. In addition, if the Options, Performance-Based RSUs and/or the Time-Based RSUs are not assumed, continued or substituted by the acquirer in a Sale Event, any outstanding unvested shares underlying the Option and the Time-Based RSUs shall vest and become exercisable (as applicable) immediately prior to the consummation of the Sale Event and with respect to any outstanding unvested Performance-Based RSUs, the Performance Measurement Period shall be measured through the date of the Sale Event and a number of Performance-Based RSUs will vest based on the Company's total shareholder return percentile ranking relative to the Nasdaq Biotech Index through the date of the Sale Event. The acceleration of vesting benefits set forth in this Section 9 shall be in addition to the benefits set forth in Section 8.

10. **Definitions**. For purposes of this letter agreement,

A. "Cause" shall mean (i) conduct by you constituting a material act of misconduct in connection with the performance of your duties, including, without limitation, misappropriation of funds or property of the Company or any of its subsidiaries or affiliates other than the occasional, customary and de minimis use of Company property for personal purposes; (ii) the commission by you of any felony or a misdemeanor involving moral turpitude or fraud, or any conduct by you that would reasonably be expected to result in material injury or material reputational harm to the Company or any of its subsidiaries and affiliates if you were retained in your position; (iii) continued material non-performance by you of your duties hereunder (other than by reason of your physical or mental illness, incapacity or disability) which has continued for more than thirty (30) days following written notice of such non-performance from the CEO; (iv) a breach by you of any applicable restrictive covenants provisions, including, without limitation, the PIIA (as defined below) that would reasonably be expected to result in material injury to the Company; (v) a material violation you of the Company's written employment policies; or (vi) failure to cooperate with a bona fide internal investigation or an investigation by regulatory or law enforcement authorities, after being instructed by the Company to cooperate, or the willful destruction or failure to preserve documents or other materials known by you to be relevant to such investigation or the inducement of others to fail to cooperate or to produce documents or other materials in connection with such investigation.

B. "Good Reason" shall mean that you have complied with the "Good Reason Process" following the occurrence of any of the following events: (i) a material diminution in your responsibilities, authority or duties, including a change in reporting such that you no longer report directly to the CEO; (ii) a material diminution in your base salary except for across-the-board salary reductions based on the Company's financial performance similarly affecting all or substantially all senior management employees of the Company; (iii) a change of more than forty (40) miles in the geographic location at which you provide services to the Company; or (iv) a material breach by the Company of this letter agreement.

C. "Good Reason Process" shall mean that (i) you reasonably determine in good faith that a "Good Reason" condition has occurred; (ii) you notify the Company in writing of the first occurrence of the Good Reason condition within sixty (60) days of the first occurrence of such condition; (iii) you cooperate in good faith with the Company's efforts, for a period not less than thirty (30) days following such notice (the "Cure Period"), to remedy the condition; (iv) notwithstanding such efforts, the Good Reason condition continues to exist; and (v) you terminate your employment within sixty (60) days after the end of the Cure Period. If the Company cures the Good Reason condition during the Cure Period, Good Reason shall be deemed not to have occurred; provided that, if the events or substantially similar events that constituted the Good Reason reoccur after the Cure Period, you shall immediately be entitled to terminate your employment and shall be deemed to have complied with the Good Reason Process.

11. **Employee Confidentiality and Assignment Agreement.** Like all Company employees, you shall be required, as a condition of your employment with the Company, to sign the Company's standard Proprietary Information and Inventions Agreement, a copy of which is attached hereto as **Exhibit A** (the "PIIA").

12. **Background Check**. The Company may conduct a background or reference check (or both). If so, then you agree to cooperate fully in those procedures, and this offer is subject to the Company's approving the outcome of those checks, in the reasonable discretion of the Company.

13. **Employment Relationship**. Employment with the Company is for no specific period of time. Your employment with the Company shall be "at will," meaning that either you or the Company may terminate your employment at any time and for any reason, with or without cause. Any contrary representations that may have been made to you are superseded by this letter agreement. Although your job duties, title, reporting relationship, compensation and benefits, as well as the Company's personnel policies and procedures, may change from time to time (subject to the rights and remedies specified herein), the "at will" nature of your employment may only be changed in an express written agreement signed by you and a duly authorized officer of the Company (other than you).

14. **Tax Matters**.

A. The parties intend that this letter agreement be administered in accordance with Section 409A of the Code. To the extent that any provision of this letter agreement is ambiguous as to its compliance with Section 409A of the Code, the provision shall be read in such a manner so that all payments hereunder comply with Section 409A of the Code. The parties agree that this letter agreement may be amended as reasonably requested by either party, and as may be necessary to fully comply with Section 409A of the Code and all related rules and regulations in order to preserve the payments and benefits provided hereunder without additional cost to either party. The Company makes no representation or warranty and shall have no liability to you or any other person if any provisions of this letter agreement are determined to constitute deferred compensation subject to Section 409A of the Code but do not satisfy an exemption from, or the conditions of, such Section. Anything in this letter agreement to the contrary notwithstanding, if at the time of your separation from service within the meaning of Section 409A of

the Code, the Company determines that you are a "specified employee" within the meaning of Section 409A(a)(2)(B)(i) of the Code, then to the extent any payment or benefit that you becomes entitled to under this letter agreement on account of your separation from service would be considered deferred compensation otherwise subject to the 20 percent additional tax imposed pursuant to Section 409A(a) of the Code as a result of the application of Section 409A(a)(2)(B)(i) of the Code, such payment shall not be payable and such benefit shall not be provided until the date that is the earlier of (i) six months and one day after your separation from service, or (ii) your death. If any such delayed cash payment is otherwise payable on an installment basis, the first payment shall include a catch-up payment covering amounts that would otherwise have been paid during the six-month period but for the application of this provision, and the balance of the installments shall be payable in accordance with their original schedule. To the extent that any payment or benefit described in this letter agreement constitutes "non-qualified deferred compensation" under Section 409A of the Code, and to the extent that such payment or benefit is payable upon your termination of employment, then such payments or benefits shall be payable only upon your "separation from service." The determination of whether and when a separation from service has occurred shall be made in accordance with the presumptions set forth in Treasury Regulation Section 1.409A-1(h). All in-kind benefits provided and expenses eligible for reimbursement under this letter agreement shall be provided by the Company or incurred by you during the time periods set forth in this letter agreement. All reimbursements shall be paid as soon as administratively practicable, but in no event shall any reimbursement be paid after the last day of the taxable year following the taxable year in which the expense was incurred. The amount of in-kind benefits provided or reimbursable expenses incurred in one taxable year shall not affect the in-kind benefits to be provided or the expenses eligible for reimbursement in any other taxable year (except for any lifetime or other aggregate limitation applicable to medical expenses). Such right to reimbursement or in-kind benefits is not subject to liquidation or exchange for another benefit.

B. In the event that the benefits provided for in this letter agreement or in any other agreement between you and the Company (the "Aggregate Payments") constitute "parachute payments" within the meaning of Section 280G of the Code, and shall be subject to the excise tax imposed by Section 4999 of the Code (the "Excise Tax"), then your Aggregate Payments payable under the terms of this letter agreement or otherwise shall be either (i) delivered in full, or (ii) delivered as to such lesser extent which would result in no portion of such Aggregate Payments being subject to the Excise Tax, whichever of the foregoing amounts, taking into account the applicable federal, state, and local income taxes and the Excise Tax, results in the receipt by you on an after-tax basis, of the greatest amount of severance benefits

C. All forms of compensation referred to in this offer letter are subject to reduction to reflect applicable withholding and payroll taxes and other deductions required by law.

15. **Interpretation, Amendment and Enforcement**. This letter agreement and Exhibit A constitute the complete agreement between you and the Company, contain all of the terms of your employment with the Company and supersede any prior agreements, representations or understandings (whether written, oral or implied) between you and the Company. This letter agreement may not be amended or modified, except by an express written agreement signed by both you and a duly authorized officer of the Company. The terms of this letter agreement and the resolution of any disputes as to the meaning, effect, performance or validity of this letter agreement or arising out of, related to, or in any way connected with, this letter agreement, your employment with the Company or any other relationship between you and the Company shall be governed by California law, excluding laws relating to conflicts or choice of law.

We hope that you will accept our offer to join the Company. You may indicate your agreement with these terms and accept this offer by signing and dating both the enclosed duplicate original of this letter agreement and the enclosed Confidentiality Agreement and returning them to me. This offer, if not accepted, shall expire at the close of business on September 20th, 2019. As required by law, your employment with the Company is contingent upon your providing legal proof of your identity and authorization to work in the United States. Should you accept this offer, your start date of employment shall be October 7, 2019 (the "Start Date") or any other date agreed upon between you and the Company.

If you have any questions, please do not hesitate to contact me.

Very truly yours,

/s/ Brian Stephenson

Brian Stephenson
CFO

I have read and accept this employment offer:

/s/ Brian Stolz
Brian Stolz

Effective as of September 19, 2019

Attachment
Exhibit A: Proprietary Information and Inventions Agreement

Exhibit 10.3

REVISED

September 9, 2019

Yi Ching Yau
via Email

Dear Yi Ching:

BridgeBio Services, Inc. is pleased to offer you employment on the following terms:

1. **Position**. Your title will be Chief Accounting Officer. You will report to the CFO, Brian Stephenson, and you shall have such powers, duties, responsibilities and accountabilities as set forth below, or as may from time to time be prescribed by the senior executives or the Board of Directors of BridgeBio Pharma, Inc. (the "Board"), provided that such duties are consistent with your position. This is a full-time position and you will be required to devote 100% of your full working time and efforts to the business and affairs of the Company. During your employment with the Company, you will not engage in any other outside employment, consulting or other business activity (whether full-time or part-time) without the Company's written consent, which shall not be unreasonably withheld. By signing this letter agreement, you confirm to the Company that you have no contractual commitments or other legal obligations that would prohibit you from performing your duties for the Company. As used in this letter agreement, the "Company" shall refer to BridgeBio Pharma, Inc. and its subsidiaries, including without limitation BridgeBio Services, Inc.; provided, that your direct employer will be BridgeBio Services, Inc.

In your role you will own and lead:

- All accounting and related finance operations, including: general ledger, consolidation, procure to pay, commercial accounting (including gross to net), cost accounting, payroll, stock administration, tax, etc.
- Treasury and cash management
- SEC reporting and technical accounting
- SOX
- Aspects of FP&A (e.g., corporate or operational FP&A)

You will also be involved in the following areas:

- Corporate finance
- Investor relations
- BOD and AC presentations, etc.

You will be responsible for:

- Preparing all financial statements, reporting packages, and financial presentations for the executive team
- Maintaining good internal controls and providing oversight in applicable audits
- Implementing and executing a budget process in collaboration with the full FP&A team
- Assisting with special projects as requested by the CEO, CFO, and executive team

2. **Salary**. The Company will pay you a starting salary at the annual rate of $450,000, payable in accordance with the Company's standard payroll schedule and subject to tax-related deductions and withholdings. This salary will be subject to adjustment pursuant to the Company's employee compensation policies in effect from time to time.

3. **Annual Bonus.** Compensation for this position also includes participation in the Company's bonus plan with an annual target bonus of 40% of your annual salary. Your bonus will be based on accomplishing the Company's overall goals as well as your individual goals. For each year during the term of this letter agreement, you will be eligible to receive a bonus (pro-rated in the case of any partial year during which you were employed by the Company) based on a determination by the Board (or a committee thereof) regarding the Company's achievement of its goals and your own successful performance of your duties through the end of the applicable year.

4. **Performance Bonus.** Additionally, the Company will pay you a one-time bonus in the amount of $1,000,000, subject to all taxes and withholdings payable in the first payroll following three years of employment (the "3rd Year Employment Anniversary"), in the event that you achieve certain performance goals determined by Brian Stephenson, Chief Financial Officer, provided, that you must continue to be employed with the Company through the date on which any such bonus is to be paid.

In the event your employment is terminated by the Company or its acquirer or successor without Cause (as defined below) within one (1) month before or twelve (12) months after a Change in Control or if you resign for Good Reason (as defined below) within one (1) month before or twelve (12) months after a Change in Control, subject to you signing a general release of claims in favor of the Company (or its acquirer or successor) that becomes irrevocable within sixty (60) days following the termination date, the Company will make a lump sum payment to you equal to 100% of your performance bonus.

Definitions. For purposes of the above, "Cause" shall mean (i) your commission of any felony or any crime involving fraud or dishonesty under the laws of the United States or any state thereof, (ii) your attempted commission of, or participation in, a fraud or act of dishonesty against the Company, (iii) your intentional and material violation of any contract or agreement between you and the Company or intentional and material violation of any statutory duty owed to the Company, (iv) your knowing unauthorized use or knowing disclosure of the Company's confidential information or trade secrets, either of which cause material damage to the Company or (v) your willful misconduct or gross negligence. "Good Reason" shall mean that you have complied with the "Good Reason Process" (hereinafter defined) following the occurrence of any of the following events: (i) a material diminution in your responsibilities, authority or duties, (ii) a diminution of over twenty-five (25%) percent in your salary or bonus potential or (iii) a change of more than twenty-five (25) miles in the geographic location at which you provide services to the Company. "Good Reason Process" shall mean that (i) you have reasonably determined in good faith that a "Good Reason" condition has occurred, (ii) you provide the Company written notice that such an event has occurred within thirty (30) days of the first occurrence of such condition, (iii) you cooperate in good faith with the Company's efforts, for a period not less than thirty (30) days following such notice (the "Cure Period"), to remedy the condition, (iv) notwithstanding such efforts, the Good Reason condition continues to exist, and (v) you terminate your employment within thirty (30) days after the end of the Cure Period.

5. **Stock Options**. Subject to approval by the Board (or a committee thereof), following your Start Date, you will be granted an option to purchase shares of BridgeBio Pharma, Inc.'s common stock (the "Option") valued at $800,000 on the date of grant, at an exercise price per share equal to the fair market value of a share of BridgeBio Pharma, Inc.'s common stock on the date that your Option is granted. Twenty-five percent (25%) of the shares of common stock underlying the Option shall vest on the first anniversary of your Start Date and the remaining shares underlying the Option shall vest in equal monthly installments over the following three years, subject to your continued service with BridgeBio Pharma, Inc. or any of its subsidiaries through each applicable vesting date. The Option will be subject to the terms and conditions of

BridgeBio Pharma, Inc.'s 2019 Stock Option and Incentive Plan (as amended from time to time, the "Plan") and the stock option agreement thereunder, which you will be required to sign as a condition to receiving your Option.

6. **Restricted Stock Units.** Subject to approval by the Board (or a committee thereof), following your Start Date, you will be granted restricted stock units (the "RSUs") valued at $400,000. Each RSU entitles you to one share of common stock of BridgeBio Pharma, Inc. if and when the RSU vests. The RSUs will vest over four years, depending upon your Start Date. The RSUs will be subject to the terms and conditions of the Plan and the RSU agreement thereunder, which you will be required to sign as a condition to receiving your RSUs.

7. **Sign-On Bonus**. Additionally, the Company will pay you a one-time sign-on bonus of $150,000 subject to all taxes and withholdings payable in the first payroll following 30 days of employment. Should you terminate your employment for any reason or the Company terminates your employment for any reason within the first three years of the Start Date, you shall repay the full gross amount of such sign-on bonus to the Company.

8. **Employee Benefits**. You will be eligible to participate in or receive benefits under the Company's employee benefit plans in effect from time to time (including, without limitation, any group health care plan and 401(k)), subject to the terms of such plans.

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

10. **Employee Confidentiality and Assignment Agreement.** Like all Company employees, you will be required, as a condition of your employment with the Company, to sign the Company's standard Proprietary Information and Inventions Agreement, a copy of which is attached hereto as **Exhibit A**.

11. **Employment Relationship**. Employment with the Company is for no specific period of time. Your employment with the Company will be "at will," meaning that either you or the Company may terminate your employment at any time and for any reason, with or without cause. Any contrary representations that may have been made to you are superseded by this letter agreement. Although your job duties, title, reporting relationship, compensation and benefits, as well as the Company's personnel policies and procedures, may change from time to time (except as otherwise provided herein), the "at will" nature of your employment may only be changed in an express written agreement signed by you and a duly authorized officer of the Company (other than you).

12. **Interpretation, Amendment and Enforcement**. This letter agreement and Exhibit A constitute the complete agreement between you and the Company, contain all of the terms of your employment with the Company and supersede any prior agreements, representations or understandings (whether written, oral or implied) between you and the Company. This letter agreement may not be amended or modified, except by an express written agreement signed by both you and a duly authorized officer of the Company. In the event the terms of this letter contradict or are in any way different from the terms contained any other document(s) provided by the Company, this letter shall control. The terms of this letter agreement and the resolution of any disputes as to the meaning, effect, performance or validity of this letter agreement or arising out of, related to, or in any way connected with, this letter agreement, your employment with the Company or any other relationship between you and the Company will be governed by California law, excluding laws relating to conflicts or choice of law.

We hope that you will accept our offer to join the Company. You may indicate your agreement with these terms and accept this offer by signing and dating both the enclosed duplicate original of this letter agreement and the enclosed Confidentiality Agreement and returning them to me. This offer, if not accepted, will expire at the close of business on September 9, 2019. As required by law, your employment with the Company is contingent upon your providing legal proof

of your identity and authorization to work in the United States. Should you accept this offer, your start date of employment will be October 7, 2019, or any other date agreed upon between you and the Company.

If you have any questions, please do not hesitate to contact me.

Very truly yours,

/s/ Brian Stephenson

Brian Stephenson
CFO

I have read and accept this employment offer:

/s/ Yi Ching Yau
Yi Ching Yau

Effective as of September 9, 2019

Attachment
Exhibit A: Proprietary Information and Inventions Agreement

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: November 8, 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: November 8, 2019

By: /s/ Brian Stephenson

Brian Stephenson, Ph.D., CFA
Chief Financial Officer
(Principal Financial 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 September 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: November 8, 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 September 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: November 8, 2019

By: /s/ Brian Stephenson

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