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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 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, 2026

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.)**
3160 Porter Drive, Suite 250, Palo Alto, CA	**94304**
(Address of principal executive offices)	**(Zip Code)**

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

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

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

As of October 22, 2026, the registrant had 194,800,782 shares of common stock, $0.001 par value per share, outstanding.

Special Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Many of these statements can be identified by the use of terminology such as "believes," "expects," "intends," "anticipates," "plans," "may," "will," "could," "would," "projects," "continues," "estimates," "potential," "opportunity" or the negative versions of these terms and other similar expressions. The forward-looking statements in this Quarterly Report on Form 10-Q include, but are not limited to, statements regarding:

- the continued commercial success of Attruby™ (acoramidis), including our expectations regarding the size and growth potential of the commercial markets for Attruby;
- the success, cost and timing of our clinical development of our late-stage product candidates, including low-dose infigratinib for achondroplasia, encaleret for ADH1, and BBP-418 for limb-girdle muscular dystrophy type 2I/R9, or LGMD2I/R9;
- our ability to continue planned nonclinical and clinical development of our respective development programs, and the timing, cost and success of any such continued nonclinical and clinical development and planned regulatory submissions;
- our ability to initiate, recruit and enroll patients in and conduct our clinical trials at the pace that we project;
- the expected timing of our regulatory submissions, and our anticipated interaction with and feedback from the U.S. Food and Drug Administration (the "FDA") and similar regulatory authorities;
- our plans to implement certain development strategies, including our ability to attract and retain potential collaborators with development, regulatory and commercialization expertise;
- our ability to obtain and maintain regulatory approval of our product candidates in any of the indications for which we are developing or we plan to develop, and any related restrictions, limitations or warnings in the label of any of our product candidates, if approved;
- our ability to successfully commercialize our current product candidates, if approved, and any other product candidates we may identify and pursue, if approved, including our ability to successfully build a specialty sales force and commercial infrastructure to market our current product candidates and any other product candidates we may identify and pursue;
- our ability to compete with companies currently marketing approved treatments or engaged in the development of treatments that may become available for any of the indications that our product candidates are designed to target;
- our reliance on third parties to conduct our clinical trials and to manufacture drug substance and drug product for our commercial product and certain of our product candidates for use in our clinical trials;
- our ability to contract with and the performance of our and our collaborators' third-party suppliers and manufacturers;
- the pricing and reimbursement of our product candidates, if approved;
- the size and growth potential of the markets for our current product candidates or other product candidates we may identify and pursue, and our ability to serve and gain acceptance by those markets;
- our ability to identify and advance through clinical development any additional product candidates;
- the impacts of public health crises or macroeconomic factors that could impact our business, such as the effects of the ongoing conflicts in the Ukraine or in the Middle East on the global economy; supply chain and inflationary pressures, or significant political, trade or regulatory developments in the jurisdictions in which we may sell our products or conduct our operations;
- our ability to retain and recruit key personnel;
- the success of competing therapies that are or may become available;
- our ability to obtain and maintain adequate intellectual property rights for our product candidates and our ability to operate our business without infringing on the intellectual property rights of others;
- our expectations regarding government and third-party payor coverage and reimbursement;

- our estimates of our expenses, ongoing losses, capital requirements and our use of cash resources, and our needs for or ability to pay for debt interests and obtain additional financing to complete the clinical trials of any of our product candidates;
- the impact of laws and regulations in the United States and foreign countries;
- our financial performance, including our anticipated funding to support the potential launch of three additional medicines globally;
- adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults, or non-performance by financial institutions or transactional counterparties; and
- developments and projections relating to our competitors or our industry.

Our actual results or experience could differ significantly from the forward-looking statements. Factors that could cause or contribute to these differences include those discussed in "Risk Factors," in Part II, Item 1A of this Quarterly Report on Form 10-Q as well as information provided elsewhere in this Quarterly Report on Form 10-Q, our Annual Report on Form 10-K for the year ended December 31, 2025, which was filed with the U.S. Securities and Exchange Commission (the "SEC") on February 24, 2026, our Quarterly Report on Form 10-Q for the quarter ended March 31, 2026, which was filed with the SEC on May 7, 2026, and our Quarterly Report on Form 10-Q for the quarter ended June 30, 2026, which was filed with the SEC on August 10, 2026. You should carefully consider that information before you make an investment decision.

You should not place undue reliance on these types of forward-looking statements, which speak only as of the date that they were made. These forward-looking statements are based on the beliefs and assumptions of the Company's management based on information currently available to management and should be considered in connection with any written or oral forward-looking statements that the Company may issue in the future as well as other cautionary statements the Company has made and may make. Except as required by law, the Company does not undertake any obligation to release publicly any revisions to these forward-looking statements after completion of the filing of this Quarterly Report on Form 10-Q to reflect later events or circumstances or the occurrence of unanticipated events.

The discussion of the Company's financial condition and results of operations should be read in conjunction with the Company's Condensed Consolidated Financial Statements and the related notes thereto included in this Quarterly Report on Form 10-Q.

Risk Factors Summary

Below is a summary of the principal factors that make an investment in our common stock speculative or risky. This summary does not address all of the risks that we face. Discussion of the risks listed below, and other risks that we face, are discussed in the section titled "Risk Factors" in Part II, Item 1A of this Quarterly Report on Form 10-Q and should be carefully considered, together with other information in this Quarterly Report on Form 10-Q and our other filings with the SEC before making investment decisions regarding our common stock.

- Our business is substantially dependent on the commercial success of Attruby and Beyonttra. The continued commercial success of this product, along with our product candidates, if approved, will depend upon the degree of market acceptance by physicians, patients, healthcare payors, and others in the medical community.
- If our sales and marketing capabilities for Attruby and Beyonttra, and our future product candidates, if approved, are not effective or we are unable to establish sales and marketing capabilities or enter into and maintain our agreements with third parties to sell and market Attruby and Beyonttra or any future product candidates approved for commercial sale, we may be unsuccessful in our commercial efforts.
- Our profitability will depend significantly on our ability to sell enough product at competitive prices and on the availability of adequate coverage and reimbursement through governmental or private third-party payors.
- Our future growth may depend, in part, on our ability to penetrate foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.
- 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 legislative measures aimed at reducing healthcare costs may have a material adverse effect on our business and results of operations.
- If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate program or other governmental pricing programs, we could be subject to additional reimbursement requirements, penalties, sanctions and fines, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.
- Federal legislative and regulatory efforts, including efforts to implement reference pricing or most-favored-nation pricing models, impose tariffs on pharmaceutical products and active pharmaceutical ingredients, and promote or require domestic manufacturing, could impact our product revenues, increase our costs and operational complexity, and materially harm our business.
- We face significant competition in an environment of rapid technological and scientific change, and there is a possibility that our competitors may achieve commercial success or 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.
- 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.
- 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.
- Preliminary, interim or topline 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.
- Although we have obtained marketing authorization for Attruby, we have multiple product candidates in our development pipeline that are still in nonclinical 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 pipeline product candidates will receive regulatory approval, which is necessary before they can be commercialized.
- 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.

- Our clinical trials may fail to demonstrate substantial evidence of the safety and efficacy 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.
- We rely entirely on third parties for the manufacturing of commercial supplies of Attruby and Beyonttra and for supplies of our product candidates that we may develop. 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.
- 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.
- If we are unable to obtain and maintain sufficient intellectual property protection for Attruby and Beyonttra and our product candidates, including low-dose infigratinib, BBP-418, and encaleret, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize products or product candidates similar or identical to ours, and our ability to successfully commercialize our product candidates may be impaired.
- Patent terms may be inadequate to protect our competitive position on product candidates for an adequate amount of time.
- 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 may 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 and commercialization efforts.

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In this Quarterly Report on Form 10-Q, unless otherwise stated or as the context requires, references to "BridgeBio," "the Company," "we," "us," "our" or similar references refer to BridgeBio Pharma, Inc., together with its consolidated subsidiaries.

BRIDGEBIO and ATTRUBY are our registered trademarks in the United States ("U.S."). BRIDGEBIO, ATTRUBY and BEYONTTRA are our registered trademarks in the European Union ("EU"), the United Kingdom ("UK"), Japan, and other jurisdictions. All other brand names and service marks, trademarks and other trade names appearing in this report are the property of their respective owners.

We use the brand name for our products when we refer to the product that has been approved and with respect to the indications on the approved label. Otherwise, including in discussions of our achondroplasia, autosomal dominant hypocalcemia type 1 (ADH1), and limb-girdle muscular dystrophy type 2I/R9 (LGMD2I/R9) development programs, we refer to our product candidates by their scientific (or generic) name or BridgeBio Pharma ("BBP") developmental designation. When referring to our commercial product that has been approved in (i) the U.S. and Australia (ii) the EU, Japan, Brazil and the UK, as applicable, we use both names Attruby™ and Beyonttra™ – e.g., "Our commercial organization focuses on supporting the appropriate use of Attruby and Beyonttra in the markets where this product has been approved."

BRIDGEBIO PHARMA, INC.
Condensed Consolidated Balance Sheets
(in thousands, except share and per share amounts)

	September 30, 2026	December 31, 2025
	(Unaudited)	(1)
Assets		
Current assets:		
Cash and cash equivalents	$ 1,533,363	$ 570,119
Marketable securities	5,492	17,363
Accounts receivable, net	375,089	139,444
Inventories	59,718	26,753
Prepaid expenses and other current assets	70,944	44,070
Total current assets	2,044,606	797,749
Equity method investments	47,783	79,972
Property and equipment, net	5,042	5,366
Operating lease right-of-use assets	15,746	8,149
Intangible assets, net	25,923	28,077
Other assets	22,686	16,712
Total assets	$ 2,161,786	$ 936,025
Liabilities, Redeemable Convertible Noncontrolling Interests and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 88,258	$ 36,228
Accrued compensation and benefits	66,686	76,703
Accrued research and development liabilities	55,018	41,436
Operating lease liabilities, current portion	1,987	6,192
Deferred revenue, current portion	4,744	7,190
2027 Notes, net	548,430	—
Other current liabilities (2)	212,114	120,222
Total current liabilities	977,237	287,971
2027 Notes, net	—	547,015
2029 Notes, net	742,437	740,890
2031 Notes, net	566,013	564,565
2033 Notes, net	620,533	—
Deferred royalty obligations, net (3)	884,053	855,030
Operating lease liabilities, net of current portion	14,645	3,811
Deferred revenue, net of current portion	8,968	13,080
Other long-term liabilities	1,405	244
Total liabilities	3,815,291	3,012,606
Commitments and contingencies (Note 7)		
Redeemable convertible noncontrolling interests	(1,363)	(570)
Stockholders' deficit:		
Undesignated preferred stock, $0.001 par value; 24,066,100 shares authorized and no shares issued and outstanding as of September 30, 2026; 25,000,000 shares authorized and no shares issued and outstanding as of December 31, 2025	—	—
Series A preferred stock, $0.001 par value; 933,900 shares authorized, issued, and outstanding as of September 30, 2026 (aggregate liquidation preference of $1,134,359 as of September 30, 2026)	942,478	—
Common stock, $0.001 par value; 500,000,000 shares authorized; 207,300,005 shares issued and 196,004,842 shares outstanding as of September 30, 2026; 202,369,129 shares issued and 194,771,957 shares outstanding as of December 31, 2025	207	202
Treasury stock, at cost; 11,295,163 shares as of September 30, 2026; 7,597,172 shares as of December 31, 2025	(580,775)	(323,276)
Additional paid-in capital	2,170,006	2,057,646
Accumulated other comprehensive income (loss)	(95)	12
Accumulated deficit	(4,194,163)	(3,821,194)
Total BridgeBio stockholders' deficit	(1,662,342)	(2,086,610)
Noncontrolling interests	10,200	10,599
Total stockholders' deficit	(1,652,142)	(2,076,011)
Total liabilities, redeemable convertible noncontrolling interests and stockholders' deficit	$ 2,161,786	$ 936,025

(1) The condensed consolidated balance sheet as of December 31, 2025 is derived from the audited consolidated financial statements as of that date.
(2) Including related party amounts of nil and $2,003 as of September 30, 2026 and December 31, 2025, respectively (as described in Note 9).
(3) Including related party amounts of nil and $204,650 as of September 30, 2026 and December 31, 2025, respectively (as described in Note 9).

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

BRIDGEBIO PHARMA, INC.
Condensed Consolidated Statements of Operations
(Unaudited)
(in thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	**2025**	**2026**	**2025**
Revenues:				
Net product revenue	$ 253,346	$ 108,111	$ 656,382	$ 216,351
License and services revenue	79,314	8,311	89,537	125,441
Royalty revenue	20,511	4,278	45,443	6,106
Total revenues, net	353,171	120,700	791,362	347,898
Operating costs and expenses:				
Cost of revenues:				
Cost of goods sold	12,317	4,028	30,577	8,910
Cost of license, services, and royalty revenue	8,133	2,535	14,858	3,945
Total cost of revenues	20,450	6,563	45,435	12,855
Research and development	143,506	112,874	419,590	335,536
Selling, general and administrative	200,854	137,621	551,011	373,140
Restructuring, impairment, and related charges	—	8,841	—	10,216
Total operating costs and expenses	364,810	265,899	1,016,036	731,747
Loss from operations	(11,639)	(145,199)	(224,674)	(383,849)
Other income (expense), net:				
Interest income	13,105	6,239	26,010	15,522
Interest expense	(13,255)	(11,739)	(39,475)	(41,467)
Noncash interest expense on deferred royalty obligations (1)	(42,282)	(36,410)	(123,500)	(86,460)
Net loss from equity method investments	(7,312)	(15,834)	(32,030)	(51,579)
Loss on extinguishment of debt	—	—	—	(21,155)
Other income, net	2,116	16,461	11,956	31,240
Total other expense, net	(47,628)	(41,283)	(157,039)	(153,899)
Loss before income taxes	(59,267)	(186,482)	(381,713)	(537,748)
Provision for (benefit from) income taxes	1,229	(1,545)	1,229	555
Net loss	(60,496)	(184,937)	(382,942)	(538,303)
Net loss attributable to redeemable convertible noncontrolling interests and noncontrolling interests	3,786	2,194	9,973	6,235
Net loss attributable to BridgeBio	(56,710)	(182,743)	(372,969)	(532,068)
Preferred stock dividends and accretion	26,293	—	26,293	—
Net loss attributable to common stockholders of BridgeBio	$ (83,003)	$ (182,743)	$ (399,262)	$ (532,068)
Net loss per share attributable to common stockholders of BridgeBio, basic and diluted	$ (0.42)	$ (0.95)	$ (2.04)	$ (2.79)
Weighted-average shares used in computing net loss per share attributable to common stockholders of BridgeBio, basic and diluted	196,029,851	191,854,152	195,539,752	190,845,133

(1) Including related party amounts of $(2,942) and $(13,878) for the period from July 1, 2026 to August 16, 2026 and for the period from January 1, 2026 to August 16, 2026, respectively, and $(5,383) and $(5,560) for the three and nine months ended September 30, 2025, respectively (as described in Note 9).

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,	
	2026	**2025**	**2026**	**2025**
Net loss	$ (60,496)	$ (184,937)	$ (382,942)	$ (538,303)
Other comprehensive loss:				
Unrealized gains (losses) on available-for-sale securities	(88)	1	(107)	(6)
Comprehensive loss	(60,584)	(184,936)	(383,049)	(538,309)
Comprehensive loss attributable to redeemable convertible noncontrolling interests and noncontrolling interests	3,786	2,194	9,973	6,235
Comprehensive loss attributable to BridgeBio	$ (56,798)	$ (182,742)	$ (373,076)	$ (532,074)

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' Deficit
(Unaudited)
(in thousands, except share amounts)

	Redeemable Convertible Noncontrolling Interests	Preferred Stock		Common Stock		Treasury Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total BridgeBio Stockholders' Deficit	Non-controlling Interests	Total Stockholders' Deficit
		Shares	Amount	Shares	Amount	Shares	Amount						
Balances as of December 31, 2025 (1)	**$ (570)**	**—**	**$ —**	**194,771,957**	**$ 202**	**7,597,172**	**$ (323,276)**	**$ 2,057,646**	**$ 12**	**$ (3,821,194)**	**$ (2,086,610)**	**$ 10,599**	**$ (2,076,011)**
Repurchase of common stock	—	—	—	(1,081,825)	—	1,081,825	(82,500)	—	—	—	(82,500)	—	(82,500)
Issuance of shares under equity compensation plans	—	—	—	1,940,523	2	—	—	22,587	—	—	22,589	—	22,589
Issuance of common stock under employee stock purchase plan (ESPP)	—	—	—	131,185	—	—	—	5,466	—	—	5,466	—	5,466
Repurchase of restricted stock unit (RSU) shares to satisfy tax withholding	—	—	—	(54,138)	—	—	—	(4,074)	—	—	(4,074)	—	(4,074)
Stock-based compensation	—	—	—	—	—	—	—	32,784	—	—	32,784	—	32,784
Issuance of noncontrolling interests	—	—	—	—	—	—	—	—	—	—	—	16	16
Transfers from (to) noncontrolling interests	1,489	—	—	—	—	—	—	(1,955)	—	—	(1,955)	466	(1,489)
Unrealized loss on available-for-sale securities	—	—	—	—	—	—	—	—	(20)	—	(20)	—	(20)
Net loss	(1,870)	—	—	—	—	—	—	—	—	(164,043)	(164,043)	(642)	(164,685)
Balances as of March 31, 2026	**(951)**	**—**	**—**	**195,707,702**	**204**	**8,678,997**	**(405,776)**	**2,112,454**	**(8)**	**(3,985,237)**	**(2,278,363)**	**10,439**	**(2,267,924)**
Repurchase of common stock	—	—	—	(1,904,001)	—	1,904,001	(127,503)	—	—	—	(127,503)	—	(127,503)
Issuance of shares under equity compensation plans	—	—	—	1,545,170	2	—	—	5,221	—	—	5,223	—	5,223
Repurchase of RSU shares to satisfy tax withholding	—	—	—	(64,519)	—	—	—	(4,267)	—	—	(4,267)	—	(4,267)
Stock-based compensation	—	—	—	—	—	—	—	45,419	—	—	45,419	—	45,419
Transfers from (to) noncontrolling interests	2,682	—	—	—	—	—	—	(3,509)	—	—	(3,509)	827	(2,682)
Unrealized gain on available-for-sale securities	—	—	—	—	—	—	—	—	1	—	1	—	1
Net loss	(2,749)	—	—	—	—	—	—	—	—	(152,216)	(152,216)	(926)	(153,142)
Balances as of June 30, 2026	**(1,018)**	**—**	**—**	**195,284,352**	**206**	**10,582,998**	**(533,279)**	**2,155,318**	**(7)**	**(4,137,453)**	**(2,515,215)**	**10,340**	**(2,504,875)**
Issuance of preferred stock, net of issuance costs	—	933,900	932,558	—	—	—	—	—	—	—	932,558	—	932,558
Accretion of preferred stock	—	—	9,920	—	—	—	—	(9,920)	—	—	—	—	—
Preferred stock dividends	—	—	—	—	—	—	—	(16,373)	—	—	(16,373)	—	(16,373)
Repurchase of common stock	—	—	—	(712,165)	—	712,165	(47,496)	—	—	—	(47,496)	—	(47,496)
Issuance of shares under equity compensation plans	—	—	—	1,430,282	1	—	—	5,899	—	—	5,900	—	5,900
Issuance of common stock under ESPP	—	—	—	66,105	—	—	—	4,262	—	—	4,262	—	4,262
Repurchase of RSU shares to satisfy tax withholding	—	—	—	(63,732)	—	—	—	(5,090)	—	—	(5,090)	—	(5,090)
Stock-based compensation	—	—	—	—	—	—	—	39,211	—	—	39,211	—	39,211
Transfers from (to) noncontrolling interests	2,500	—	—	—	—	—	—	(3,301)	—	—	(3,301)	801	(2,500)
Unrealized loss on available-for-sale securities	—	—	—	—	—	—	—	—	(88)	—	(88)	—	(88)
Net loss	(2,845)	—	—	—	—	—	—	—	—	(56,710)	(56,710)	(941)	(57,651)
Balances as of September 30, 2026	**$ (1,363)**	**933,900**	**$ 942,478**	**196,004,842**	**$ 207**	**11,295,163**	**$ (580,775)**	**$ 2,170,006**	**$ (95)**	**$ (4,194,163)**	**$ (1,662,342)**	**$ 10,200**	**$ (1,652,142)**

(1) The consolidated balances as of December 31, 2025 and 2024 are derived from the audited consolidated financial statements as of those dates.

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

	Redeemable Convertible Noncontrolling Interests	Common Stock		Treasury Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total BridgeBio Stockholders' Deficit	Non-controlling Interests	Total Stockholders' Deficit
		Shares	Amount	Shares	Amount						
Balances as of December 31, 2024 (1)	**$ 142**	**190,044,473**	**$ 196**	**6,191,761**	**$ (275,000)**	**$ 1,903,155**	**$ 8**	**$ (3,096,263)**	**$ (1,467,904)**	**$ 10,150**	**$ (1,457,754)**
Repurchase of common stock	—	(1,405,411)	—	1,405,411	(48,276)	—	—	—	(48,276)	—	(48,276)
Issuance of shares under equity compensation plans	—	1,081,744	1	—	—	2,520	—	—	2,521	—	2,521
Issuance of common stock under ESPP	—	156,097	—	—	—	3,237	—	—	3,237	—	3,237
Repurchase of RSU shares to satisfy tax withholding	—	(50,880)	—	—	—	(1,776)	—	—	(1,776)	—	(1,776)
Stock-based compensation	—	—	—	—	—	32,057	—	—	32,057	—	32,057
Issuance of noncontrolling interests	800	—	—	—	—	—	—	—	—	—	—
Transfers from (to) noncontrolling interests	379	—	—	—	—	(824)	—	—	(824)	445	(379)
Unrealized loss on available-for-sale securities	—	—	—	—	—	—	(8)	—	(8)	—	(8)
Net loss	(1,548)	—	—	—	—	—	—	(167,422)	(167,422)	(638)	(168,060)
Balances as of March 31, 2025	**(227)**	**189,826,023**	**197**	**7,597,172**	**(323,276)**	**1,938,369**	**—**	**(3,263,685)**	**(1,648,395)**	**9,957**	**(1,638,438)**
Issuance of shares under equity compensation plans	—	1,395,587	1	—	—	7,158	—	—	7,159	—	7,159
Repurchase of RSU shares to satisfy tax withholding	—	(58,951)	—	—	—	(1,995)	—	—	(1,995)	—	(1,995)
Stock-based compensation	—	—	—	—	—	38,089	—	—	38,089	—	38,089
Issuance of noncontrolling interests	750	—	—	—	—	—	—	—	—	—	—
Transfers from (to) noncontrolling interests	400	—	—	—	—	(816)	—	—	(816)	416	(400)
Unrealized gain on available-for-sale securities	—	—	—	—	—	—	1	—	1	—	1
Net loss	(1,368)	—	—	—	—	—	—	(181,903)	(181,903)	(487)	(182,390)
Balances as of June 30, 2025	**(445)**	**191,162,659**	**198**	**7,597,172**	**(323,276)**	**1,980,805**	**1**	**(3,445,588)**	**(1,787,860)**	**9,886**	**(1,777,974)**
Issuance of shares under equity compensation plans	—	1,424,255	2	—	—	4,841	—	—	4,843	—	4,843
Issuance of common stock under ESPP	—	105,325	—	—	—	3,177	—	—	3,177	—	3,177
Repurchase of RSU shares to satisfy tax withholding	—	(58,953)	—	—	—	(3,025)	—	—	(3,025)	—	(3,025)
Stock-based compensation	—	—	—	—	—	35,631	—	—	35,631	—	35,631
Transfers from (to) noncontrolling interests	2,068	—	—	—	—	(3,094)	—	—	(3,094)	1,026	(2,068)
Unrealized gain on available-for-sale securities	—	—	—	—	—	—	1	—	1	—	1
Net loss	(1,600)	—	—	—	—	—	—	(182,743)	(182,743)	(594)	(183,337)
Balances as of September 30, 2025	**$ 23**	**192,633,286**	**$ 200**	**7,597,172**	**$ (323,276)**	**$ 2,018,335**	**$ 2**	**$ (3,628,331)**	**$ (1,933,070)**	**$ 10,318**	**$ (1,922,752)**

(1) The consolidated balances as of December 31, 2025 and 2024 are derived from the audited consolidated financial statements as of those dates.

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

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BRIDGEBIO PHARMA, INC.
Condensed Consolidated Statements of Cash Flows
(Unaudited)
(in thousands)

	Nine Months Ended September 30,	
	2026	**2025**
Operating activities:		
Net loss	$ (382,942)	$ (538,303)
Adjustments to reconcile net loss to net cash used in operating activities:		
Noncash interest expense on deferred royalty obligations (1)	123,500	86,460
Stock-based compensation	117,171	98,385
Net loss from equity method investments	32,030	51,579
Change in fair value of the embedded derivative associated with the deferred royalty obligation	(7,098)	(11,062)
Amortization of debt discount and issuance costs	5,670	4,515
Depreciation and amortization	3,308	3,999
Noncash lease expense	4,714	3,443
Loss on extinguishment of debt	—	21,155
Noncash income from an equity method investment	—	(7,769)
Other noncash adjustments, net	2,233	(1,217)
Changes in operating assets and liabilities:		
Accounts receivable, net	(235,646)	(111,796)
Inventories	(35,641)	(23,356)
Prepaid expenses and other current assets	(26,872)	(17,527)
Other assets	(5,849)	568
Accounts payable	51,993	9,084
Accrued compensation and benefits	(9,049)	3,212
Accrued research and development liabilities	13,583	347
Operating lease liabilities	(5,494)	(4,757)
Deferred revenue	(6,558)	(9,480)
Other liabilities (2)	48,397	53,030
Net cash used in operating activities	(312,550)	(389,490)
Investing activities:		
Purchases of marketable securities	(63,937)	(10,876)
Maturities of marketable securities	76,500	8,000
Proceeds from special cash dividends received from an investment in equity securities	—	2,302
Payment for intangible assets	—	(8,495)
Purchases of property and equipment	(802)	(1,064)
Net cash provided by (used in) investing activities	11,761	(10,133)
Financing activities:		
Proceeds from issuance of 2033 Notes	632,500	—
Issuance costs and discounts associated with 2033 Notes	(13,227)	—
Proceeds from issuance of 2031 Notes	—	575,000
Issuance costs and discounts associated with 2031 Notes	—	(12,034)
Repayment of term loans	—	(459,000)
Proceeds from royalty obligation under Royalty Purchase Agreement (as described in Note 9)	—	300,000
Issuance costs associated with royalty obligation under Royalty Purchase Agreement	—	(3,010)
Repayments of deferred royalty obligations (3)	(62,507)	(6,896)
Proceeds from issuance of preferred stock	933,900	—
Issuance costs associated with preferred stock	(1,342)	—
Payment of preferred stock dividends	(2,694)	—
Repurchase of common stock	(252,502)	(48,276)
Proceeds from stock option exercises, net of repurchases	33,712	14,523
Proceeds from common stock issuances under ESPP	9,728	6,414
Repurchase of RSU shares to satisfy tax withholding	(13,431)	(6,796)
Transactions with noncontrolling interests	—	1,550
Net cash provided by financing activities	1,264,137	361,475
Net increase (decrease) in cash, cash equivalents, and restricted cash	963,348	(38,148)
Cash, cash equivalents, and restricted cash at beginning of period	572,140	683,244
Cash, cash equivalents, and restricted cash at end of period	$ 1,535,488	$ 645,096

(1) Including related party amounts of $13,878 and $5,560 for the period from January 1, 2026 to August 16, 2026 and for the nine months ended September 30, 2025, respectively (as described in Note 9).
(2) Including related party amounts of nil and $1,647 for the period from January 1, 2026 to August 16, 2026 and for the nine months ended September 30, 2025, respectively (as described in Note 9).
(3) Including related party amounts of $(5,784) and $(665) for the period from January 1, 2026 to August 16, 2026 and for the nine months ended September 30, 2025, respectively (as described in Note 9).

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

BRIDGEBIO PHARMA, INC.
Condensed Consolidated Statements of Cash Flows
(Continued)
(Unaudited)
(in thousands)

	Nine Months Ended September 30,	
	2026	**2025**
Supplemental Disclosure of Cash Flow Information:		
Cash paid for interest	$ 43,135	$ 43,670
Supplemental Disclosures of Noncash Investing and Financing Information:		
Accretion of preferred stock	$ 9,920	$ —
Accrued cash dividends on preferred stock	$ 13,679	$ —
Accrual for repurchase of common stock	$ 4,997	$ —
Transfers to noncontrolling interests	$ (8,765)	$ (4,734)
Reconciliation of Cash, Cash Equivalents and Restricted Cash:		
Cash and cash equivalents	$ 1,533,363	$ 642,951
Restricted cash — Included in “Prepaid expenses and other current assets”	550	126
Restricted cash — Included in “Other assets”	1,575	2,019
Total cash, cash equivalents and restricted cash at end of periods shown on the condensed consolidated statements of cash flows	$ 1,535,488	$ 645,096

BRIDGEBIO PHARMA, INC.

Notes to Condensed Consolidated Financial Statements
(Unaudited)

1. Organization and Description of Business

BridgeBio Pharma, Inc. ("BridgeBio," the "Company," or "we"), is a commercial-stage, multi-product biopharmaceutical company organized around a portfolio operating model to discover, develop, and deliver medicines for patients with genetic diseases. We seek to translate advances in genetic science into therapies for patient populations with significant unmet medical needs. BridgeBio was founded in 2015, and its team of experienced drug discoverers, developers and innovators are committed to applying advances in genetic medicine to help patients as quickly as possible.

On November 22, 2024, the Company received approval from the U.S. Food and Drug Administration ("FDA") for Attruby™ (acoramidis) and began to generate product revenue from the commercialization of Attruby in the U.S. On February 10, 2025, the European Commission ("EC") approved Beyonttra™ (acoramidis) for the treatment of transthyretin amyloid cardiomyopathy (ATTR-CM) in the EU. On March 27, 2025, the Japanese Ministry of Health, Labour and Welfare approved Beyonttra for the treatment of ATTR-CM in Japan, and on May 21, 2025, the National Health Insurance in Japan approved the pricing of Beyonttra. In April 2025, the United Kingdom Medicines and Healthcare products Regulatory Agency approved Beyonttra for the treatment of ATTR-CM in the UK. In May 2026, the Brazilian Health Regulatory Agency approved Beyonttra for the treatment of ATTR-CM and in October 2026, the Australian Therapeutic Goods Administration approved Attruby for the treatment of ATTR-CM.

In addition, our development portfolio includes three registrational-stage product candidates, each supported by positive Phase 3 results and for which New Drug Applications ("NDAs") have been filed with the FDA:

- On March 30, 2026, we submitted our NDA to the FDA for oral BBP-418 for the treatment of LGMD2I/R9. The FDA accepted our NDA for filing, granted Priority Review and assigned a Prescription Drug User Fee Act ("PDUFA") target action date of November 27, 2026, for BBP-418.
- On May 12, 2026, we submitted our NDA to the FDA for encaleret as a potential targeted treatment for ADH1. The FDA accepted our NDA for filing, granted Priority Review and assigned a PDUFA target action date of May 8, 2027, for encaleret.
- On August 4, 2026, we submitted our NDA to the FDA for low-dose infigratinib for achondroplasia. The FDA accepted our NDA for filing, granted Priority Review and assigned a PDUFA target action date of February 4, 2027, for infigratinib.

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

2. Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

The condensed consolidated financial statements include the accounts of BridgeBio and its wholly-owned subsidiaries and controlled entities, substantially all of which are denominated in U.S. dollars. All intercompany balances and transactions have been eliminated in consolidation. For consolidated entities where we own or are exposed to less than 100% of the economics, we record "Net loss attributable to redeemable convertible noncontrolling interests and noncontrolling interests" on our condensed consolidated statements of operations equal to the percentage of the economic or ownership interest retained in such entities by the respective noncontrolling parties.

In determining whether an entity is considered a controlled entity, we applied the VIE and Voting Interest Entity ("VOE") models. We assess whether we are the primary beneficiary of a VIE based on our power to direct the activities of the VIE that most significantly impact the VIE's economic performance and our obligation to absorb losses or the right to receive benefits from the VIE that could potentially be significant to the VIE. 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 has a controlling financial interest in the entity through its ownership of greater than 50% of the outstanding voting shares of the entity and that other equity holders do not have substantive voting, participating or liquidation rights. We assess whether we are the primary beneficiary of a VIE or whether we have a majority voting interest for entities consolidated under the VOE model at the inception of the arrangement and at each reporting date.

BRIDGEBIO PHARMA, INC.

Notes to Condensed Consolidated Financial Statements
(Unaudited)

The accompanying condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States ("U.S. GAAP") and applicable rules and regulations of the U.S. Securities and Exchange Commission (the "SEC") regarding interim financial reporting. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. Certain reclassifications have been made to prior period amounts to conform to current period presentations. The accompanying unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2025, filed with the SEC.

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 and recurring adjustments, necessary for a fair statement of our financial position, our results of operations and comprehensive loss, stockholders' deficit and our cash flows for the periods presented. The results of operations for the three and nine months ended September 30, 2026 are not necessarily indicative of the results to be expected for the year ending December 31, 2026 or for any other future annual or interim periods.

Use of Estimates

The preparation of condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities and disclosure of contingent liabilities at the date of the condensed consolidated financial statements, and the reported amounts of revenues and expenses during the reporting periods. Significant estimates and assumptions made in the accompanying condensed consolidated financial statements include, but are not limited to:

- revenue recognition for transactions accounted for under Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 606, *Revenue from Contracts with Customers* ("ASC 606"), including estimating the impact of the variable consideration and determining and allocating the transaction price to performance obligations,
- accruals for research and development activities, such as clinical, development, regulatory, and sales-based milestone payments in our in-licensing agreements,
- deferred royalty obligations, related embedded derivative liability and underlying assumptions,
- accruals for performance-based milestone compensation arrangements,
- the expected redemption period of our convertible preferred stock and related discount accretion,
- additional charges as a result of, or that are associated with, any restructuring initiative as well as impairment and related charges,
- inventory valuation and related reserves,
- valuation of equity awards and related stock-based compensation,
- the expected recoverability and estimated useful lives of our long-lived assets, and
- allowance for credit losses.

We base our estimates on historical experience and on various other assumptions that are believed to be reasonable. Actual results may differ from those estimates or assumptions.

Concentration of Credit Risk and Other Risks and Uncertainties

Financial instruments that subject us to significant concentrations of credit risk consist primarily of cash, cash equivalents, marketable securities, and accounts receivable. Amounts on deposit may at times exceed federally insured limits. Although management currently believes that the financial institutions with whom the Company does business will be able to fulfill their commitments to the Company, there is no assurance that those institutions will be able to continue to do so. The Company has not experienced any credit losses associated with its balances as of September 30, 2026 and December 31, 2025.

BRIDGEBIO PHARMA, INC.

Notes to Condensed Consolidated Financial Statements
(Unaudited)

The following table summarizes customers that represent 10% or greater of our consolidated total gross revenues:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Bayer (as described in Note 10)	19.4%	*	10.9%	20.5%
Customer A	16.1%	20.6%	17.3%	17.3%
Customer B	19.1%	22.5%	23.4%	17.1%
Customer C	18.3%	17.4%	19.3%	12.7%
Customer D	12.2%	17.4%	13.1%	12.9%
Customer E	13.8%	14.4%	14.9%	*

* Represents less than 10% and/or not a customer in the applicable period.

We are subject to credit risk from our accounts receivable which primarily consist of amounts due from product sales to customers and from license and collaboration agreements with strategic partners. We have not experienced any material losses related to receivables from individual customers or groups of customers. We also do not require any collateral. Accounts receivable are recorded net of allowance for credit losses, if any. As of September 30, 2026, five customers each accounted for more than 10% of our consolidated gross accounts receivable balance, at 23.7%, 18.6%, 16.6%, 15.2% and 13.3%. As of December 31, 2025, five customers each accounted for more than 10% of our consolidated gross accounts receivable balance, at 27.0%, 20.3%, 19.1%, 15.0% and 14.9%.

We are subject to certain risks and uncertainties and we believe that changes in any of the following areas could have a material adverse effect on future financial position or results of operations: ability to obtain future financing, regulatory approval and market acceptance of, and reimbursement for, product candidates, performance of third-party contract research organizations and manufacturers upon which we rely, development of sales channels, protection of our intellectual property, litigation or claims against us based on intellectual property, patent, product, regulatory, clinical or other factors, and our ability to attract and retain employees necessary to support our growth.

We are dependent on third-party contract manufacturing organizations (“CMOs”) to supply Attruby and Beyonttra and for research and development activities in our programs. In particular, we rely and expect to continue to rely on a small number of manufacturers to supply us with our requirements for the active pharmaceutical ingredients and formulated drugs related to the sale of our commercial product and the research and development of our other clinical product candidates. For certain clinical product candidates, we rely on a single manufacturer. Sales of our commercial product and the development of our other clinical product candidates could be adversely affected by a significant interruption in the supply of active pharmaceutical ingredients and formulated drugs.

Cash, Cash Equivalents, Marketable Securities, and Restricted Cash

We consider all highly liquid investments purchased with original maturities of 90 days or less from the purchase date to be cash equivalents. Cash equivalents consist primarily of amounts invested in money market instruments, such as money market funds, commercial paper, U.S. treasury bills, agency discount notes, and other securities issued by the U.S. government or its agencies.

Our marketable securities consist of high investment grade fixed income securities invested in U.S. treasury bills and notes, and agency discount notes. In accordance with ASC 320, *Investments - Debt Securities*, we classify our marketable securities as available-for-sale securities and report them at fair value in cash equivalents or marketable securities on the condensed consolidated balance sheets with related unrealized gains and losses included as a component of stockholders’ deficit. We classify our marketable securities as either short-term or long-term based on each instrument’s underlying contractual maturity date. The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity which is included in interest income on the condensed consolidated statements of operations. Realized gains and losses and declines in value judged to be other-than-temporary, if any, on available-for-sale securities are included in “Other income (expense), net” on our condensed consolidated statements of operations. The cost of securities sold is based on the specific identification method. Interest and dividends on securities classified as available-for-sale are included in interest income.

Our cash, cash equivalents, marketable securities, and restricted cash are exposed to credit risk in the event of default by the financial institutions that hold or issue such assets. Our cash, cash equivalents, marketable securities, and restricted cash are held by financial institutions that management believes are of high credit quality. Our investment policy limits investments to fixed income securities denominated and payable in U.S. dollars such as commercial paper, U.S. government obligations, treasury bills, and money market funds, and places restrictions on maturities and concentrations by type and issuer.

Restricted cash primarily represents certain letters of credit for lease agreements, for which we have pledged cash and cash equivalents as collateral.

Other Current Liabilities

Other current liabilities presented on the condensed consolidated balance sheets consisted of the following balances:

	September 30, 2026	December 31, 2025
	(in thousands)	
Accrued rebates and other related costs	$ 92,937	$ 45,909
Accrued commercial	43,582	35,773
Deferred royalty obligations, current portion (1)	36,094	11,221
Accrued cash dividends on preferred stock	13,679	—
Accrued interest	5,043	14,411
Accrued professional services	8,938	3,665
Other accrued liabilities	11,841	9,243
Total other current liabilities	$ 212,114	$ 120,222

(1) Including related party amounts of nil and $2,003 as of September 30, 2026 and December 31, 2025, respectively (as described in Note 9).

Segments

We are a single operating and reportable segment, which is in the business of identifying, advancing and commercializing transformative medicines to treat patients. We operate in one segment because our business offerings have similar economics and other characteristics, including the nature of products, clinical and manufacturing processes, types of customers, distribution methods, and regulatory environments. We are managed in the aggregate as one business segment by the Chief Operating Decision Maker ("CODM"), who is our Chief Executive Officer.

While we operate as a single reportable segment, our research and development expenses for our significant programs are tracked and regularly reported to our CODM. Research and development costs consist primarily of external costs, such as fees paid to consultants, contractors, CMOs, and contract research organizations ("CROs"), and purchase of active pharmaceutical ingredients ("APIs"), in connection with our nonclinical, contract manufacturing and clinical development activities; as well as internal costs, such as personnel and facility costs, and are tracked on a program-by-program basis. License fees and other costs incurred after a product candidate has been designated and that are directly related to the product candidate are included in the specific program expense. License fees and other costs incurred prior to designating a product candidate are included in early-stage development and research programs, which are presented in the following table in "Other development programs" and "Other research programs," respectively.

BRIDGEBIO PHARMA, INC.

Notes to Condensed Consolidated Financial Statements
(Unaudited)

The following table summarizes our segment information for significant operating expenses:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
	(in thousands)		(in thousands)	
Revenues:				
Net product revenue	$ 253,346	$ 108,111	$ 656,382	$ 216,351
License and services revenue	79,314	8,311	89,537	125,441
Royalty revenue	20,511	4,278	45,443	6,106
Total revenues, net	353,171	120,700	791,362	347,898
Operating costs and expenses:				
Cost of revenues:				
Cost of goods sold	12,317	4,028	30,577	8,910
Cost of license, services, and royalty revenue	8,133	2,535	14,858	3,945
Total cost of revenues	20,450	6,563	45,435	12,855
Research and development by significant program:				
Acoramidis for the treatment of ATTR-CM and primary prevention in asymptomatic carriers of a pathogenic TTR variant	33,782	31,978	101,695	84,639
Infigratinib for achondroplasia and hypochondroplasia	34,089	30,756	105,082	88,881
BBP-418 for LGMD2I/R9	24,971	14,253	67,232	39,705
Encaleret for ADH1	27,048	16,046	71,555	44,633
Other development programs	3,292	357	16,815	22,323
Other research programs	20,324	19,484	57,211	55,355
Total segment research and development	143,506	112,874	419,590	335,536
Selling, general and administrative	200,854	137,621	551,011	373,140
Restructuring, impairment, and related charges	—	8,841	—	10,216
Total operating costs and expenses	364,810	265,899	1,016,036	731,747
Loss from operations	(11,639)	(145,199)	(224,674)	(383,849)
Other income (expense), net:				
Interest income	13,105	6,239	26,010	15,522
Interest expense	(13,255)	(11,739)	(39,475)	(41,467)
Noncash interest expense on deferred royalty obligations (1)	(42,282)	(36,410)	(123,500)	(86,460)
Net loss from equity method investments	(7,312)	(15,834)	(32,030)	(51,579)
Loss on extinguishment of debt	—	—	—	(21,155)
Other income, net	2,116	16,461	11,956	31,240
Total other expense, net	(47,628)	(41,283)	(157,039)	(153,899)
Loss before income taxes	(59,267)	(186,482)	(381,713)	(537,748)
Provision for (benefit from) income taxes	1,229	(1,545)	1,229	555
Net loss	(60,496)	(184,937)	(382,942)	(538,303)
Net loss attributable to redeemable convertible noncontrolling interests and noncontrolling interests	3,786	2,194	9,973	6,235
Net loss attributable to BridgeBio	(56,710)	(182,743)	(372,969)	(532,068)
Preferred stock dividends and accretion	26,293	—	26,293	—
Segment net loss attributable to common stockholders of BridgeBio	$ (83,003)	$ (182,743)	$ (399,262)	$ (532,068)

(1) Including related party amounts of $(2,942) and $(13,878) for the period from July 1, 2026 to August 16, 2026 and for the period from January 1, 2026 to August 16, 2026, respectively, and $(5,383) and $(5,560) for the three and nine months ended September 30, 2025, respectively (as described in Note 9).

There are no reconciling items or adjustments between segment “Total revenues, net” and “Net loss attributable to common stockholders of BridgeBio,” and consolidated “Total revenues, net” and “Net loss attributable to common stockholders of BridgeBio.”

Total revenues, net is attributed to regions based on the location of our customers or license and collaboration partners.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
U.S.	71.7 %	89.6 %	82.9 %	62.2 %
Europe, Middle East, and Africa (EMEA)	27.6 %	7.7 %	16.3 %	34.9 %
Asia-Pacific (APAC)	0.7 %	2.7 %	0.8 %	2.9 %
Total	100.0 %	100.0 %	100.0 %	100.0 %

The CODM does not review assets at a different asset level or category than the amounts disclosed in the condensed consolidated balance sheets. As of September 30, 2026, our capitalized property and equipment located in the U.S., Canada and the rest of the world are approximately 49.3%, 45.3%, and 5.4%, respectively. As of December 31, 2025, our capitalized property and equipment located in the U.S., Canada and the rest of the world are approximately 44.2%, 51.6% and 4.2%, respectively.

Deferred Royalty Obligations, net

We treat the debt obligations to the Royalty Agreement Purchasers and Funding Agreement Purchasers (as defined and discussed further in Note 9) as deferred royalty obligations, and amortize using the effective interest rate method over the estimated life of the respective revenue streams. We recognize interest expense thereon using the effective rate, which is based on our current estimates of future net sales over the life of the related arrangements. In connection therewith, we assess our expected net product sales of acoramidis at the end of each reporting period using internal projections, impute interest on the carrying value of the deferred royalty obligations, and record interest expense using the imputed effective interest rate.

We assess at the end of each reporting period the amount and timing of expected royalty payments using a combination of internal projections and data from external sources. The estimates of future net product sales, and resulting royalty payments, are based on key assumptions including patient population, market penetration, gross-to-net assumptions, and sales price, among others. To the extent our revised estimates of future global net sales are greater or less than previous estimates, or the estimated timing of such payments is different from previous estimates, we account for any such changes by adjusting the effective interest rate utilizing the prospective method. Changes in the effective interest rate also affect the period over which unamortized debt discount and issuance costs are amortized.

Series A Cumulative Convertible Participating Preferred Stock

In July 2026, the Company issued shares of a newly designated series of convertible preferred stock (see Note 13). The Company accounts for its Series A Cumulative Convertible Participating Preferred Stock, par value $0.001 per share (the “Preferred Stock”) as permanent equity. Dividends on the Preferred Stock accrue and accumulate on a daily basis at an initial annual rate of 7.00% of the accumulated amount per share, initially the $1,000 per share original issue price, whether or not declared by the Company’s Board of Directors, and are subject to contractual increases in the dividend rate over time and upon specified events. To the extent not paid in cash (the “PIK Dividends”) on a quarterly dividend payment date, accrued PIK Dividends automatically compound and are added to the accumulated amount of each share. Because PIK Dividends accrue and compound whether or not declared and increase both the number of shares of common stock issuable upon conversion and the amounts payable upon liquidation or redemption, the Company recognizes PIK Dividends as they accumulate as an increase in the carrying value of the Preferred Stock, with a corresponding charge to retained earnings, or additional paid-in capital in the absence of retained earnings. Accumulated and unpaid PIK Dividends are not recognized as a liability at each balance sheet date, as the Company has no obligation to transfer assets until such dividends are declared and paid. Through September 30, 2026, the Company has elected to pay all dividends on the Preferred Stock in cash, and no PIK Dividends have accumulated (see Note 13).

The Preferred Stock has similar characteristics of an "Increasing Rate Security" as described by SEC Staff Accounting Bulletin Topic 5.Q, *Increasing Rate Preferred Stock*. The Preferred Stock's initial carrying value was recorded at a discount to its liquidation preference (i.e., the difference between the issuance price and estimated call price) due to being issued with an increasing rate dividend, in addition to its issuance costs. Such discount is considered an unstated dividend cost and is amortized over the expected redemption period using the effective interest method, by charging the imputed dividend cost against additional paid-in capital in the absence of retained earnings and increasing the carrying amount of the Preferred Stock by a corresponding amount. The amortization in each period is the amount which, together with the stated dividend in the period, results in a constant rate of effective cost with regard to the carrying amount of the Preferred Stock.

Net Loss per Share Attributable to Common Stockholders of BridgeBio

We calculate basic net loss per share using the two-class method as a result of the issuance of the Preferred Stock in July 2026 (see Note 13). The two-class method determines net income (loss) per common share for each class of common stock and participating securities according to dividends declared or accumulated and participation rights in undistributed earnings. The two-class method requires undistributed earnings for the period to be allocated between common stock and participating securities based upon their respective rights to receive dividends as if all income for the period had been distributed. The Preferred Stock contractually entitles the holders of such shares to participate in dividends declared on common stock on an as-converted basis, but does not contractually require the holders of such shares to participate in the Company's losses. Accordingly, no losses are allocated to the Preferred Stock, and the Preferred Stock is excluded from the computation of basic net loss per share in periods in which the Company reports a net loss. However, the cumulative dividends that accrete on the Preferred Stock for the period, whether or not declared, reduce net income or increase net loss attributable to common stockholders.

Basic net loss per share attributable to common stockholders of BridgeBio is computed by dividing the net loss attributable to common stockholders of BridgeBio by the weighted-average number of shares of BridgeBio's common stock outstanding for the period, without consideration for potential dilutive shares of common stock, such as stock options, unvested restricted stock units ("RSUs"), performance-based milestone compensation awards, shares issuable under our employee stock purchase plan ("ESPP"), and assumed conversion of our 2027 Notes, 2029 Notes, 2031 Notes, 2033 Notes, and Preferred Stock. The common stock equivalents of performance-based milestone compensation arrangements are included as potentially dilutive shares only if the performance condition has been met as of the end of the reporting period. Shares of common stock subject to repurchase are excluded from the weighted-average shares. Diluted net loss per share is computed by giving effect to all potentially dilutive securities outstanding for the period, determined using the more dilutive of the treasury stock method, the if-converted method, or the two-class method, as applicable. Because the Company reported a net loss for all periods presented, all potentially dilutive securities were antidilutive, and basic and diluted net loss per share are the same.

Revenue Recognition

For elements or transactions that we determine should be accounted for under ASC 606, we perform 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) we satisfy our performance obligation. We apply the five-step model to contracts when it is probable that we will collect the consideration to which we are entitled in exchange for the goods or services we transfer to the customer.

At inception of the arrangement, we assess the promised goods or services to identify the performance obligations within the contract. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation, on a relative standalone selling price basis, when (or as) the performance obligation is satisfied, either at a point in time or over time. If the performance obligation is satisfied over time, we recognize revenue based on the use of an input method. As part of the accounting for these arrangements, we develop assumptions that require judgment to determine the standalone selling price for each performance obligation identified in the contract. These key assumptions may include forecasted revenue or costs, development timelines, discount rates and probabilities of clinical and regulatory success.

- *Net product revenue:* Revenue is recognized when our customers, primarily specialty pharmacies and specialty distributors, obtain control of the product and revenue is adjusted to reflect discounts, chargebacks, rebates, returns and other allowances associated with the respective sales as further described below.

- *License fees*: For arrangements that include a grant of a license to our intellectual property, we consider whether the license grant is distinct from the other performance obligations included in the arrangement. We determine the license to be distinct if the customer is able to benefit from the license with the resources available to it. For licenses that are distinct, we recognize revenues from nonrefundable, upfront license fees and other consideration allocated to the license when the license term has begun and we have provided all necessary information regarding the underlying intellectual property to the customer, which generally occurs at or near the inception of the arrangement. For licenses that are bundled with other promises, we determine whether the combined performance obligation is satisfied over time or at a point in time. If the combined performance obligation is satisfied over time, we use judgment in determining the appropriate method of measuring progress for purposes of recognizing revenue from the upfront license fees. We evaluate the measure of progress for each reporting period and, if necessary, adjust the measure of performance and related revenue recognition.
- *Development and regulatory milestone payments*: At the inception of each arrangement that includes development and regulatory milestone payments, we evaluate whether the milestones are considered probable of being achieved and estimate the amount to be included in the transaction price using the most likely amount method. We generally include these milestone payments in the transaction price when they are achieved because there is considerable uncertainty in the research and development processes that trigger these payments under our agreements. Similarly, we include approval milestone payments in the transaction price once the product is approved by the applicable regulatory agency. At the end of each subsequent reporting period, we re-evaluate the probability of achieving such development and regulatory milestones and any related constraint, and if necessary, adjust our estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis.
- *Sales-based milestone payments and royalties*: For arrangements that include sales-based royalties, including milestone payments based on the volume of sales, we 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, we 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). Our partners generally report sales information with a time lag. Thus, we estimate the expected royalty proceeds based on an analysis of historical experience and interim data provided by our partners. Differences between actual and estimated royalty revenues are adjusted in the period in which they become known, typically the following quarter.
- *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. We will assess if these options provide a material right to the licensee and if so, they are accounted for as separate performance obligations and recognized when the future goods or services related to the option are provided or the option expires.
- *Research and development services*: For arrangements that include research and development services, we will recognize revenue over time using an input method, representing the transfer of goods or services as we perform activities over the term of the arrangement.

Revenues from product sales are recorded at the net sales price, or "transaction price", which includes estimates of variable consideration for which reserves are established that result from discounts and fees, chargebacks, rebates, returns, co-pay assistance and other allowances that are offered within contracts between us and our customers, healthcare providers and other indirect customers relating to the sale of Attruby. These reserves are based on amounts earned or to be claimed on the related sale and are classified as reductions of accounts receivable (if the amount is payable to the customer) or other current liabilities (if the amount is payable to a third party other than a customer). We use the expected value method, which is the sum of probability-weighted amounts in a range of possible consideration amounts, or the most likely amount method, which is the single most likely amount in a range of possible considerations, to estimate variable consideration related to our product revenue. The estimates of reserves established for variable consideration reflect current contractual and statutory requirements, our historical experience, specific known market events and trends, industry data and forecasted customer buying and payment patterns. The amount of variable consideration that is included in the transaction price may be constrained and is included in net product revenue only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Actual amounts of consideration ultimately received may differ from our estimates. If actual results vary from our estimates, we will adjust these estimates prospectively in the period such change in estimate becomes known, which could affect net product revenue and earnings in the period of adjustment.

The following are the components of variable consideration related to net product revenue:

- *Chargebacks:* Chargebacks result from contractual commitments with the government and other entities to sell products to qualified healthcare providers at prices lower than the list prices charged to our customers. Our customers charge us for the difference between what they pay for the product and the selling price to the qualified healthcare providers. We record reserves and reduce our product revenue for these chargebacks related to product sold to our customers during the reporting period as well as our estimate of product that remains in the distribution channel at the end of the reporting period that we expect will be sold to qualified healthcare providers in future periods. Our established reserve for chargebacks is included as an offset against our "Accounts receivable, net" balance on our condensed consolidated balance sheets.
- *Trade discounts and allowances*: We provide customary invoice discounts on sales to our U.S. customers for prompt payment. The discounts are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue, and the establishment of a reserve that is offset against our "Accounts receivable, net" balance on our condensed consolidated balance sheets.
- *Distribution fees:* We receive and pay for various distribution services provided by our customers. These fees are generally accounted for as a reduction of product revenue in the same period the related revenue is recognized, and the establishment of a reserve is offset against our "Accounts receivable, net" balance on our condensed consolidated balance sheets. To the extent that the services received are distinct from the sale of products to our customers, we classify these payments as "Selling, general and administrative expenses" on our condensed consolidated statements of operations.
- *Government rebates:* We are subject to discount obligations under government programs, including Medicare and Medicaid programs in the U.S. Rebates are amounts owed after the final dispensing of the product to a benefit plan participant and are based upon contractual agreements with payers or statutory requirements pertaining to Medicare and Medicaid benefit providers. The allowance for rebates is based on contractual or statutory discount rates, estimated payer mix, and expected utilization. Our estimates for the expected utilization of rebates are based on historical dispense data received from our customers and invoices received. We monitor sales trends and adjust the allowance on a quarterly basis to reflect the most recent rebate experience. Our reserve for these rebates is recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of the liability that is included in "Other current liabilities" on our condensed consolidated balance sheets.
- *Other incentives:* Other incentives include co-payment assistance that we provide to patients with commercial insurance that have coverage and qualify for co-payment assistance. Co-payment assistance is accrued based on an estimate of the number of co-payment assistance claims and the cost per claim that we expect to receive associated with products that have been recognized as product revenue. The estimate is recorded as a reduction of product revenue in the same period that the related revenue is recognized and also results in the establishment of a liability which is included in "Other current liabilities" on our condensed consolidated balance sheets.

- *Product returns:* Consistent with industry practice, we offer our customers limited product return rights for damages, shipment errors, and expiring product; provided that the return is within a specified period around the product expiration date as set forth in the applicable individual distribution or customer agreement. In estimating for product returns, we consider historical product returns, the underlying product demand, and industry specific data. We estimate the amount of product sales that may be returned and record the estimate as a reduction of revenue and a refund liability included in "Other current liabilities" on our condensed consolidated balance sheets in the period the related product revenue is recognized.

There were no significant changes in estimates of variable considerations during the three and nine months ended September 30, 2026.

For revenue recognized under licensing and collaboration arrangements, we identify the performance obligations and allocate the total consideration we expect to receive on a relative standalone selling price basis to each performance obligation. Variable considerations, such as performance-based milestones, will be included in the total consideration if we expect to receive such consideration and if it is probable that the inclusion of the variable consideration will not result in a significant reversal in the cumulative amount of revenue recognized under the arrangement. Our estimate of the total consideration we expect to receive under each licensing and collaboration arrangement is updated for each reporting period, and any adjustments to revenue are recorded on a cumulative catch-up basis.

Inventories

Inventory is recorded at the lower of cost or net realizable value. The cost of raw materials, work in process and finished goods is determined using a standard cost approach, which approximates actual cost determined on a first-in, first-out basis. Raw and intermediate materials that may be used for either research and development or commercial purposes are classified as inventory until the material is consumed or otherwise allocated for research and development. If the material is used for research and development, it is expensed as research and development once that determination is made. We capitalize inventory costs that are expected to be sold commercially once we determine it is probable that the inventory costs will be recovered through commercial sales. We periodically review inventories to identify excess, dated, or obsolete inventory and record reserves and write-downs as necessary to reflect inventories at net realizable value. Provisions for inventory reserves and write-downs are recorded within "Cost of revenues" on the condensed consolidated statements of operations.

Inventories presented on the condensed consolidated balance sheets consisted of the following balances:

	September 30, 2026	December 31, 2025
	(in thousands)	
Raw materials	$ 30,003	$ 14,997
Work in process	16,025	6,104
Finished goods	17,641	6,509
Inventory reserve	(3,951)	(857)
Total inventories	$ 59,718	$ 26,753

Cost of Revenues

Cost of revenues consists of the following classifications, which are presented accordingly on our condensed consolidated statements of operations:

- *Cost of goods sold*: Cost of goods sold consists of contract manufacturing costs, transportation and freight-in, indirect overhead costs (including salary related and stock-based compensation expenses) associated with the commercial manufacturing and distribution of Attruby, and third-party royalties payable on our net product revenue. Cost of goods sold may also include period costs related to excess, dated or obsolete inventory adjustment charges, unabsorbed manufacturing and overhead costs, and manufacturing variances.
- *Cost of license, services, and royalty revenue*: Cost of license, services, and royalty revenue consists of manufacturing costs relating to product supply of Beyonttra to our collaboration partners, royalties and license fees owed to a third party related to the net sales of our licensed product, as well as amortization of intangible assets associated with our license and collaboration agreements, which are amortized over the life of the underlying intellectual property rights.

Advertising Expense

Advertising expenses include costs incurred to market the Company's branded product. Advertising production costs, which include costs incurred during production rather than when the advertising takes place, are expensed as incurred. Advertising communication costs, which include costs to run the ad campaign on digital or traditional marketing channels, such as on third-party websites, television, and social and print media, are expensed over the period of the campaign run. Advertising costs are included in "Selling, general and administrative expenses" on the condensed consolidated statements of operations. Deferred advertising costs primarily consist of vendor payments made in advance to secure media spots across various media channels. Deferred advertising costs are not expensed until the advertising is broadcast.

Recently Adopted Accounting Pronouncements

In November 2024, the FASB issued Accounting Standards Update ("ASU") 2024-04, *Debt with Conversion and Other Options (Subtopic 470-20): Induced Conversions of Convertible Debt Instruments*, which seeks to clarify the requirements for determining whether certain settlements of convertible debt instruments should be accounted for as an induced conversion. This ASU is effective for fiscal years beginning after December 15, 2025. Early adoption is permitted. The Company adopted this standard effective January 1, 2026, and the adoption of this ASU did not have an impact on its consolidated financial statements and related disclosures.

In July 2025, the FASB issued ASU 2025-05, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses for Accounts Receivable and Contract Assets*. This ASU provides a practical expedient that all entities can use when estimating expected credit losses for current accounts receivable and current contract assets arising from transactions accounted for under ASC 606. Under this practical expedient, an entity is allowed to assume that the current conditions it has applied in determining credit loss allowances for current accounts receivable and current contract assets remain unchanged for the remaining life of those assets. This ASU is effective for fiscal years beginning after December 15, 2025, and interim reporting periods in those years. Entities that elect the practical expedient and, if applicable, make the accounting policy election are required to apply the amendments prospectively. The Company adopted this standard effective January 1, 2026, and the adoption of this ASU did not have an impact on its consolidated financial statements and related disclosures.

In April 2026, the FASB issued ASU 2026-01, *Equity (Topic 505): Initial Measurement of Paid-in-Kind Dividends on Equity-Classified Preferred Stock*. The amendments in this ASU require entities to initially measure paid-in-kind ("PIK") dividends on equity-classified preferred stock using the PIK dividend rate stated in the preferred stock agreement, rather than at fair value. This ASU may be applied on either a prospective or modified retrospective basis, and is effective for annual reporting periods beginning after December 15, 2026 and interim reporting periods within those annual reporting periods. The Company early adopted this standard on a prospective basis effective July 1, 2026, concurrent with its issuance of its Preferred Stock (see Note 13). The adoption did not have an impact on the Company's consolidated financial statements other than the related disclosures. The Preferred Stock provides for cumulative dividends at an initial rate of 7% per annum, payable quarterly in cash or in kind at the Company's election. Through September 30, 2026, the Company elected to pay all such dividends in cash and therefore has not measured any PIK dividends under ASU 2026-01.

New Accounting Pronouncements Not Yet Adopted

In November 2024, the FASB issued ASU 2024-03, *Income Statement-Reporting Comprehensive Income-Expense Disaggregation Disclosures (Subtopic 220-40)*, which requires public companies to disclose, in interim and annual reporting periods, additional information about certain expenses in notes to financial statements, including purchases of inventory, employee compensation, depreciation, amortization of intangible assets, and selling expenses. This ASU is effective for fiscal years beginning after December 15, 2026, and for interim periods within fiscal years beginning after December 15, 2027. We plan to adopt this pronouncement and make the necessary updates to our disclosures for the year ending December 31, 2027, and, aside from these disclosure changes, we do not expect the amendments to have a material effect on our consolidated financial statements and related disclosures.

In September 2025, the FASB issued ASU 2025-06, *Intangibles - Goodwill and Other - Internal-Use Software (Subtopic 350-40): Targeted Improvements to the Accounting for Internal-Use Software*. This ASU makes targeted improvements to the accounting for internal-use software, and the ASU will be effective for the first quarter of 2028, with early adoption permitted. This ASU provides for adoption on a prospective basis, with retrospective or modified retrospective application permitted. The Company is currently evaluating the timing and effects of its adoption of this new guidance on its consolidated financial statements and related disclosures.

In September 2025, the FASB issued ASU 2025-07, *Derivatives and Hedging (Topic 815) and Revenue from Contracts with Customers (Topic 606): Derivatives Scope Refinements and Scope Clarification for Share-Based Non-cash Consideration from a Customer in a Revenue Contract*. The guidance refines the scope of ASC 815 to clarify which contracts are subject to derivative accounting. The guidance also provides clarification under ASC 606 for share-based payments from a customer in a revenue contract. The amendments in this ASU are effective for fiscal years beginning after December 15, 2026, and interim reporting periods, with early adoption permitted. The Company plans to adopt this guidance in fiscal year 2027 and does not expect the adoption of this ASU to have a material impact on its consolidated financial statements and related disclosures.

In December 2025, the FASB issued ASU 2025-10, *Government Grants (Topic 832): Accounting for Government Grants Received by Business Entities*, which provides updated guidance on how to recognize, measure, and present government grants. This ASU is effective for fiscal years beginning after December 15, 2028, including interim periods within those fiscal years, and permits modified prospective, modified retrospective, or full retrospective adoption. The Company plans to adopt this guidance in fiscal year 2029 and does not expect the adoption of this ASU to have a material impact on its consolidated financial statements and related disclosures.

In December 2025, the FASB issued ASU 2025-11, *Interim Reporting: Narrow-Scope Improvements*. This ASU improves clarity for interim financial reporting requirements under the existing guidance within ASC 270, *Interim Reporting*, by creating a comprehensive list of interim disclosure requirements, clarifying scope and applicability, along with adding a principle to disclose all material events that have occurred since the most recently filed Form 10-K. This ASU is effective for interim periods within annual periods beginning after December 15, 2027. Early adoption is permitted. The Company plans to adopt this guidance for interim periods within its fiscal year beginning January 1, 2028 and does not expect the adoption of this ASU to have a material impact on its consolidated financial statements and related disclosures.

In December 2025, the FASB issued ASU 2025-12, *Codification Improvements*, to address suggestions received from stakeholders on the Accounting Standards Codification and to make other incremental improvements to U.S. GAAP. The update represents changes to the Accounting Standards Codification that (1) clarify, (2) correct errors, or (3) make minor improvements. The amendments make the Accounting Standards Codification easier to understand and apply. The guidance is effective for fiscal years beginning after December 15, 2026, including interim periods within those fiscal years. The Company plans to adopt this guidance in fiscal year 2027 and does not expect the adoption of this ASU to have a material impact on its consolidated financial statements and related disclosures.

3. Fair Value Measurements

Assets and liabilities recorded at fair value on a recurring basis in the condensed consolidated balance sheets are categorized based upon the level of judgment associated with the inputs used to measure their fair values. Fair value is defined as the exchange price that would be received for an asset or an exit price that would be paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The authoritative guidance on fair value measurements establishes a three-tier fair value hierarchy for disclosure of fair value measurements as follows:

Level 1 - Observable inputs such as unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date.

Level 2 - Inputs (other than quoted prices included in Level 1) are either directly or indirectly observable for the asset or liability. These include quoted prices for similar assets or liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active; and

Level 3 - Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment we exercise in determining fair value is greatest for instruments categorized in Level 3. A financial instrument’s level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

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

BRIDGEBIO PHARMA, INC.

Notes to Condensed Consolidated Financial Statements
(Unaudited)

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

	September 30, 2026			
	Total	Level 1	Level 2	Level 3
	(in thousands)			
Assets				
Cash equivalents:				
Money market funds	$ 313,677	$ 313,677	$ —	$ —
U.S. Treasury securities	359,486	—	359,486	—
Commercial paper	546,005	—	546,005	—
Total cash equivalents	1,219,168	313,677	905,491	—
Marketable securities:				
U.S. Treasury securities	1,999	—	1,999	—
Agency discount notes	3,493	—	3,493	—
Total marketable securities	5,492	—	5,492	—
Total financial assets	$ 1,224,660	$ 313,677	$ 910,983	$ —
Liability				
Embedded derivative (included in “Deferred royalty obligations, net”)	$ 14,341	$ —	$ —	$ 14,341

	December 31, 2025			
	Total	Level 1	Level 2	Level 3
	(in thousands)			
Assets				
Cash equivalents:				
Money market funds	$ 132,602	$ 132,602	$ —	$ —
U.S. Treasury securities	11,960	—	11,960	—
Agency discount notes	25,938	—	25,938	—
Total cash equivalents	170,500	132,602	37,898	—
Marketable securities:				
U.S. Treasury securities	9,421	—	9,421	—
Agency discount notes	7,942	—	7,942	—
Total marketable securities	17,363	—	17,363	—
Total financial assets	$ 187,863	$ 132,602	$ 55,261	$ —
Liability				
Embedded derivative (included in “Deferred royalty obligations, net”)	$ 21,439	$ —	$ —	$ 21,439

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

There are uncertainties on the fair value measurement of the instruments classified under Level 3 due to the use of unobservable inputs and interrelationships between these unobservable inputs, which could result in higher or lower fair value measurements.

Marketable Securities

The fair value of our marketable securities classified within Level 2 is based upon observable inputs that may include benchmark yields, reported trades, broker/dealer quotes, issuer spreads, two-sided markets, benchmark securities, bids, offers, and reference data including market research publications.

Notes

The fair values of our 2.50% convertible senior notes due 2027 (the "2027 Notes"), 2.25% convertible senior notes due 2029 (the "2029 Notes"), 1.75% convertible senior notes due 2031 (the "2031 Notes"), and 0.75% convertible senior notes due 2033 (the "2033 Notes") (collectively, the "Notes"; refer to Note 8), which differ from their respective carrying values, are determined by prices for the Notes observed in market trading. The market for trading of the Notes is not considered to be an active market and therefore the estimate of fair value is based on Level 2 inputs.

The following table presents the aggregate face values and the fair values of the Notes, based on their market prices on the last trading day for the periods presented:

	September 30, 2026		December 31, 2025	
	Aggregate Face Values	Estimated Fair Values	Aggregate Face Values	Estimated Fair Values
	(in thousands)			
2027 Convertible Notes	$ 550,000	$ 830,500	$ 550,000	$ 1,019,975
2029 Convertible Notes	$ 747,500	$ 754,975	$ 747,500	$ 833,625
2031 Convertible Notes	$ 575,000	$ 924,049	$ 575,000	$ 1,003,783
2033 Convertible Notes	$ 632,500	$ 570,552	$ —	$ —

Deferred royalty obligations and embedded derivative liability

The embedded derivative liability associated with our deferred royalty obligation under the Funding Agreement, as defined and discussed further in Note 9, is measured at fair value using an option pricing Monte Carlo simulation model and is included as a component of the "Deferred royalty obligations, net" on the condensed consolidated balance sheets. The embedded derivative liability is subject to remeasurement at the end of each reporting period, with changes in fair value recognized as a component of "Other income (expense), net" on our condensed consolidated statements of operations. The assumptions used in the option pricing Monte Carlo simulation model incorporate certain Level 3 inputs including: (1) our estimates of the probability and timing of related events; (2) the probability-weighted global net product sales of acoramidis; (3) our risk-adjusted discount rate; (4) volatility; and (5) the probability of a change in control occurring during the term of the instrument.

Under the Monte Carlo simulation model discussed above, the deferred royalty obligation under the Funding Agreement (refer to Note 9), net of the bifurcated embedded derivative liability, had an estimated fair value of $533.6 million and $565.5 million as of September 30, 2026 and December 31, 2025, respectively. For the three and nine months ended September 30, 2026, we recognized a $1.4 million and $7.1 million gain, respectively, and for the three and nine months ended September 30, 2025, we recognized a $5.6 million and $11.1 million gain, respectively, related to the change in fair value of the embedded derivative liability in "Other income (expense), net" on our condensed consolidated statements of operations.

The deferred royalty obligation under the Royalty Purchase Agreement, as defined and discussed further in Note 9, had an estimated fair value of $338.8 million and $343.0 million as of September 30, 2026 and December 31, 2025, respectively, based on the Monte Carlo simulation model.

4. Cash Equivalents and Marketable Securities

We invest in certain commercial paper and U.S. government money market funds, treasury bills, and agency discount notes classified as cash equivalents. Our marketable securities consist of high investment grade fixed income securities that are invested in U.S. treasury bills and notes.

Cash equivalents and marketable securities consisted of the following:

	September 30, 2026			
	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Estimated Fair Value
	(in thousands)			
Cash equivalents:				
Money market funds	$ 313,677	$ —	$ —	$ 313,677
U.S. Treasury securities	359,493	—	(7)	359,486
Commercial paper	546,093	—	(88)	546,005
Total cash equivalents	1,219,263	—	(95)	1,219,168
Marketable securities:				
U.S. Treasury securities	1,999	—	—	1,999
Agency discount notes	3,493	—	—	3,493
Total marketable securities	5,492	—	—	5,492
Total cash equivalents and marketable securities	$ 1,224,755	$ —	$ (95)	$ 1,224,660

	December 31, 2025			
	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Estimated Fair Value
	(in thousands)			
Cash equivalents:				
Money market funds	$ 132,602	$ —	$ —	$ 132,602
U.S. Treasury securities	11,957	3	—	11,960
Agency discount notes	25,933	5	—	25,938
Total cash equivalents	170,492	8	—	170,500
Marketable securities:				
U.S. Treasury securities	9,419	2	—	9,421
Agency discount notes	7,940	2	—	7,942
Total marketable securities	17,359	4	—	17,363
Total cash equivalents and marketable securities	$ 187,851	$ 12	$ —	$ 187,863

The contractual maturities of securities classified as available-for-sale, regardless of their classification on our condensed consolidated balance sheets, are less than one year.

5. Equity Method Investments

GondolaBio

Since inception through August 16, 2024, Portal Therapeutics, Inc. and Sub21, Inc. were majority-owned consolidated subsidiaries of the Company. On August 16, 2024, the Company contributed its equity ownership in these entities to GondolaBio, LLC ("GondolaBio") and as a result, Portal Therapeutics, Inc. and Sub21, Inc. were deconsolidated in conjunction with the GondolaBio transaction, as further described below.

GondolaBio was formed on June 5, 2024 and the Company was the sole member. In August 2024, the Company entered into the Transaction Agreement providing for the formation and funding by certain third-party investors of GondolaBio, a legal joint venture entity for the purpose of researching, developing, manufacturing and commercializing pharmaceutical products, including those contributed to GondolaBio by the Company. The third-party investors providing financing to GondolaBio consist of an investor syndicate, including Viking Global Investors LP, Patient Square Capital, Aisling Capital and an entity owned by Neil Kumar, the Company's Chief Executive Officer, who are related parties of the Company. The Company contributed certain assets and its equity in Portal Therapeutics, Inc. and Sub21, Inc. to GondolaBio. Upon completion of the initial contributions, the Company's equity ownership in GondolaBio was 45.5%. As of September 30, 2026, the Company's equity ownership percentage in GondolaBio was 13.1%.

In August 2024, in conjunction with the Transaction Agreement, the limited liability company agreement of GondolaBio was amended and restated (the "A&R LLC Agreement"). The A&R LLC Agreement sets forth, among other things, the economic and governance rights of the members of GondolaBio, including governance rights, economic preferences, privileges, restrictions and obligations of the members. The change in governance structure and composition of the board of managers was deemed a VIE reconsideration event, and GondolaBio was deemed a VIE. As a result of the change in governance structure and composition of the board of managers, BridgeBio is no longer the primary beneficiary, as it no longer has the power over key decisions that significantly impact GondolaBio's economic performance. Accordingly, BridgeBio deconsolidated GondolaBio, inclusive of Portal Therapeutics, Inc. and Sub21, Inc., on August 16, 2024.

Upon the deconsolidation of GondolaBio, BridgeBio accounted for its investment in GondolaBio, for which it has significant influence through its ownership interest, using the equity method of accounting under ASC 323. GondolaBio was also deemed a related party. For the three and nine months ended September 30, 2026, the Company recognized a net loss from equity method investment of nil and $6.4 million, respectively. For the three and nine months ended September 30, 2025, the Company recognized a net loss from equity method investment of $7.1 million and $23.0 million, respectively. During the three and nine months ended September 30, 2026, the Company's share of GondolaBio's net loss exceeded the carrying value of its investment. Accordingly, the Company recognized losses only to the extent of its investment, and the carrying value of the investment was reduced to zero. As of December 31, 2025, the aggregate carrying amount of the Company's equity method investment in GondolaBio was $6.4 million, and is presented as part of "Equity method investments" on the condensed consolidated balance sheets.

In addition, the Company and GondolaBio ServiceCo, Inc., a wholly-owned subsidiary of GondolaBio, have an existing transition services agreement (the "GondolaBio Transition Services Agreement") for the provision of certain consulting services by the Company and GondolaBio. The Company and GondolaBio are also parties to an agreement for a partial sublease of a facility (the "Sublease Agreement"). Under the GondolaBio Transition Services Agreement and Sublease Agreement, the Company recognized $1.8 million and $6.5 million, respectively, in other income, and $0.6 million and $3.1 million, respectively, of pass-through costs and sublease income recorded as an offset against operating expenses, during the three and nine months ended September 30, 2026. Under the GondolaBio Transition Services Agreement and Sublease Agreement, the Company recognized $3.2 million and $8.6 million, respectively, in other income, and $1.4 million and $4.1 million, respectively, of pass-through costs and sublease income recorded as an offset against operating expenses, during the three and nine months ended September 30, 2025. As of September 30, 2026 and December 31, 2025, the Company had $1.0 million and $4.5 million, respectively, in prepaid expenses and other current assets for consulting services provided by BridgeBio to GondolaBio and for sublease income. The Company also recognized $0.4 million and $0.8 million, respectively, in research and development expenses for the three and nine months ended September 30, 2026 for consulting services provided by GondolaBio to BridgeBio. The Company recognized an immaterial amount and $1.2 million, respectively, in research and development expenses for the three and nine months ended September 30, 2025 for consulting services provided by GondolaBio to BridgeBio. As of September 30, 2026 and December 31, 2025, the Company also had $1.0 million and $1.5 million, respectively, in other current liabilities for consulting services provided by GondolaBio to BridgeBio.

BridgeBio Oncology Therapeutics, Inc.

On April 30, 2024, TheRas, Inc., doing business as BridgeBio Oncology Therapeutics ("Legacy BBOT"), a majority-owned subsidiary of the Company, completed a $200.0 million private equity financing with external investors to accelerate the development of its oncology portfolio. Upon completion of the private equity financing, the Company's ownership of Legacy BBOT's equity was reduced to approximately 37.9%.

As part of the private equity financing transaction, Legacy BBOT's Certificate of Incorporation and Investors' Rights Agreement were amended and restated to reflect a change to BBOT's governance structure and composition of the board of directors, which was determined to be a VIE reconsideration event. Based on the VIE reconsideration assessment, Legacy BBOT was deemed a VIE. As a result of the change in governance structure and composition of the board of directors, BridgeBio was no longer the primary beneficiary of BBOT, as it no longer had the power over key decisions that significantly impact Legacy BBOT's economic performance. Accordingly, BridgeBio deconsolidated Legacy BBOT on April 30, 2024.

Upon the deconsolidation of Legacy BBOT, BridgeBio accounted for its retained investment in Legacy BBOT, for which it has significant influence through its ownership interest, using the equity method of accounting under ASC 323. Legacy BBOT was also deemed a related party.

On February 28, 2025, Legacy BBOT and Helix Acquisition Corp. II ("Helix"), a special purpose acquisition company, entered into a business combination agreement with Helix II Merger Sub, Inc., a Delaware corporation and wholly-owned subsidiary of Helix, and Legacy BBOT. On August 11, 2025, the business combination with Helix closed, and the combined company was renamed "BridgeBio Oncology Therapeutics, Inc." BridgeBio Oncology Therapeutics, Inc. began publicly trading on the Nasdaq Global Market under the ticker symbol "BBOT" on August 12, 2025.

The Company's equity ownership percentage in BBOT was 18.2% as of September 30, 2026. BridgeBio continues to account for its retained investment in BBOT, for which it has significant influence, using the equity method of accounting.

For the three and nine months ended September 30, 2026, we recognized a net loss from equity method investment of $7.1 million and $25.0 million, respectively. For the three and nine months ended September 30, 2025, we recognized a net loss from equity method investment of $8.7 million and $28.6 million, respectively. As of September 30, 2026 and December 31, 2025, the aggregate carrying amount of our equity method investment in BBOT was $47.5 million and $72.5 million, respectively, and is presented as part of "Equity method investments" on our condensed consolidated balance sheets. As of September 30, 2026 and December 31, 2025, the Level 1 fair value of our investment in BBOT was $59.8 million and $182.7 million, respectively, based on the quoted market price of BBOT's common stock as of those reporting dates.

6. Intangible Assets, net

The following table summarizes our recognized intangible assets as a result of the arrangements described in the following sections:

	September 30, 2026		December 31, 2025	
	Weighted-average Estimated Useful Lives	Amount	Weighted-average Estimated Useful Lives	Amount
		(in thousands)		(in thousands)
Gross amount	13.7 years	$ 39,400	13.7 years	$ 39,400
Less accumulated amortization		(13,477)		(11,323)
Total		$ 25,923		$ 28,077

Amortization expense, recorded as part of "Cost of license, services, and royalty revenue" on our condensed consolidated statements of operations, was $0.7 million and $2.1 million for the three and nine months ended September 30, 2026, respectively, and $0.7 million and $2.0 million for the three and nine months ended September 30, 2025, respectively. Estimated future amortization expense is $0.7 million for the remainder of 2026, $2.9 million for each of the years from 2027 to 2031 and $10.7 million thereafter.

7. Commitments and Contingencies

Milestone Compensation Arrangements

We have performance-based milestone compensation arrangements with certain employees, whose vesting is contingent upon meeting various regulatory, development and sales milestones, with fixed monetary amounts known at inception that can be settled in the form of cash or equity at our sole discretion. We also have performance-based milestone compensation arrangements with certain employees and consultants as part of the Company's equity incentive plans. The compensation arrangements under certain equity incentive plans are to be settled in the form of equity only. Performance-based milestone awards that are settled in the form of equity are satisfied in the form of fully-vested common stock. We accrue for such contingent compensation when the related milestone is probable of achievement and is recorded in "Accrued compensation and benefits" for the current portion and in "Other long-term liabilities" for the noncurrent portion on the condensed consolidated balance sheets. There is no accrued compensation expense for performance-based milestone awards that are assessed to be not probable of achievement. The table below shows our commitment for the potential milestone amounts and the accruals for milestones deemed probable of achievement as of September 30, 2026.

Settlement Type	Potential Fixed Monetary Amount [1]	Accrued Amount [2]
	(in thousands)	
Cash	$ 672	$ —
Stock [3]	11,748	—
Cash or stock at our sole discretion	108,451	1,184
Total	$ 120,871	$ 1,184

(1) Potential milestone amounts are presented at the maximum potential amounts payable under the respective agreements.
(2) Amount recorded for performance-based milestone awards that are probable of achievement.
(3) Includes the performance-based milestone awards.

Other Commercial and Research and Development Agreements

We may also enter into contracts in the normal course of business with various counterparties, including vendors for our commercial product and product candidates, contract research organizations for services related to clinical trials, CMOs for clinical supplies, and other vendors for nonclinical studies, supplies, and other operating purposes. These contracts generally provide for termination on notice with potential termination charges. As of September 30, 2026 and December 31, 2025, there were no material amounts accrued related to termination charges.

In the normal course of business, we have also entered into contracts which contain minimum noncancelable purchase commitments and obligations. These include commitments for the supply, manufacturing, and packaging of our commercial product as well as agreements to support the sales and marketing activities for Attruby. As of September 30, 2026, we had minimum noncancelable commitments in an aggregate amount of $159.4 million.

Indemnification

In the ordinary course of business, we may provide indemnifications of varying scope and terms to vendors, lessors, business partners, board members, officers, and other parties with respect to certain matters, including, but not limited to, losses arising out of breach of such agreements, services to be provided by us, our negligence or willful misconduct, violations of law, or intellectual property infringement claims made by third-parties. In addition, we have entered into indemnification agreements with directors and certain officers and employees that will require us, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors, officers, or employees. No material demands have been made upon us to provide indemnification under such agreements, and thus, there are no claims that we are aware of that could have a material effect on our condensed consolidated financial statements.

We also maintain director and officer insurance, which may cover certain liabilities arising from our obligation to indemnify our directors and certain officers. To date, we have not paid any claims related to our indemnification obligations, incurred any material costs and have not accrued any material liabilities on the condensed consolidated financial statements as a result of these provisions.

Contingencies

From time to time, we may become involved in legal proceedings arising in the ordinary course of business. We are not currently a party to any material legal proceedings.

8. Debt

Notes

2027 Notes, net

On March 9, 2020, we issued an aggregate principal amount of $550.0 million of our 2027 Notes, pursuant to an Indenture dated March 9, 2020 (the "2027 Notes Indenture"), between us and U.S. Bank National Association, as trustee (the "2027 Notes Trustee"), in a private offering to qualified institutional buyers (the "2020 Note Offering") pursuant to Rule 144A under the Securities Act. The 2027 Notes issued in the 2020 Note Offering include $75.0 million in aggregate principal amount of 2027 Notes sold to the initial purchasers (the "2027 Notes Initial Purchasers") resulting from the exercise in full of their option to purchase additional 2027 Notes.

The 2027 Notes will accrue interest payable semiannually in arrears on March 15 and September 15 of each year, beginning on September 15, 2020, at a rate of 2.50% per year. The 2027 Notes will mature on March 15, 2027, unless earlier converted or repurchased. The 2027 Notes are convertible into cash, shares of BridgeBio's common stock or a combination of cash and shares of BridgeBio's common stock, at our election.

We received net proceeds from the 2020 Note Offering of approximately $537.0 million, after deducting the 2027 Notes Initial Purchasers' discount and offering expenses. We used approximately $49.3 million of the net proceeds from the 2020 Note Offering to pay for the cost of the 2020 Capped Call Transactions described below, and approximately $75.0 million to pay for the repurchase of shares of BridgeBio's common stock described below.

A holder of 2027 Notes may convert all or any portion of its 2027 Notes at its option at any time prior to the close of business on the business day immediately preceding December 15, 2026 in multiples of $1,000 only under the following circumstances:

- During any calendar quarter commencing after the calendar quarter ending on June 30, 2020 (and only during such calendar quarter), if the last reported sale price of BridgeBio's common stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending on, and including, the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the conversion price on each applicable trading day;
- During the five-business day period after any five consecutive trading day period (the "measurement period") in which the "trading price" (as defined in the 2027 Notes Indenture) per $1,000 principal amount of 2027 Notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price of BridgeBio's common stock and the conversion rate on each such trading day; or
- Upon the occurrence of specified corporate events, as defined in the 2027 Notes Indenture.

The 2027 Notes are convertible for a limited period from October 1, 2026 through December 14, 2026, as an early conversion condition based on the price of BridgeBio's common stock, as described above, was satisfied. On or after December 15, 2026 until the close of business on the second scheduled trading day immediately preceding the maturity date, a holder may convert all or any portion of its 2027 Notes at any time.

The conversion rate will initially be 23.4151 shares of BridgeBio's common stock per $1,000 principal amount of 2027 Notes (equivalent to an initial conversion price of approximately $42.71 per share of BridgeBio's common stock, for a total of approximately 12,878,305 shares).

The conversion rate is subject to adjustment in some events but will not be adjusted for any accrued and unpaid interest. In addition, following certain corporate events that occur prior to the maturity date, we will, in certain circumstances, increase the conversion rate for a holder who elects to convert its 2027 Notes in connection with such a corporate event. The maximum potential number of shares issuable should there be an increase in the conversion rate is 17,707,635 shares of BridgeBio's common stock.

Conversions of the 2027 Notes with a conversion date on or after December 15, 2026 will be settled using the same settlement method. For earlier conversions, we must use the same settlement method for all conversions occurring on the same conversion date, but may use different settlement methods for different conversion dates. Unless we change the default settlement method under the 2027 Notes Indenture, the default settlement method is combination settlement with a specified dollar amount of $1,000 per $1,000 principal amount of the 2027 Notes. If we do not timely elect a settlement method, or if we elect combination settlement but do not specify the specified dollar amount, we will be deemed to have elected the default settlement method.

We may not redeem the 2027 Notes prior to the maturity date, and no sinking fund is provided for the 2027 Notes. If we undergo a fundamental change (as defined in the 2027 Notes Indenture), holders may require us to repurchase for cash all or any portion of their 2027 Notes at a fundamental change repurchase price equal to 100% of the principal amount of the 2027 Notes to be repurchased, plus any accrued and unpaid interest to, but excluding, the fundamental change repurchase date. The 2027 Notes Indenture contains customary terms and covenants, including that upon certain events of default occurring and continuing, either the 2027 Notes Trustee or the holders of not less than 25% in aggregate principal amount of the 2027 Notes then outstanding may declare the entire principal amount of all the 2027 Notes plus accrued special interest, if any, to be immediately due and payable. The 2027 Notes are our general unsecured obligations and rank senior in right of payment to all of our indebtedness that is expressly subordinated in right of payment to the 2027 Notes; equal in right of payment with all of BridgeBio's liabilities that are not so subordinated, including our 2029 Notes, 2031 Notes and 2033 Notes; effectively junior to any of BridgeBio's secured indebtedness to the extent of the value of the assets securing such indebtedness; and structurally junior to all indebtedness and other liabilities (including trade payables) of our subsidiaries.

In connection with the issuance of the 2027 Notes, we incurred approximately $13.0 million of debt issuance costs, which primarily consisted of initial purchasers' discounts and legal and other professional fees. This was recorded as a reduction in the carrying value of the debt on the condensed consolidated balance sheets and is amortized to interest expense using the effective interest method over the expected life of the 2027 Notes, which is approximately seven years.

The 2027 Notes, which mature on March 15, 2027, were classified as current liabilities as of September 30, 2026.

2029 Notes, net

On January 28, 2021, we issued an aggregate of $717.5 million principal amount of our 2029 Notes pursuant to an Indenture dated January 28, 2021 (the "2029 Notes Indenture"), between us and U.S. Bank National Association, as trustee (the "2029 Notes Trustee"), in a private offering to qualified institutional buyers (the "2021 Note Offering") pursuant to Rule 144A under the Securities Act. The 2029 Notes issued in the 2021 Note Offering include $67.5 million aggregate principal amount of 2029 Notes sold to the initial purchasers (the "2029 Notes Initial Purchasers") pursuant to the exercise in part of the 2029 Notes Initial Purchasers' option to purchase $97.5 million principal amount of additional 2029 Notes. On January 28, 2021, the 2029 Notes Initial Purchasers exercised the remaining portion of their option to purchase $30.0 million principal amount of additional 2029 Notes. The sale of those additional 2029 Notes closed on February 2, 2021, which resulted in the total aggregate principal amount of $747.5 million.

The 2029 Notes are senior, unsecured obligations of BridgeBio and will accrue interest payable semiannually in arrears on February 1 and August 1 of each year, beginning on August 1, 2021, at a rate of 2.25% per year. The 2029 Notes will mature on February 1, 2029, unless earlier converted, redeemed or repurchased. The 2029 Notes are convertible into cash, shares of BridgeBio's common stock or a combination of cash and shares of BridgeBio's common stock, at our election.

We received net proceeds from the 2021 Note Offering of approximately $731.4 million, after deducting the 2029 Notes Initial Purchasers' discount (there were no direct offering expenses borne by us for the 2029 Notes). We used approximately $61.3 million of the net proceeds from the 2021 Note Offering to pay for the cost of the 2021 Capped Call Transactions described below and approximately $50.0 million to pay for the repurchase of shares of BridgeBio's common stock described below.

A holder of 2029 Notes may convert all or any portion of its 2029 Notes at its option at any time prior to the close of business on the business day immediately preceding November 1, 2028 in multiples of $1,000 only under the following circumstances:

- During any calendar quarter commencing after the calendar quarter ending on June 30, 2021 (and only during such calendar quarter), if the last reported sale price of BridgeBio's common stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending on, and including, the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the conversion price on each applicable trading day;
- During the five-business day period after any five consecutive trading day period (the "measurement period") in which the "trading price" (as defined in the 2029 Notes Indenture) per $1,000 principal amount of 2029 Notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price of BridgeBio's common stock and the conversion rate on each such trading day;
- If we call such notes for redemption, at any time prior to the close of business on the second business day immediately preceding the redemption date; or
- Upon the occurrence of specified corporate events, as defined in the 2029 Notes Indenture.

On or after November 1, 2028 until the close of business on the second scheduled trading day immediately preceding the maturity date, a holder may convert all or any portion of its 2029 Notes at any time, regardless of the foregoing.

The conversion rate will initially be 10.3050 shares of BridgeBio's common stock per $1,000 principal amount of 2029 Notes (equivalent to an initial conversion price of approximately $97.04 per share of BridgeBio's common stock, for a total of approximately 7,702,988 shares).

The conversion rate is subject to adjustment in some events but will not be adjusted for any accrued and unpaid interest. In addition, following certain corporate events that occur prior to the maturity date or if we deliver a notice of redemption, we will, in certain circumstances, increase the conversion rate for a holder who elects to convert its 2029 Notes in connection with such a corporate event. The maximum potential number of shares issuable should there be an increase in the conversion rate is 11,361,851 shares of BridgeBio's common stock.

We may not redeem the 2029 Notes prior to February 6, 2026. We may redeem for cash all or any portion of the 2029 Notes, at our option, on a redemption date occurring on or after February 6, 2026 and on or before the 41st scheduled trading day immediately before the maturity date, under certain circumstances. No sinking fund is provided for the 2029 Notes. If we undergo a fundamental change (as defined in the 2029 Notes Indenture), holders may require us to repurchase for cash all or any portion of their 2029 Notes at a fundamental change repurchase price equal to 100% of the principal amount of the 2029 Notes to be repurchased, plus any accrued and unpaid interest to, but excluding, the fundamental change repurchase date. The 2029 Notes Indenture contains customary terms and covenants, including that upon certain events of default occurring and continuing, either the 2029 Notes Trustee or the holders of not less than 25% in aggregate principal amount of the 2029 Notes then outstanding may declare the entire principal amount of all the 2029 Notes plus accrued special interest, if any, to be immediately due and payable. The 2029 Notes are our general unsecured obligations and rank senior in right of payment to all of our indebtedness that is expressly subordinated in right of payment to the 2029 Notes; equal in right of payment with all of our liabilities that are not so subordinated, including our 2027 Notes, 2031 Notes and 2033 Notes; effectively junior to any of our secured indebtedness to the extent of the value of the assets securing such indebtedness; and structurally junior to all indebtedness and other liabilities (including trade payables) of our subsidiaries.

In connection with the issuance of the 2029 Notes, we incurred approximately $16.1 million of debt issuance costs, which consisted of initial purchasers' discounts. This was recorded as a reduction in the carrying value of the debt on the condensed consolidated balance sheets and is amortized to interest expense using the effective interest method over the expected life of the 2029 Notes, which is approximately eight years.

As of September 30, 2026, the 2029 Notes were not convertible pursuant to their terms.

2031 Notes, net

On February 28, 2025, we issued an aggregate of $575.0 million principal amount of our 2031 Notes pursuant to an Indenture dated February 28, 2025 (the "2031 Notes Indenture"), between us and U.S. Bank Trust Company, National Association, as trustee (the "2031 Notes Trustee"), in a private offering to qualified institutional buyers (the "2025 Note Offering") pursuant to Rule 144A under the Securities Act. The 2031 Notes issued in the 2025 Note Offering include $75.0 million aggregate principal amount of 2031 Notes sold to the initial purchasers of the 2031 Notes (the "2031 Notes Initial Purchasers") pursuant to the exercise in full of the 2031 Notes Initial Purchasers' option to purchase additional 2031 Notes.

The 2031 Notes are senior, unsecured obligations of BridgeBio and will accrue interest payable semiannually in arrears on March 1 and September 1 of each year, beginning on September 1, 2025, at a rate of 1.75% per year. The 2031 Notes will mature on March 1, 2031, unless earlier converted, redeemed or repurchased. The 2031 Notes are convertible into cash, shares of BridgeBio's common stock or a combination of cash and shares of BridgeBio's common stock, at our election.

We received net proceeds from the 2025 Note Offering of approximately $563.0 million, after deducting the 2031 Notes Initial Purchasers' discount and offering costs. We used approximately $48.3 million of the net proceeds from the 2025 Note Offering to pay for the repurchase of shares of BridgeBio's common stock as described below and used a portion of the net proceeds from the 2025 Note Offering to repay all outstanding borrowings under, and terminate, the Financing Agreement, as defined below, and pay any fees related thereto.

A holder of 2031 Notes may convert all or any portion of its 2031 Notes at its option at any time prior to the close of business on the business day immediately preceding December 2, 2030, in multiples of $1,000 only under the following circumstances:

- During any calendar quarter commencing after the calendar quarter ending on June 30, 2025 (and only during such calendar quarter), if the last reported sale price of BridgeBio's common stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending on, and including, the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the conversion price on each applicable trading day;
- During the five-business day period after any five consecutive trading day period (the "measurement period") in which the "trading price" (as defined in the 2031 Notes Indenture) per $1,000 principal amount of 2031 Notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price of BridgeBio's common stock and the conversion rate on each such trading day;
- If we call such notes for redemption, at any time prior to the close of business on the second business day immediately preceding the redemption date; or
- Upon the occurrence of specified corporate events, as defined in the 2031 Notes Indenture.

On or after December 2, 2030 until the close of business on the second scheduled trading day immediately preceding the maturity date, a holder may convert all or any portion of its 2031 Notes at any time, regardless of the foregoing.

The conversion rate will initially be 20.0773 shares of BridgeBio's common stock per $1,000 principal amount of 2031 Notes (equivalent to an initial conversion price of approximately $49.81 per share of BridgeBio's common stock, for a total of approximately 11,544,448 shares).

The conversion rate is subject to adjustment in some events but will not be adjusted for any accrued and unpaid interest. In addition, following certain corporate events that occur prior to the maturity date or if we deliver a notice of redemption, we will, in certain circumstances, increase the conversion rate for a holder who elects to convert its 2031 Notes in connection with such a corporate event. The maximum potential number of shares issuable should there be an increase in the conversion rate is 16,739,400 shares of BridgeBio's common stock.

We may not redeem the 2031 Notes prior to March 6, 2028. We may redeem for cash all or any portion of the 2031 Notes, at our option, on a redemption date occurring on or after March 6, 2028 and on or before the 41st scheduled trading day immediately before the maturity date, under certain circumstances. No sinking fund is provided for the 2031 Notes. If we undergo a fundamental change (as defined in the 2031 Notes Indenture), holders may require us to repurchase for cash all or any portion of their 2031 Notes at a fundamental change repurchase price equal to 100% of the principal amount of the 2031 Notes to be repurchased, plus any accrued and unpaid interest to, but excluding, the fundamental change repurchase date. The 2031 Notes Indenture contains customary terms and covenants, including that upon certain events of default occurring and continuing, either the 2031 Notes Trustee or the holders of not less than 25% in aggregate principal amount of the 2031 Notes then outstanding may declare the entire principal amount of all the 2031 Notes plus accrued special interest, if any, to be immediately due and payable. The 2031 Notes are our general unsecured obligations and rank senior in right of payment to all of our indebtedness that is expressly subordinated in right of payment to the 2031 Notes; equal in right of payment with all of our liabilities that are not so subordinated, including our 2027 Notes, 2029 Notes and 2033 Notes; effectively junior to any of our secured indebtedness to the extent of the value of the assets securing such indebtedness; and structurally junior to all indebtedness and other liabilities (including trade payables) of our subsidiaries.

In connection with the issuance of the 2031 Notes, we incurred approximately $12.0 million of debt issuance costs, which consisted of initial purchasers' discounts, legal and professional fees. This was recorded as a reduction in the carrying value of the debt on the condensed consolidated balance sheets and is amortized to interest expense using the effective interest method over the expected life of the 2031 Notes, which is approximately six years.

The 2031 Notes are convertible for a limited period from October 1, 2026 through December 31, 2026, as an early conversion condition based on the price of BridgeBio's common stock, as described above, was satisfied. Notwithstanding the satisfaction of this conversion condition, the 2031 Notes were classified as noncurrent liabilities as of September 30, 2026 because we have the ability to settle any conversions in shares of BridgeBio's common stock, as permitted under the terms of the 2031 Notes Indenture.

2033 Notes, net

On January 21, 2026, we issued an aggregate of $632.5 million principal amount of our 0.75% Convertible Senior Notes due 2033 (the "2033 Notes"), pursuant to an Indenture dated January 21, 2026 (the "2033 Notes Indenture"), between us and U.S. Bank Trust Company, National Association, as trustee (the "2033 Notes Trustee"), in a private offering to qualified institutional buyers (the "2026 Note Offering") pursuant to Rule 144A under the Securities Act of 1933, as amended (the "Securities Act"). The 2033 Notes issued in the 2026 Note Offering include $82.5 million aggregate principal amount of 2033 Notes sold to the initial purchasers of the 2033 Notes (the "2033 Notes Initial Purchasers") pursuant to the exercise in full of the 2033 Notes Initial Purchasers' option to purchase additional 2033 Notes.

The 2033 Notes are senior, unsecured obligations of BridgeBio and accrue interest payable semiannually in arrears on February 1 and August 1 of each year, beginning on August 1, 2026, at a rate of 0.75% per year. The 2033 Notes will mature on February 1, 2033, unless earlier converted, redeemed or repurchased. The 2033 Notes are convertible into cash, shares of BridgeBio's common stock or a combination of cash and shares of BridgeBio's common stock, at our election.

We received net proceeds from the 2026 Note Offering of approximately $619.3 million, after deducting the 2033 Notes Initial Purchasers' discount and offering costs. We used approximately $82.5 million of the net proceeds from the 2026 Note Offering to pay for the repurchase of 1,081,825 shares of BridgeBio's common stock from certain purchasers of the 2033 Notes in privately negotiated transactions. We intend to use the remainder of the net proceeds from the 2026 Note Offering to settle future conversion obligations in respect of or repay at maturity a portion of our 2027 Notes, on or before the maturity date of the 2027 Notes and for general corporate purposes, which may include working capital, capital expenditures and/or debt repayment.

A holder of 2033 Notes may convert all or any portion of its 2033 Notes at its option at any time prior to the close of business on the business day immediately preceding November 1, 2032 only under the following circumstances:

- During any calendar quarter commencing after the calendar quarter ending on March 31, 2026 (and only during such calendar quarter), if the last reported sale price of the common stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending on, and including, the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the conversion price on each applicable trading day;

- During the five business day period after any five consecutive trading day period (the "measurement period") in which the "trading price" (as defined in the 2033 Notes Indenture) per $1,000 principal amount of notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price of our common stock and the conversion rate on each such trading day;
- If we call such notes for redemption, at any time prior to the close of business on the second business day immediately preceding the redemption date; or
- Upon the occurrence of specified corporate events, as defined in the 2033 Notes Indenture.

On or after November 1, 2032 until the close of business on the second scheduled trading day immediately preceding the maturity date, a holder may convert all or any portion of its notes at any time, regardless of the foregoing circumstances.

The conversion rate will initially be 9.0435 shares of BridgeBio's common stock per $1,000 principal amount of 2033 Notes (equivalent to an initial conversion price of approximately $110.58 per share of BridgeBio's common stock, for a total of approximately 5,720,014 shares).

The conversion rate is subject to adjustment in some events but will not be adjusted for any accrued and unpaid interest. In addition, following certain corporate events that occur prior to the maturity date, we will, in certain circumstances, increase the conversion rate for a holder who elects to convert its 2033 Notes in connection with such a corporate event. The maximum potential number of shares issuable should there be an increase in the conversion rate is 8,293,973 shares of BridgeBio's common stock.

We may not redeem the 2033 Notes prior to February 6, 2030. We may redeem for cash all or any portion of the 2033 Notes, at our option, on a redemption date occurring on or after February 6, 2030 and on or before the 21st scheduled trading day immediately before the maturity date, under certain circumstances. No sinking fund is provided for the 2033 Notes. If we undergo a fundamental change (as defined in the 2033 Notes Indenture), holders may require us to repurchase for cash all or any portion of their 2033 Notes at a fundamental change repurchase price equal to 100% of the principal amount of the 2033 Notes to be repurchased, plus any accrued and unpaid interest to, but excluding, the fundamental change repurchase date. The 2033 Notes Indenture contains customary terms and covenants, including that upon certain events of default occurring and continuing, either the 2033 Notes Trustee or the holders of not less than 25% in aggregate principal amount of the 2033 Notes then outstanding may declare the entire principal amount of all the 2033 Notes plus accrued special interest, if any, to be immediately due and payable. The 2033 Notes are our general unsecured obligations and rank senior in right of payment to all of our indebtedness that is expressly subordinated in right of payment to the 2033 Notes; equal in right of payment with all of our liabilities that are not so subordinated, including our 2027 Notes, 2029 Notes and 2031 Notes; effectively junior to any of our secured indebtedness and obligations, including our obligations under our Funding Agreement (refer to Note 9), to the extent of the value of the assets securing such indebtedness; and structurally junior to all indebtedness and other liabilities (including trade payables) of our subsidiaries, including obligations under our Royalty Purchase Agreement (refer to Note 9).

In connection with the issuance of the 2033 Notes, we incurred approximately $13.2 million of debt issuance costs, which consisted of the 2033 Notes Initial Purchasers' discounts, legal and professional fees. This was recorded as a reduction in the carrying value of the debt on the condensed consolidated balance sheets and is amortized to interest expense using the effective interest method over the expected life of the 2033 Notes, which is approximately seven years.

As of September 30, 2026, the 2033 Notes were not convertible pursuant to their terms.

Additional Information Related to the Notes

The outstanding Notes' balances consisted of the following:

	September 30, 2026			
	2027 Notes	2029 Notes	2031 Notes	2033 Notes
	(in thousands)			
Principal	$ 550,000	$ 747,500	$ 575,000	$ 632,500
Unamortized debt discount and issuance costs	(1,570)	(5,063)	(8,987)	(11,967)
Net carrying amount	$ 548,430	$ 742,437	$ 566,013	$ 620,533

BRIDGEBIO PHARMA, INC.

Notes to Condensed Consolidated Financial Statements
(Unaudited)

	December 31, 2025		
	2027 Notes	2029 Notes	2031 Notes
	(in thousands)		
Principal	$ 550,000	$ 747,500	$ 575,000
Unamortized debt discount and issuance costs	(2,985)	(6,610)	(10,435)
Net carrying amount	$ 547,015	$ 740,890	$ 564,565

The following table sets forth the total interest expense recognized and effective interest rates related to the Notes for the periods presented:

	Three Months Ended September 30, 2026				
	2027 Notes	2029 Notes	2031 Notes	2033 Notes	Total
			(in thousands)		
Contractual interest expense	$ 3,437	$ 4,204	$ 2,515	$ 1,172	$ 11,328
Amortization of debt discount and issuance costs	475	519	485	446	1,925
Total interest and amortization expense	$ 3,912	$ 4,723	$ 3,000	$ 1,618	$ 13,253
Effective interest rate	2.8%	2.6%	2.1%	1.0%	

	Three Months Ended September 30, 2025			
	2027 Notes	2029 Notes	2031 Notes	Total
		(in thousands)		
Contractual interest expense	$ 3,438	$ 4,205	$ 2,600	$ 10,243
Amortization of debt discount and issuance costs	462	506	490	1,458
Total interest and amortization expense	$ 3,900	$ 4,711	$ 3,090	$ 11,701
Effective interest rate	2.8%	2.6%	2.1%	

	Nine Months Ended September 30, 2026				
	2027 Notes	2029 Notes	2031 Notes	2033 Notes	Total
			(in thousands)		
Contractual interest expense	$ 10,312	$ 12,613	$ 7,546	$ 3,294	$ 33,765
Amortization of debt discount and issuance costs	1,415	1,547	1,448	1,260	5,670
Total interest and amortization expense	$ 11,727	$ 14,160	$ 8,994	$ 4,554	$ 39,435
Effective interest rate	2.8%	2.6%	2.1%	1.0%	

	Nine Months Ended September 30, 2025			
	2027 Notes	2029 Notes	2031 Notes	Total
		(in thousands)		
Contractual interest expense	$ 10,313	$ 12,614	$ 5,954	$ 28,881
Amortization of debt discount and issuance costs	1,377	1,508	1,121	4,006
Total interest and amortization expense	$ 11,690	$ 14,122	$ 7,075	$ 32,887
Effective interest rate	2.8 %	2.6 %	2.1 %	

Interest payable on the Notes is included in “Other current liabilities” on our condensed consolidated balance sheets and consisted of the following balances:

BRIDGEBIO PHARMA, INC.

Notes to Condensed Consolidated Financial Statements
(Unaudited)

	September 30, 2026	December 31, 2025
	(in thousands)	
2027 Notes	$ 610	$ 4,049
2029 Notes	2,803	7,008
2031 Notes	839	3,354
2033 Notes	791	—
Total	$ 5,043	$ 14,411

Future minimum payments under the Notes as of September 30, 2026 are as follows:

	2027 Notes	2029 Notes	2031 Notes	2033 Notes	Total
			(in thousands)		
Year ending December 31:					
2027	$ 556,875	$ 16,819	$ 10,063	$ 4,744	$ 588,501
2028	—	16,819	10,063	4,744	31,626
2029	—	755,909	10,063	4,744	770,716
2030	—	—	10,063	4,744	14,807
2031	—	—	580,031	4,744	584,775
Thereafter	—	—	—	639,629	639,629
Total future payments	556,875	789,547	620,283	663,349	2,630,054
Less amounts representing interest	(6,875)	(42,047)	(45,283)	(30,849)	(125,054)
Total principal amount	$ 550,000	$ 747,500	$ 575,000	$ 632,500	$ 2,505,000

Capped Call Transactions with Respect to the 2029 Notes and 2027 Notes

On each of January 25, 2021 and March 4, 2020, concurrently with the pricing of the 2029 Notes and 2027 Notes, respectively, we entered into separate privately negotiated capped call transactions (the "2021 Capped Call Transactions" and the "2020 Capped Call Transactions," respectively), or, together, the Capped Call Transactions, with certain financial institutions (the "Capped Call Counterparties"). We used approximately $61.3 million and $49.3 million of the net proceeds from the 2021 Note Offering and 2020 Note Offering, respectively, to pay for the cost of the respective Capped Call Transactions. The Capped Call Transactions are expected generally to reduce the potential dilution to BridgeBio's common stock upon any conversion of Notes and/or offset any cash payments we are required to make in excess of the principal amount of converted 2029 Notes and 2027 Notes, as the case may be, with such reduction and/or offset subject to a cap initially equal to $131.58 for the 2021 Capped Call Transactions and $62.12 for the 2020 Capped Call Transactions (both of which represented a premium of 100% over the last reported sale price of BridgeBio's common stock on the date of the Capped Call Transactions) and are subject to certain adjustments under the terms of the Capped Call Transactions. The 2021 Capped Calls and 2020 Capped Calls cover 7,702,988 shares and 12,878,305 shares, respectively, of our common stock (subject to anti-dilution and certain other adjustments), which are the same number of shares of common stock that initially underlie the 2029 Notes and 2027 Notes. The 2021 Capped Calls have an initial strike price of approximately $97.04 per share, which corresponds to the initial conversion price of the 2029 Notes. The 2020 Capped Calls have an initial strike price of approximately $42.71 per share, which corresponds to the initial conversion price of the 2027 Notes. The Capped Call Transactions are separate transactions, entered into by us with the Capped Call Counterparties, and are not part of the terms of the 2029 Notes and 2027 Notes.

These Capped Call instruments meet the conditions outlined in ASC 815-40, to be classified in stockholders' deficit and are not subsequently remeasured as long as the conditions for equity classification continue to be met. We recorded a total reduction to additional paid-in capital of approximately $110.6 million related to the premium payments for the Capped Call Transactions.

Share Repurchase Transactions with Respect to the Notes

In connection with each of the above Notes offerings, we used a portion of the net proceeds to repurchase shares of our common stock concurrently with the closing of each respective offering in privately negotiated transactions with certain of the applicable Initial Purchasers, at a purchase price equal to the last reported sale price of our common stock on the Nasdaq Global Select Market on the applicable pricing date as follows:

Date of Repurchase	Note Offering	Net Proceeds Used (in thousands)	Shares Repurchased	Agreed-upon Purchase Price per Share
March 4, 2020	2020 Note Offering	$ 75,000	2,414,681	$ 31.06
January 25, 2021	2021 Note Offering	$ 50,000	759,993	$ 65.79
February 25, 2025	2025 Note Offering	$ 48,276	1,405,411	$ 34.35
January 15, 2026	2026 Note Offering	$ 82,500	1,081,825	$ 76.26

The shares repurchased were recorded as "Treasury stock" on our condensed consolidated balance sheets and statements of redeemable convertible noncontrolling interests and stockholders' deficit.

Term Loan, net

Financing Agreement

In January 2024, the Company and certain guarantors entered into a Financing Agreement with the lenders party thereto and Blue Owl Capital Corporation, as administrative agent, which was amended in February 2024 and June 2024 (the "Amended Financing Agreement"). The Amended Financing Agreement provided for a senior secured credit facility with aggregate commitments of up to $750.0 million, consisting of a $450.0 million initial term loan and up to $300.0 million of incremental term loans. In January 2024, the Company received net proceeds of $434.0 million from the initial term loan after deducting debt discount and issuance costs.

On February 28, 2025, the Company fully repaid the Amended Financing Agreement for $467.0 million using the proceeds from the 2031 Notes and recognized a loss on extinguishment of debt of $21.2 million. From January 1, 2025 to February 28, 2025, we recognized interest expense related to the Amended Financing Agreement of $8.5 million of which $0.5 million relates to amortization of debt discount and issuance costs.

9. Deferred Royalty Obligations, net

Royalty Interest Purchase and Sale Agreement

On June 27, 2025 (the "Closing Date"), the Company and its subsidiary, Eidos Therapeutics, Inc. ("Eidos"), entered into a Royalty Interest Purchase and Sale Agreement (the "Royalty Purchase Agreement") with Acoramidis Royalty SPV, LP ("ARS"), an affiliate of HealthCare Royalty Management, LLC ("HCRx"), as a purchaser and the purchaser representative (in such capacity, the "Purchaser Representative"), and LSI Financing Fund, LP, an affiliate of Blue Owl Capital Corporation, as a purchaser (together with ARS as a purchaser and any future permitted assignees of a purchaser, the "Royalty Agreement Purchasers"). Subsequent to the Closing Date, on July 30, 2025, KKR & Co. Inc. ("KKR") acquired a majority ownership interest in HCRx. At that time, KKR beneficially owned more than five percent of the Company's outstanding common stock, and HCRx accordingly became a related party. On August 17, 2026, KKR sold a portion of its shares of our common stock and is no longer a beneficial owner of more than five percent of our outstanding shares of common stock. Accordingly, KKR and HCRx ceased to be related parties of the Company as of August 17, 2026.

Pursuant to the Royalty Purchase Agreement, Eidos sold to the Royalty Agreement Purchasers certain of Eidos' right to receive certain royalty payments ("Purchased Royalty Payment") on net sales of certain products containing acoramidis (the "Licensed Products") made in the EU and all member and extension states of the European Patent Organization (the "Licensed Territory") under (i) an exclusive license agreement, dated as of March 1, 2024, by and among Bayer (as described in Note 10), Eidos and the other subsidiaries of the Company party thereto, as amended from time to time (the "Bayer License Agreement") and (ii) an amended and restated license agreement, effective as of June 30, 2023, by and between Eidos and one of the other Company's subsidiaries, BridgeBio International GmbH. As consideration for the sale of the Purchased Royalty Payment, the Royalty Agreement Purchasers agreed to pay Eidos $300.0 million in cash (the "Purchase Price"), which was funded in full on the Closing Date. The Royalty Agreement Purchasers' rights to the Purchased Royalty Payment are subject to (a) an annual cap equal to 60% of all royalty payments paid by Bayer to Eidos and its affiliates under the Bayer License Agreement on the first $500.0 million of annual net sales of Licensed Products in the Licensed Territory under the Bayer License Agreement and (b) an initial hard cap equal to 145% of the Purchase Price.

In addition, the Company and Eidos granted the Purchaser Representative, for the benefit of the Royalty Agreement Purchasers, a security interest in specific assets related to the Purchased Royalty Payment. The Royalty Purchase Agreement also contains certain representations and warranties, indemnification obligations, events of default and other provisions that are customary for transactions of this nature.

Upon the occurrence of a change of control of the Company, the successor entity has an option to either (a) assume the obligations of the Company and/or Eidos under the Royalty Purchase Agreement or (b) pay the Royalty Agreement Purchasers an amount equal to the then-applicable hard cap, less total payments already made to the Royalty Agreement Purchasers, plus any other amounts payable under the Royalty Purchase Agreement (the "Change of Control Payment"), upon payment of which no further payments will be due to the Royalty Agreement Purchasers or the Purchaser Representative under the Royalty Purchase Agreement.

If an event of default occurs and is continuing, Eidos is required to immediately pay the Change of Control Payment to the Royalty Agreement Purchasers.

We have evaluated the terms of the Royalty Purchase Agreement and concluded that the features are similar to those of a debt instrument. Accordingly, we have accounted for the transaction as long-term debt, with the short-term portion presented as part of "Other current liabilities" and the long-term portion presented as part of "Deferred royalty obligations, net" on our condensed consolidated balance sheets. We recognized net cash proceeds of $297.0 million in June 2025, after deducting debt issuance costs of $3.0 million.

Funding Agreement

On January 17, 2024, the Company and its subsidiaries, Eidos, BridgeBio Europe B.V. and BridgeBio International GmbH (collectively, the "Seller Parties"), entered into a Funding Agreement (the "Funding Agreement") with LSI Financing 1 Designated Activity Company and CPPIB Credit Europe S.à r.l. (together and with any future permitted assignees of a seller party, the "Funding Agreement Purchasers"), and Alter Domus (US) LLC, as the collateral agent.

Pursuant to the Funding Agreement, the Funding Agreement Purchasers agreed to pay to the Company $500.0 million (net of certain transaction expenses) (the "Investment Amount") upon the first FDA approval of acoramidis, subject to certain conditions relating to the FDA approval and other customary conditions (such date of payment, the "Funding Date").

In return, the Company granted the Funding Agreement Purchasers the right to receive payments (the "Royalty Interest Payments") equal to 5% of the global net sales of acoramidis (the "Net Sales"). Under certain conditions relating to the sales performance of acoramidis, the rate of the Royalty Interest Payments may adjust to a maximum rate of 10% in 2027. Each Royalty Interest Payment will become payable to the Funding Agreement Purchasers on a quarterly basis after the Funding Date. In addition, the Seller Parties granted the collateral agent, for the benefit of the Funding Agreement Purchasers, a security interest in specific assets related to acoramidis.

The Funding Agreement Purchasers' rights to the Royalty Interest Payments and ownership interest in Net Sales will terminate upon the earlier of the Funding Agreement Purchasers' receipt of (a) Royalty Interest Payments equal to $950.0 million (the "Cap Amount") and (b) a buy-out payment (the "Buy-Out Payment") in an amount determined in accordance with the Funding Agreement but that will not exceed the Cap Amount. In the event that a change of control (as customarily defined in the Funding Agreement) occurs on or after the effective date of the Funding Agreement, the Purchasers may elect to require the Seller Parties to make the Buy-Out Payment and the Funding Agreement will be terminated upon payment in-full of the Seller Parties' obligations under the Funding Agreement (including the Buy-Out Payment and all reimbursable expenses). The Funding Agreement will also terminate upon customary events.

Under the Funding Agreement, the Seller Parties are required to comply with various covenants, including using commercially reasonable efforts to obtain regulatory approval for and commercialize acoramidis, providing the Funding Agreement Purchasers with certain clinical, commercial, regulatory and intellectual property updates and certain financial statements, and providing notices upon the occurrence of certain events, each as agreed under the Funding Agreement. The Funding Agreement also contains certain representations and warranties, indemnification obligations, put-option events and other provisions that are customary for transactions of this nature.

Following the FDA approval of Attruby in November 2024, the Company received gross proceeds of $500.0 million under the Funding Agreement in December 2024.

We have evaluated the terms of the Funding Agreement and concluded that the features are similar to those of a debt instrument. Accordingly, we have accounted for the transaction as long-term debt and presented it as part of "Deferred royalty obligations, net" on our condensed consolidated balance sheets. The Company recognized net cash proceeds of $472.5 million in December 2024, after deducting debt discount and issuance costs paid in cash of $27.5 million.

We have further evaluated the terms of the Funding Agreement and determined that the repayment of the Cap Amount of $950.0 million, less any payments made to date, upon a change of control is an embedded derivative that requires bifurcation from the debt instrument and fair value recognition. We determined the fair value of the derivative using an option pricing Monte Carlo simulation model taking into account the probability of change of control occurring and potential repayment amounts and timing of such payments would result under various scenarios as further described in Note 3. The aggregate fair value of the embedded derivative liability was $14.3 million and $21.4 million as of September 30, 2026 and December 31, 2025, respectively. We remeasure the embedded derivative to fair value each reporting period until the time the features lapse and/or termination of the deferred royalty obligation.

In connection with the Royalty Purchase Agreement described above, the Funding Agreement was amended on June 27, 2025. All terms and conditions of the Funding Agreement remain substantially unchanged.

Additional Information Related to the Deferred Royalty Obligations, net

The carrying value balances of our deferred royalty obligations, net under the Funding Agreement and the Royalty Purchase Agreement consisted of the following:

	September 30, 2026		
	Funding Agreement	Royalty Purchase Agreement	Total
		(in thousands)	
Carrying value of deferred royalty obligations, net	$ 605,351	$ 308,542	$ 913,893
Fair value of embedded derivative liability	14,341	—	14,341
Unamortized debt discount and issuance costs	(42,072)	(2,109)	(44,181)
Deferred royalty obligations, net	$ 577,620	$ 306,433	$ 884,053

	December 31, 2025		
	Funding Agreement	Royalty Purchase Agreement (1)	Total
		(in thousands)	
Carrying value of deferred royalty obligations, net	$ 581,759	$ 309,629	$ 891,388
Fair value of embedded derivative liability	21,439	—	21,439
Unamortized debt discount and issuance costs	(55,143)	(2,654)	(57,797)
Deferred royalty obligations, net	$ 548,055	$ 306,975	$ 855,030

(1) Including related party amounts of $206,419 for the carrying value of deferred royalty obligations, net and $(1,769) for the unamortized debt discount and issuance costs as of December 31, 2025.

Noncash interest expense under the Funding Agreement and Royalty Purchase Agreement is determined using the effective interest method, as described in Note 2. The effective interest rate for each instrument is derived by estimating the total expected royalty payments over the life of the arrangement based on projected future net product sales of acoramidis and the estimated timing of cap amount achievement, and solving for the rate that equates the present value of those projected payments to the initial carrying value. The effective interest rate is reassessed at each reporting period end, with changes in projected net sales or estimated repayment timing accounted for utilizing the prospective method.

The effective interest rate as of September 30, 2026 and December 31, 2025 was 22.2% and 22.2%, respectively, for the Funding Agreement. For the three and nine months ended September 30, 2026, we recognized noncash interest expense related to the Funding Agreement of $33.7 million and $98.5 million, respectively, of which $4.4 million and $13.0 million, respectively, relates to amortization of debt discount and issuance costs. For the three and nine months ended September 30, 2025, we recognized noncash interest expense related to the Funding Agreement of $28.3 million and $78.2 million, respectively, of which $3.7 million and $10.0 million, respectively, relate to amortization of debt discount and issuance costs. As of September 30, 2026 and December 31, 2025, the current portion of the deferred royalty obligation related to the Funding Agreement of $24.6 million and $8.2 million, respectively, is presented within “Other current liabilities” on our condensed consolidated balance sheets.

The effective interest rate as of September 30, 2026 and December 31, 2025 was 11.2% and 10.4%, respectively, for the Royalty Purchase Agreement. For the three and nine months ended September 30, 2026, we recognized noncash interest expense related to the Royalty Purchase Agreement of $8.6 million and $25.0 million, respectively, of which $0.2 million and $0.6 million, respectively, relates to amortization of debt discount and issuance costs. For the three and nine months ended September 30, 2025, we recognized noncash interest expense related to the Royalty Purchase Agreement of $8.1 million and $8.3 million, respectively, of which $0.2 million and $0.2 million, respectively, relates to amortization of debt discount and issuance costs. As of September 30, 2026 and December 31, 2025, the current portion of the deferred royalty obligation related to the Royalty Purchase Agreement of $11.5 million and $3.0 million, respectively, is presented within “Other current liabilities” on our condensed consolidated balance sheets.

10. License and Collaboration Agreements

Bayer Exclusive License

On March 1, 2024, certain subsidiaries of the Company, including Eidos, BridgeBio International GmbH and BridgeBio Europe B.V. (collectively, the “Seller Parties”), entered into an exclusive license agreement (the “Bayer License Agreement”) with Bayer Consumer Care AG, a wholly-owned subsidiary of Bayer AG (“Bayer”), to develop and commercialize acoramidis as a treatment for transthyretin amyloidosis in the EU and all member and extension states of the European Patent Organization (the “Licensed Territory”).

Under the terms of the Bayer License Agreement, the Seller Parties granted Bayer an exclusive license on March 26, 2024 to certain of the Seller Parties’ intellectual property rights to develop, manufacture and commercialize acoramidis (previously known as AG10) in the Licensed Territory. In consideration for the license grant, the Seller Parties are entitled to receive an upfront payment of $135.0 million, up to $150.0 million in regulatory and sales milestone payments through 2026, and additional payments up to $450.0 million subject to the achievement of certain sales milestones under the Bayer License Agreement. To date, the upfront payment and the regulatory and sales milestones achieved under the Bayer License Agreement total $285.0 million. In addition, the Seller Parties are entitled to receive royalties according to a tiered structure starting in the low-thirties percent on net sales by Bayer of acoramidis in the Licensed Territory, subject to reduction under certain circumstances as provided in the Bayer License Agreement.

Unless earlier terminated, the Bayer License Agreement will expire at the end of the royalty term for a licensed product, provided that the licenses granted to Bayer for such licensed product survive such expiration on a non-exclusive basis. Either party may terminate the Bayer License Agreement in the event of a material breach or insolvency of the other party or in the event merger control proceedings are started and clearances are not obtained. Additionally, Bayer may terminate the Bayer License Agreement for convenience upon at least 270 days prior written notice, and the Seller Parties may terminate the Bayer License Agreement in the event Bayer ceases exploitation of acoramidis under certain circumstances or challenges the validity or enforceability of the Seller Parties' patent rights.

We determined that the Bayer License Agreement falls within the scope of ASC 606 as Bayer is a customer in this arrangement, and we identified the following performance obligations in the agreement:

- an exclusive license to develop and commercialize acoramidis in the Licensed Territory and the related know-how; and
- research and development services to conduct ongoing clinical trials.

We determined that the performance obligations outlined above are capable of being distinct and distinct within the context of the contract given such rights and activities are independent of each other. The license can be used by Bayer without the development services. Similarly, those services provide a distinct benefit to Bayer within the context of the contract, separate from the license, as the services could be provided by Bayer or another third party without our assistance.

We determined the initial transaction price at inception of the Bayer License Agreement to be $135.0 million, which is composed of the fixed and nonrefundable upfront payment. The remaining future potential regulatory and sales milestone payments were not included in the initial transaction price as they were determined to be fully constrained under ASC 606. We include variable consideration in our transaction price to the extent that it is probable that it will not result in a significant revenue reversal when the uncertainty associated with the variable consideration is subsequently resolved. As part of management's evaluation of the variable consideration, we considered numerous factors, including the fact that achievement of the milestones is outside of our control, contingent upon the success of our existing clinical trials, Bayer's efforts, and receipt of regulatory approval that is subject to scientific risks of success. Royalty arrangements and sales-based milestones will be recognized when the sales occur or the milestones are achieved pursuant to the sales-based royalty exception under ASC 606 because the license is the predominant item to which the royalties or sales-based milestones relate. In February 2025, the EC granted marketing authorization in the EU for acoramidis, under the brand name Beyonttra. Since the uncertainty of the variable consideration related to the regulatory milestone was resolved, we updated the transaction price to include this consideration, and accordingly, we recognized $75.0 million as license and services revenue during the three months ended March 31, 2025. During the three months ended September 30, 2026, a sales milestone under the Bayer License Agreement was achieved. Since the uncertainty of the variable consideration related to the sales milestone was resolved, we updated the transaction price to include this consideration, and accordingly, we recognized $75.0 million as license and services revenue during the three months ended September 30, 2026. We will continue to re-evaluate the transaction price at each reporting period as uncertainties are resolved or other changes in circumstances occur. Upon receiving marketing authorization in the EU, Bayer began selling Beyonttra, of which we are entitled to royalties on net product revenue.

We allocated the initial transaction price of $135.0 million based on the stand-alone selling prices ("SSP") of each of the performance obligations as follows:

- $130.5 million for the upfront transfer of the license; and
- $4.5 million for the research and development services to conduct the ongoing clinical trials.

The SSP for the license was determined using an approach that considered discounted, probability-weighted cash flows related to the license transferred. The SSP for the ongoing research and development services were based on estimates of the associated effort and cost of these services, adjusted for a reasonable gross profit margin that would be expected to be realized under similar contracts.

We recognize revenue for each of the two performance obligations as follows:

- We recognize revenue related to the license at a point in time upon transfer of the rights and control of the license to Bayer. The transfer of the rights and control of the license occurred in March 2024; thus, we recognized the full amount allocated to the license and related know-how in 2024.

- We recognize revenue related to the research and development services for the ongoing clinical trials over time using an input method to measure progress by utilizing costs incurred to date relative to total expected costs. We expect the research and development services for ongoing clinical trials to extend through 2029. We recognized $0.2 million and $0.6 million of license and services revenue relating to this performance obligation during the three and nine months ended September 30, 2026, respectively. We recognized $0.3 million and $1.0 million of license and services revenue relating to this performance obligation during the three and nine months ended September 30, 2025, respectively.

As of September 30, 2026 and December 31, 2025, there were $94.2 million and $5.0 million, respectively, of outstanding receivables relating to the Bayer License Agreement on our condensed consolidated balance sheets. The receivable balance at September 30, 2026 primarily relates to the $75.0 million sales-based milestone achieved during the three months ended September 30, 2026, which was unbilled as of September 30, 2026 and included in "Accounts receivable, net" on our condensed consolidated balance sheets. During the three and nine months ended September 30, 2026, we recognized license and services revenue and royalty revenue of $94.4 million and $122.3 million, respectively, under the Bayer License Agreement. During the three and nine months ended September 30, 2025, we recognized license and services revenue and royalty revenue of $9.1 million and $89.4 million, respectively, under the Bayer License Agreement. Our condensed consolidated balance sheet as of September 30, 2026 includes a deferred revenue balance of $2.3 million ($0.8 million presented as "Deferred revenue, current portion" and $1.5 million as "Deferred revenue, net of current portion") related to our research and development services obligations. Our condensed consolidated balance sheet as of December 31, 2025, includes a deferred revenue balance of $2.9 million ($0.8 million presented as "Deferred revenue, current portion" and $2.1 million as "Deferred revenue, net of current portion") related to our research and development services obligations.

Kyowa Kirin Exclusive License

In February 2024, the Company's subsidiary, QED Therapeutics, Inc. ("QED"), and Kyowa Kirin Co., Ltd. ("Kyowa Kirin" or "KKC") entered into a license and collaboration agreement pursuant to which QED granted Kyowa Kirin an exclusive license to develop, manufacture, and commercialize infigratinib for achondroplasia, hypochondroplasia, and other skeletal dysplasias in Japan, in accordance with the terms therein (the "KKC License Agreement"). In consideration for the license grant, QED is entitled to receive an upfront payment of $100.0 million and development and sales milestone payments up to $81.4 million. To date, we have received $100.0 million relating to the upfront payment. In addition, QED is entitled to receive royalties up to the mid-twenties percent on net sales of infigratinib in Japan.

Unless earlier terminated, the KKC License Agreement will expire at the end of the royalty term for a licensed product, provided that the licenses granted to Kyowa Kirin for such licensed product survive such expiration on a non-exclusive basis. Either party may terminate the KKC License Agreement in the event of a material breach or insolvency of the other party. Additionally, Kyowa Kirin may terminate the KKC License Agreement for convenience upon at least 180 days' prior written notice, and QED may terminate the KKC License Agreement in the event Kyowa Kirin ceases exploitation of infigratinib under certain circumstances or challenges the validity or enforceability of Kyowa Kirin's patent rights.

We determined that the KKC License Agreement falls within the scope of ASC 606 as Kyowa Kirin is a customer in this arrangement, and we identified the following performance obligations in the agreement:

- an exclusive license to develop and commercialize infigratinib for achondroplasia, hypochondroplasia and other skeletal dysplasias in Japan and the related know-how; and
- research and development services to conduct ongoing clinical trials.

We determined that the performance obligations outlined above are capable of being distinct and distinct within the context of the contract given such rights and activities are independent of each other. The license can be used by Kyowa Kirin without any development activities. Similarly, those services provide a distinct benefit to Kyowa Kirin within the context of the contract, separate from the license, as the services could be provided by Kyowa Kirin or another third party without our assistance.

We determined the initial transaction price at inception of the KKC License Agreement to be $100.0 million, which consisted of the fixed and nonrefundable upfront payment. No additional development or sales milestone payments are included in the transaction price, as all such payments are variable consideration that are fully constrained as of September 30, 2026. We include variable consideration in our transaction price to the extent that it is probable that it will not result in a significant revenue reversal when the uncertainty associated with the variable consideration is subsequently resolved. As part of management's evaluation of the variable consideration, we considered numerous factors, including the fact that achievement of the milestones is outside of our control, contingent upon the success of our existing and future clinical trials, Kyowa Kirin's efforts, and receipt of regulatory approval that is subject to scientific risks of success. Royalty arrangements and commercial-based milestones will be recognized when the sales occur or the milestones are achieved pursuant to the sales-based royalty exception under ASC 606 because the license is the predominant item to which the royalties or commercial-based milestones relate. We will re-evaluate the transaction price at each reporting period and as uncertain events are resolved or other changes in circumstances occur.

We allocated the transaction price of $100.0 million based on the SSP of each of the performance obligations as follows:

- $69.1 million for the upfront transfer of the license; and
- $30.9 million for research and development services to conduct the ongoing clinical trials.

The SSP for the license was determined using an approach that considered discounted, probability-weighted cash flows related to the license transferred. The SSP for the ongoing research and development services were based on estimates of the associated effort and cost of these services, adjusted for a reasonable gross profit margin that would be expected to be realized under similar contracts.

We recognize revenue for each of the two performance obligations as follows:

- We recognize revenue related to the license at a point in time upon transfer of the rights and control of the license to KKC. The transfer of the rights and control of the license occurred in February 2024; thus, we recognized the full amount allocated to the license and related know-how in 2024.
- We recognize revenue relating to the research and development services for the ongoing clinical trials over time using an input method to measure progress by utilizing costs incurred to date relative to total expected costs. We expect the research and development services to extend through 2030. We recognized $1.4 million and $4.9 million of license and services revenue relating to this performance obligation during the three and nine months ended September 30, 2026, respectively. We recognized $2.7 million and $8.5 million of license and services revenue relating to this performance obligation during the three and nine months ended September 30, 2025, respectively.

During the three and nine months ended September 30, 2026, we recognized license and services revenue of $2.5 million and $6.5 million, respectively, under the KKC License Agreement. During the three and nine months ended September 30, 2025, we recognized license and services revenue of $3.3 million and $9.9 million, respectively, under the KKC License Agreement. Our condensed consolidated balance sheet as of September 30, 2026 includes a deferred revenue balance of $9.6 million ($3.0 million presented as "Deferred revenue, current portion" and $6.6 million as "Deferred revenue, net of current portion") related to our research and development services obligation. Our condensed consolidated balance sheet as of December 31, 2025 includes a deferred revenue balance of $14.6 million ($5.4 million presented as "Deferred revenue, current portion" and $9.2 million as "Deferred revenue, net of current portion") related to our research and development services obligation.

License Agreement with Alexion

In September 2019, Eidos entered into an exclusive license agreement with Alexion Pharma International Operations Limited Company, a subsidiary of Alexion Pharmaceuticals, Inc. (together, "Alexion") (the "Eidos-Alexion License Agreement"), to develop, manufacture, and commercialize in Japan the compound known as acoramidis (previously known as AG10) and any of its various chemical forms and any pharmaceutical products containing acoramidis. Under the Eidos-Alexion License Agreement, Eidos received an upfront nonrefundable payment of $25.0 million and became eligible to receive a regulatory milestone payment of $30.0 million. Following pricing approval from the National Health Insurance in Japan in May 2025, the regulatory milestone was fully achieved and recognized as license and services revenue. Under the Eidos-Alexion License Agreement, Eidos is eligible to receive royalties in the low-teens percent on net sales by Alexion of acoramidis 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 acoramidis in Japan, or upon the introduction of generic competition into the market.

Eidos accounted for the Eidos-Alexion License Agreement under ASC 606 and identified the exclusive license as a distinct performance obligation since Alexion can benefit from the license on its own by developing and commercializing the underlying product using its own resources.

During the three and nine months ended September 30, 2026, we recognized license and services and royalty revenue of $2.8 million and $5.9 million, respectively, under the Eidos-Alexion License Agreement. During the three and nine months ended September 30, 2025, we recognized license and services and royalty revenue of $0.1 million and $32.1 million, respectively, under the Eidos-Alexion License Agreement.

11. In-licensing and Other Research and Development 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 and its amendments, Eidos has been granted certain worldwide exclusive licenses to make, use, and sell products that are covered by licensed patent rights. Eidos may also be required to make future payments of up to approximately $1.0 million to Stanford University upon achievement of specific intellectual property, clinical and regulatory milestone events, and pay royalties of up to low single-digit percentages on future net sales, if any. In addition, Eidos is obligated to pay Stanford University a percentage of nonroyalty revenue received by Eidos from its sublicensees, with the amount owed decreasing annually for three years based on when the applicable sublicense agreement is executed.

Additionally, under the license agreement with Stanford University, we will pay Stanford University a portion of all nonroyalty sublicensing consideration attributable to the sublicense of the licensed compounds. During the three and nine months ended September 30, 2026, we incurred $8.4 million and $17.0 million, respectively, in royalties related to commercial sales of Attruby and Beyonttra. During the three and nine months ended September 30, 2025, we incurred $1.9 million and $3.6 million, respectively, in royalties related to commercial sales of Attruby and Beyonttra. For the three and nine months ended September 30, 2026, we incurred a $4.5 million license fee payable to Stanford University, which was related to the $75.0 million sales milestone achieved in September 2026 under the Bayer License Agreement (refer to Note 10), which was recognized within "Cost of license, services, and royalty revenue" on our condensed consolidated statements of operations. For the three and nine months ended September 30, 2025, we incurred nil and $6.9 million, respectively, of license fees payable to Stanford University, which was related to the regulatory milestone achieved in February 2025 under the Bayer License Agreement as well as the regulatory milestone achieved in May 2025 under the Eidos-Alexion License Agreement (refer to Note 10), and were capitalized as finite-lived intangible assets.

Other License and Collaboration Agreements

In addition to the agreements described above, we have also entered into other license and collaboration agreements with various institutions and business entities on terms similar to those described above, none of which are material individually or in the aggregate.

12. Leases

We have operating leases for our corporate headquarters, office spaces and laboratory facilities. One of our office space leases has a finance lease component representing lessor provided furniture and office equipment. Our finance lease, which is presented as part of "Property and equipment, net" on our condensed consolidated balance sheets, is not material.

Certain leases include renewal options at our election and we include the renewal options when we are reasonably certain that the renewal option will be exercised. The lease liabilities were measured using a weighted-average discount rate based on the most recent borrowing rate as of the calculation of the respective lease liability, adjusted for the remaining lease term and aggregate amount of the lease.

The components of lease costs are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
	(in thousands)		(in thousands)	
Straight-line operating lease costs	$ 1,620	$ 1,213	$ 4,714	$ 3,443
Finance lease costs	—	91	29	278
Variable lease costs	975	1,342	2,692	3,822
Total lease costs	$ 2,595	$ 2,646	$ 7,435	$ 7,543

Supplemental cash flow information related to leases are as follows:

	Nine Months Ended September 30,	
	2026	2025
	(in thousands)	
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows for operating leases	$ 5,494	$ 4,757
Operating cash flows for finance lease	$ —	$ 344
Operating lease right-of-use assets obtained in exchange for operating lease obligations	$ 11,580	$ 3,714

As of September 30, 2026, future minimum lease payments for our noncancelable operating leases are as follows. Future minimum lease payments under our finance lease are not material.

	Amount (in thousands)
Remainder of 2026	$ 1,075
Year ending December 31:	
2027	2,425
2028	3,488
2029	3,106
2030	3,183
2031	3,030
Thereafter	4,674
Total future minimum lease payments	20,981
Imputed interest	(4,349)
Total	$ 16,632

Reported as of September 30, 2026	
Operating lease liabilities, current portion	$ 1,987
Operating lease liabilities, net of current portion	14,645
Total operating lease liabilities	$ 16,632

During the three and nine months ended September 30, 2026 and 2025, we did not identify any indicators of impairment, and no impairment loss was recognized during those periods.

13. Stockholders' Deficit

Series A Cumulative Convertible Participating Preferred Stock

On July 1, 2026 (the "Preferred Stock Closing Date"), we entered into an Investment Agreement (the "Investment Agreement") with Chinotto Investments, LLC (the "Sixth Street Purchaser") and HCRx Investments HoldCo, L.P. (the "HCR Purchaser") (collectively, the "Purchasers"), providing for the issuance and sale by the Company to the Purchasers of shares of the Company's Preferred Stock. Pursuant to the Investment Agreement, the Purchasers purchased an aggregate of 933,900 shares of Preferred Stock (collectively, the "Purchased Shares") at a purchase price of $1,000 per share, for an aggregate purchase price of $933.9 million, consisting of 800,000 shares purchased by the Sixth Street Purchaser for an aggregate purchase price of $800.0 million and 133,900 shares purchased by the HCR Purchaser for an aggregate purchase price of $133.9 million. The terms of the Preferred Stock are set forth in the Certificate of Designations of Series A Cumulative Convertible Participating Preferred Stock filed with the Secretary of State of the State of Delaware on the Preferred Stock Closing Date (the "Certificate of Designations"). The Preferred Stock is convertible into shares of our common stock, par value $0.001 per share (the "Common Stock"), at an initial conversion price of $137.79 per share, subject to adjustment as set forth in the Certificate of Designations.

The Preferred Stock is redeemable solely at the option of the Company and, as such, is classified within permanent equity in our condensed consolidated balance sheet as of September 30, 2026. The holders of the Preferred Stock are entitled to the rights, preferences and privileges, and are subject to the restrictions, described below with respect to voting, dividends, redemption, liquidation, and conversion.

Voting Rights

Holders of the Preferred Stock generally are entitled to vote with the holders of the Common Stock on an as-converted basis on all matters submitted to a vote of the Company's stockholders, voting together as a single class, subject to the beneficial ownership and other limitations set forth in the Certificate of Designations. In addition, the approval of the holders of a majority of the outstanding shares of Preferred Stock, voting as a separate class, is required for the Company to take certain actions, including amending its organizational documents or the Certificate of Designations in a manner that adversely affects the Preferred Stock, authorizing, creating or issuing any senior or parity equity securities, and increasing or decreasing the authorized number of shares of Preferred Stock or issuing additional shares of Preferred Stock.

Dividends

The Preferred Stock ranks senior to the Common Stock and each other class or series of our equity securities with respect to the payment of dividends and rights on liquidation, dissolution or winding up. Holders of the Preferred Stock are entitled to dividends that accrue and accumulate daily, whether or not declared, at an initial rate of 7.00% per annum on the Accumulated Amount (as defined in the Certificate of Designations) of such shares, payable quarterly in arrears on January 15, April 15, July 15 and October 15 of each year and, at our option, either in cash or by compounding and adding to the Accumulated Amount. The dividend rate is subject to increase, including (i) by 500 basis points on the seventh anniversary of July 1, 2026 (the "Original Issuance Date"), (ii) by an additional 125 basis points commencing on the eighth anniversary of the Original Issuance Date and at the end of each third month thereafter, up to a dividend rate cap of 17.00% per annum, (iii) by 300 basis points upon the occurrence and during the continuation of a Triggering Event (as defined in the Certificate of Designations) and (iv) by 200 basis points in connection with certain change of control transactions in which the Preferred Stock is not redeemed and remains outstanding.

Holders of the Preferred Stock are also entitled to participate in dividends declared or paid on the Common Stock on an as-converted basis, and no dividends may be paid on the Common Stock unless the full participating dividends are paid at the same time to the holders of the Preferred Stock.

Through September 30, 2026, the Company has elected to pay all dividends on the Preferred Stock in cash at the initial rate of 7.00% per annum. The Preferred Stock's initial carrying value was recorded at a discount to its liquidation preference (i.e., the difference between the issuance price and estimated call price) due to being issued with an increasing rate dividend, in addition to its issuance costs. In accordance with the SEC's Staff Accounting Bulletin Topic 5.Q, *Increasing Rate Preferred Stoc*k, the discount is considered an unstated dividend cost that must be amortized over the expected redemption period using the effective interest method, by charging the imputed dividend cost against additional paid-in capital in the absence of retained earnings and increasing the carrying amount of the Preferred Stock by a corresponding amount. The discount is therefore being amortized over the expected redemption period of six years using an 11.17% effective interest rate, assuming all dividends during the period are paid in cash. The six-year term represents the expected life of the Preferred Stock as the Company expects the Preferred Stock to be converted by such date and if not, the Company expects to exercise its redemption right with respect to such shares prior to the increase in the dividend rate on the seventh anniversary of the Original Issuance Date. The accretion includes approximately $1.3 million of issuance costs paid to third parties. The amortization in each period is the amount which, together with the stated dividend in the period, results in a constant rate of effective cost with regard to the carrying amount of the Preferred Stock. For the period from the Preferred Stock Closing Date to September 30, 2026, the Company recognized dividends of $26.3 million, which includes accretion of the implied discount of $9.9 million.

Following the requisite corporate approvals and in accordance with the Certificate of Designations, cash dividends of $2.7 million and $16.3 million were paid to the holders of the Preferred Stock on July 15, 2026 and October 15, 2026, respectively. As of September 30, 2026, accrued cash dividends of $13.7 million were presented within "Other current liabilities" on our condensed consolidated balance sheets.

Redemption

The Preferred Stock is redeemable solely at the option of the Company and is not redeemable at the option of the holders. At any time following the third anniversary of the Original Issuance Date, we may redeem all or any portion of the outstanding shares of Preferred Stock at a redemption price per share equal to the greatest of (i) the as-converted value of such share based on the Market Price (as defined in the Certificate of Designations) of the Common Stock, (ii) 120% of the Original Issue Price (as defined in the Certificate of Designations) plus the accrued balance of the Preferred Stock, which percentage increases to 125% following the fourth anniversary of the Original Issuance Date and by an additional 5% on each subsequent anniversary, up to a maximum of 140%, and (iii) if either (A) the Company has not paid cash dividends on the Preferred Stock for more than eight quarters prior to the redemption date or (B) the redemption occurs on or after the seventh anniversary of the Original Issuance Date, an amount sufficient to generate a 13% internal pre-tax rate of return on such share.

In the event of a Change of Control (as defined in the Certificate of Designations), we (or our successor or an affiliate thereof) have the option to purchase all, but not less than all, of the outstanding shares of Preferred Stock at a price per share, payable in cash, equal to the greatest of the following as of the date of such purchase: (i) 120% of the Original Issue Price plus the accrued balance of the Preferred Stock, which percentage increases to 125% following the fourth anniversary of the Original Issuance Date and by an additional 5% on each subsequent anniversary, up to a maximum of 140%, (ii) an amount sufficient to generate a 13% internal pre-tax rate of return on such share and (iii) the amount a holder would have received had such shares of Preferred Stock been converted into shares of Common Stock immediately prior to such Change of Control. As of September 30, 2026, no such Change of Control has occurred.

Upon any redemption by the Company, the holders of the Preferred Stock may elect to have such redemption settled by conversion into shares of our Common Stock.

Liquidation Preference

In the event of any Liquidation Event (as defined in the Certificate of Designations), each holder of Preferred Stock shall be entitled to receive liquidating distributions out of the assets of the Company, before any payment or distribution of any assets of the Company shall be made or set apart for holders of all other classes or series of equity securities of the Company, including any other preferred stock or the Common Stock, for such holder's shares of Preferred Stock in an amount equal to the Liquidation Preference (as defined in the Certificate of Designations). A Change of Control shall not by itself be deemed a Liquidation Event.

Conversion Rights

The holders of the Preferred Stock have the right, at any time and from time to time, to convert their shares of Preferred Stock into shares of Common Stock at the then-effective conversion price, which is initially $137.79 per share and, on and after the fifth anniversary of the Original Issuance Date, $153.10 per share, in each case subject to customary anti-dilution adjustments.

On or after the third anniversary of the Original Issuance Date, we may, at our option, require conversion of all outstanding shares of Preferred Stock if the Market Price of the Common Stock exceeds 200% of the then-applicable conversion price for at least 20 trading days during any 30 consecutive trading day period, subject to the satisfaction of the Common Stock Liquidity Conditions (as defined in the Certificate of Designations). Prior to receipt of the Requisite Stockholder Approval (as defined in the Certificate of Designations), the number of shares of Common Stock issuable to any one holder upon conversion is subject to a beneficial ownership limitation of 19.9% of the total voting power of the Common Stock, calculated on an as-converted basis.

As of September 30, 2026, based on the initial conversion price of $137.79 per share and excluding the accrued cash dividends of $13.7 million, which the Company has elected to pay in cash, the 933,900 shares of Preferred Stock were convertible into an aggregate of 6,777,704 shares of our Common Stock.

2023 Shelf Registration Statement and ATM Agreement

In May 2023, we filed a shelf registration statement on Form S-3 (the "2023 Shelf") with the SEC in relation to the registration of common stock, preferred stock, debt securities, warrants and units or any combination thereof. We also concurrently entered into an Equity Distribution Agreement (the "ATM Agreement") with Goldman Sachs & Co. LLC and SVB Securities LLC (collectively, the "ATM Sales Agents"), with respect to an "at-the-market" offering program under which we may issue and sell, from time to time at our sole discretion and pursuant to a prospectus supplement, shares of our common stock, par value $0.001 per share, having an aggregate offering price of up to $450.0 million through the ATM Sales Agents. We paid the ATM Sales Agents a commission of up to 3.0% of the aggregate gross proceeds received from all sales of the common stock under the ATM Agreement. Since inception of the ATM Agreement through its termination on May 7, 2026, the Company had issued and sold 3,233,208 shares of common stock under the ATM Agreement for aggregate gross proceeds of $104.7 million.

2026 Shelf Registration Statement and ATM Agreement

In May 2026, we filed a shelf registration statement on Form S-3 (the "2026 Shelf") with the SEC in relation to the registration of common stock, preferred stock, debt securities, warrants and units or any combination thereof. We also concurrently entered into an Equity Distribution Agreement (the "2026 ATM Agreement") with Goldman Sachs & Co. LLC and Leerink Partners LLC (collectively, the "2026 ATM Sales Agents"), with respect to an "at-the-market" offering program under which we may issue and sell, from time to time at our sole discretion and pursuant to a prospectus supplement, shares of our common stock, par value $0.001 per share, having an aggregate offering price of up to $500.0 million through the 2026 ATM Sales Agents. Under the 2026 ATM Agreement, we have agreed to pay the 2026 ATM Sales Agents a customary commission of up to 3.0% of the aggregate gross proceeds from all sales of the common stock. As of September 30, 2026, $500.0 million remained available to be sold pursuant to the 2026 ATM Agreement under the 2026 Shelf.

2026 Share Repurchase Program

In May 2026, our Board of Directors approved a stock repurchase program pursuant to which we may purchase up to $500.0 million of our outstanding common stock. Stock repurchases under the program may be made from time to time, in the open market, in privately negotiated transactions and otherwise, at the discretion of our management and in accordance with applicable federal securities laws, including Rule 10b-18 of the Securities Exchange Act of 1934, as amended, and other applicable legal requirements. The timing, pricing, and amounts of these repurchases will depend on a number of factors, including the market price of our common stock and general market and economic conditions. The stock repurchase program does not obligate us to repurchase any dollar amount or number of shares, and the program may be suspended or discontinued at any time. As of September 30, 2026, we had repurchased 2,616,166 shares under the share repurchase program in the open market at an average price of $66.88 per share for a total of approximately $175.0 million, of which $5.0 million remained unpaid as of that date. The repurchased shares were held as treasury stock as of September 30, 2026.

14. Stock-Based Compensation

Under each of our equity incentive plans, we recorded stock-based compensation in the following expense categories on our condensed consolidated statements of operations:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
	(in thousands)		(in thousands)	
Cost of goods sold	$ 374	$ 361	$ 2,029	$ 578
Research and development	14,921	12,328	42,504	37,582
Selling, general and administrative	24,562	21,866	73,209	63,077
Restructuring, impairment, and related charges	—	709	—	755
Total stock-based compensation	$ 39,857	$ 35,264	$ 117,742	$ 101,992

15. Restructuring, Impairment, and Related Charges

From time to time management may decide to restructure our business to streamline costs and expenses. We also continue to explore business opportunities to partner, divest or delay certain research and development programs to drive operational changes in our business processes, efficiencies and cost savings to advance our corporate strategy and development programs. We expect that these initiatives, including restructuring, will reduce our operating expenses.

We continuously evaluate our restructuring initiatives to streamline our operations and are committed to a restructuring program designed to drive operational changes, improve efficiencies and achieve cost savings to advance our corporate strategy and development programs. Our restructuring initiatives could include, among other components, consolidation and rationalization of our facilities, reprioritization of development programs and the reduction in our workforce. Our estimate of the costs is subject to certain assumptions and actual results may differ from those estimates or assumptions. We may also incur additional costs that are not currently foreseeable as we continue to evaluate our restructuring alternatives to drive operational changes in business processes, efficiencies and cost savings.

16. Income Taxes

BridgeBio is subject to U.S. federal, state and foreign income taxes as a corporation. BridgeBio's tax provision and the resulting effective tax rate for interim periods are determined based upon its estimated annual effective tax rate adjusted for the effect of discrete items arising in that quarter.

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, we have recorded a full valuation allowance against our otherwise recognizable net deferred tax assets.

Our 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 condensed consolidated balance sheets. To date, we have not recognized any interest and penalties on our condensed consolidated statements of operations, nor have we accrued for or made payments for interest and penalties. Our unrecognized gross tax benefits would not reduce the estimated annual effective tax rate if recognized because we have recorded a full valuation allowance on our deferred tax assets.

On July 4, 2025, the current administration signed the One Big Beautiful Bill Act ("OBBBA"), which includes comprehensive U.S. corporate tax legislation. The legislation includes the modification and permanent extension of prior tax law under the Tax Cuts and Jobs Act and the introduction of new provisions such as permanently reinstating the immediate deduction of domestic specified research and experimental expenditures, permanent changes in the limitations for deducting business interest expense, and permanently restoring bonus depreciation allowances. Following the enactment of the OBBBA, we are no longer capitalizing domestic research and experimental expenditures.

The Company's provision for income tax for the three and nine months ended September 30, 2026 was $1.2 million, primarily related to current foreign income tax expense. The Company's provision for (benefit from) income tax for the three and nine months ended September 30, 2025 was $(1.5) million and $0.6 million, respectively, primarily related to the benefit recognized from the OBBBA for the three-month period and current foreign income tax expense for the nine-month period.

17. Net Loss Per Share

We calculate basic net loss per share using the two-class method as a result of the issuance of the Preferred Stock in July 2026 (see Note 13). The two-class method determines net income (loss) per common share for each class of common stock and participating securities according to dividends declared or accumulated and participation rights in undistributed earnings. The two-class method requires undistributed earnings for the period to be allocated between common stock and participating securities based upon their respective rights to receive dividends as if all income for the period had been distributed. The Preferred Stock contractually entitles the holders of such shares to participate in dividends declared on Common Stock on an as-converted basis, but does not contractually require the holders of such shares to participate in the Company's losses. Accordingly, no losses are allocated to the Preferred Stock, and the Preferred Stock is excluded from the computation of basic net loss per share in periods in which the Company reports a net loss. However, the cumulative dividends that accrete on the Preferred Stock for the period, whether or not declared, reduce net income or increase net loss attributable to common stockholders. For the period from the Preferred Stock Closing Date to September 30, 2026, the Company recognized dividends of $26.3 million, which includes accretion of the implied discount of $9.9 million.

Basic net loss per share attributable to common stockholders of BridgeBio is computed by dividing net loss attributable to common stockholders of BridgeBio by the weighted-average number of shares of common stock outstanding. Diluted net loss per share attributable to common stockholders of BridgeBio is computed by dividing net loss attributable to common stockholders of BridgeBio by the weighted-average number of shares of common stock outstanding, plus all additional common shares that would have been outstanding, assuming dilutive potential common shares had been issued for other dilutive securities. For the three and nine months ended September 30, 2026 and 2025, diluted and basic net loss per share attributable to common stockholders of BridgeBio were identical since potential common shares were excluded from the calculation, as their effect was antidilutive.

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

	As of September 30,	
	2026	2025
Unvested RSUs	7,997,782	10,694,969
Unvested performance-based RSUs	285,973	194,943
Unvested market-based RSUs	—	375,000
Common stock options issued and outstanding	9,779,350	11,909,994
Estimated shares issuable under performance-based milestone compensation arrangements	1,735,060	1,330,341
Estimated shares issuable under the ESPP	39,429	42,842
Assumed conversion of 2027 Notes	12,878,305	12,878,305
Assumed conversion of 2029 Notes	7,702,988	7,702,988
Assumed conversion of 2031 Notes	11,544,448	11,544,448
Assumed conversion of 2033 Notes	5,720,014	—
Assumed conversion of Preferred Stock	6,777,704	—
	64,461,053	56,673,830

Our Notes are convertible, based on the applicable conversion rate, into cash, shares of our common stock or a combination thereof, at our election.

Holders of the Preferred Stock have the right, at any time and from time to time, to convert their shares of Preferred Stock into shares of common stock at the then-effective conversion price, which is initially $137.79 per share and, on and after the fifth anniversary of the Original Issuance Date, $153.10 per share, in each case subject to customary anti-dilution adjustments. As of September 30, 2026, the assumed conversion of the Preferred Stock excludes the accrued cash dividends of $13.7 million, which the Company has elected to pay in cash, as described in Note 13.

We have performance-based milestone compensation arrangements, whose vesting is contingent upon meeting various regulatory, development and sales milestones, with fixed monetary amounts known at inception that can be settled in the form of cash or equity at our sole election, upon achievement of each contingent milestone. The common stock equivalents of such arrangements were estimated as if the contingent milestones were achieved as of the reporting date and the arrangements were all settled in equity.

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 unaudited condensed consolidated financial statements and related notes included in this Quarterly Report on Form 10-Q and our audited consolidated financial statements and related notes thereto for the year ended December 31, 2025 included in our Annual Report on Form 10-K for the year ended December 31, 2025, as filed with the U.S. Securities and Exchange Commission (the "SEC") on February 24, 2026.

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 Part I, Item 1A, "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2025, as updated by the information, if any, in Part II, Item 1A, "Risk Factors" included in this Quarterly Report on Form 10-Q. 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

BridgeBio Pharma, Inc. ("BridgeBio," the "Company," or "we"), is a commercial-stage, multi-product biopharmaceutical company organized around a portfolio operating model to discover, develop, and deliver medicines for patients with genetic diseases. We seek to translate advances in genetic science into therapies for patient populations with significant unmet medical needs.

We currently generate material revenues from one commercial product and have multiple product candidates that have advanced into registrational and late-stage development. Acoramidis received U.S. Food and Drug Administration ("FDA") approval in November 2024 as Attruby and also received approval as Attruby from the Australian Therapeutic Goods Administration in late October 2026, and it received approval as Beyonttra from (i) the European Commission ("EC") on February 10, 2025, (ii) the Japanese Ministry of Health, Labour and Welfare on March 27, 2025 (pricing approval from the National Health Insurance in Japan was subsequently obtained on May 21, 2025), (iii) the United Kingdom Medicines and Healthcare products Regulatory Agency in the UK in April 2025 and (iv) the Brazilian Health Regulatory Agency in Brazil in May 2026. On March 30, 2026, we submitted our New Drug Application ("NDA") to the FDA for oral BBP-418 for the treatment of LGMD2I/R9. The FDA accepted our NDA for filing, granted Priority Review and assigned a Prescription Drug User Fee Act ("PDUFA") target action date of November 27, 2026, for BBP-418. On May 12, 2026, we submitted our NDA to the FDA for encaleret as a potential targeted treatment for ADH1. The FDA accepted our NDA for filing, granted Priority Review and assigned a PDUFA target action date of May 8, 2027, for encaleret. On August 4, 2026, we submitted our NDA to the FDA for low-dose infigratinib for achondroplasia. The FDA accepted our NDA for filing, granted Priority Review and assigned a PDUFA target action date of February 4, 2027, for infigratinib.

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 and commercial product, and driving commercialization of acoramidis 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 ("VIE model"), or the voting interest entity ("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 or controlled entities, (iii) recruit key management team members, (iv) raise and allocate capital across the portfolio and (v) provide certain shared services, including accounting, legal, information technology, administrative, and human resources, as well as workspaces. To date, we have funded our operations with proceeds from the sale of our equity securities, issuance of convertible notes, debt borrowings, royalty monetization, cash proceeds from net product revenue and royalty revenue, and upfront and milestone payments received from licensing arrangements.

We have incurred significant operating losses since our inception. For the nine months ended September 30, 2026 and 2025, we incurred net losses of $382.9 million and $538.3 million, respectively. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the success of our commercialization strategy for Attruby and Beyonttra, and the development and eventual commercialization of our product candidates at our wholly-owned subsidiaries and controlled entities. Further, we may not realize the anticipated efficiencies and other benefits of our past and any future restructuring initiatives. Failure to generate sufficient cash flows from operations, raise additional capital or reduce certain discretionary spending may have a material adverse effect on our ability to achieve our intended business objectives. We expect to continue to incur operating and net losses for at least the next several years.

On July 1, 2026, we entered into an Investment Agreement (the "Investment Agreement") with Chinotto Investments, LLC (the "Sixth Street Purchaser") and HCRx Investments HoldCo, L.P. (the "HCR Purchaser") (collectively, the "Purchasers"), providing for the issuance and sale of Series A Cumulative Convertible Participating Preferred Stock, par value $0.001 per share (the "Preferred Stock"). Pursuant to the Investment Agreement, the Purchasers purchased an aggregate of 933,900 shares of Preferred Stock at a purchase price of $1,000 per share, for an aggregate purchase price of $933.9 million, consisting of 800,000 shares purchased by the Sixth Street Purchaser for an aggregate purchase price of $800.0 million and 133,900 shares purchased by the HCR Purchaser for an aggregate purchase price of $133.9 million. The Preferred Stock is convertible into shares of our common stock at an initial conversion price of $137.79 per share, subject to adjustment as set forth in the certificate of designations for the Preferred Stock.

In May 2026, we filed a shelf registration statement on Form S-3 (the "2026 Shelf") with the SEC in relation to the registration of common stock, preferred stock, debt securities, warrants and units or any combination thereof. We also concurrently entered into an Equity Distribution Agreement (the "2026 ATM Agreement") with Goldman Sachs & Co. LLC and Leerink Partners LLC (collectively, the "2026 ATM Sales Agents"), with respect to an "at-the-market" offering program under which we may issue and sell, from time to time at our sole discretion and pursuant to a prospectus supplement, shares of our common stock, par value $0.001 per share, having an aggregate offering price of up to $500.0 million through the 2026 ATM Sales Agents. Under the 2026 ATM Agreement, we have agreed to pay the 2026 ATM Sales Agents a customary commission of up to 3.0% of the aggregate gross proceeds from all sales of the common stock. As of September 30, 2026, $500.0 million remained available to be sold pursuant to the 2026 ATM Agreement under the 2026 Shelf.

In May 2026, our Board of Directors approved a stock repurchase program pursuant to which we may purchase up to $500.0 million of our outstanding common stock. Stock repurchases under the program may be made from time to time, in the open market, in privately negotiated transactions and otherwise, at the discretion of our management and in accordance with applicable federal securities laws, including Rule 10b-18 of the Exchange Act, and other applicable legal requirements. The timing, pricing, and amounts of these repurchases will depend on a number of factors, including the market price of our common stock and general market and economic conditions. The stock repurchase program does not obligate us to repurchase any dollar amount or number of shares, and the program may be suspended or discontinued at any time. As of September 30, 2026, we had repurchased 2,616,166 shares in the open market at an average price of $66.88 per share for a total of approximately $175.0 million. The repurchased shares were held as treasury stock as of September 30, 2026.

On January 21, 2026, we issued an aggregate of $632.5 million principal amount of our 0.75% Convertible Senior Notes due 2033 (the "2033 Notes"), pursuant to an Indenture dated January 21, 2026 (the "2033 Notes Indenture"), between us and U.S. Bank Trust Company, National Association, as trustee (the "2033 Notes Trustee"), in a private offering to qualified institutional buyers (the "2026 Note Offering") pursuant to Rule 144A under the Securities Act of 1933, as amended (the "Securities Act"). The 2033 Notes issued in the 2026 Note Offering include $82.5 million aggregate principal amount of the 2033 Notes sold to the initial purchasers of the 2033 Notes (the "2033 Notes Initial Purchasers") pursuant to the exercise in full of the 2033 Notes Initial Purchasers' option to purchase additional 2033 Notes. We received net proceeds from the 2026 Note Offering of approximately $619.3 million, after deducting the 2033 Notes Initial Purchasers' discount and offering costs. We used approximately $82.5 million of the net proceeds from the 2026 Note Offering to pay for the repurchase of 1,081,825 shares of BridgeBio's common stock. We intend to use the remainder of the net proceeds from the 2026 Note Offering to settle future conversion obligations in respect of or repay at maturity a portion of our 2.50% Convertible Senior Notes due 2027 (the "2027 Notes"), on or before the maturity date of the 2027 Notes and for general corporate purposes, which may include working capital, capital expenditures and/or debt repayment.

On June 27, 2025 (the "Closing Date"), we and our subsidiary, Eidos Therapeutics, Inc. ("Eidos"), entered into a Royalty Interest Purchase and Sale Agreement (the "Royalty Purchase Agreement") with Acoramidis Royalty SPV, LP ("ARS"), an affiliate of HealthCare Royalty Management, LLC ("HCRx"), as a purchaser and the purchaser representative (in such capacity, the "Purchaser Representative"), and LSI Financing Fund, LP, an affiliate of Blue Owl Capital Corporation, as a purchaser (together with ARS as a purchaser and any future permitted assignees of a purchaser, the "Royalty Agreement Purchasers"). Subsequent to the Closing Date, on July 30, 2025, KKR & Co. Inc. ("KKR") acquired a majority ownership interest in HCRx. At that time, KKR beneficially owned more than five percent of the Company's outstanding common stock, and HCRx accordingly became a related party. On August 17, 2026, KKR sold a portion of its shares of our common stock and is no longer a beneficial owner of more than five percent of our outstanding shares of common stock. Accordingly, KKR and HCRx ceased to be related parties of the Company as of August 17, 2026.

Pursuant to the Royalty Purchase Agreement, Eidos sold to the Royalty Agreement Purchasers certain of Eidos' right to receive certain royalty payments ("Purchased Royalty Payment") on net sales of certain products containing acoramidis (the "Licensed Products") made in the European Union ("EU") and all member and extension states of the European Patent Organization (the "Licensed Territory") under (i) an exclusive license agreement, dated as of March 1, 2024, by and among Bayer Consumer Care AG ("Bayer"), Eidos and our other subsidiaries party thereto, as amended from time to time (the "Bayer License Agreement") and (ii) an amended and restated license agreement, effective as of June 30, 2023, by and between Eidos and our other subsidiary, BridgeBio International GmbH. As consideration for the sale of the Purchased Royalty Payment, the Royalty Agreement Purchasers agreed to pay Eidos $300.0 million in cash (the "Purchase Price"), which was funded in full on the Closing Date. The Royalty Agreement Purchasers' rights to the Purchased Royalty Payment are subject to (a) an annual cap equal to 60% of all royalty payments paid by Bayer to Eidos and its affiliates under the Bayer License Agreement on the first $500.0 million of annual net sales of Licensed Products in the Licensed Territory under the Bayer License Agreement and (b) an initial hard cap equal to 145% of the Purchase Price. Refer to *Liquidity and Capital Resources* section for additional details regarding this agreement.

On February 28, 2025, we issued an aggregate of $575.0 million principal amount of our 2031 Notes pursuant to an Indenture dated February 28, 2025 (the "2031 Notes Indenture"), between us and U.S. Bank Trust Company, National Association, as trustee (the "2031 Notes Trustee"), in a private offering to qualified institutional buyers (the "2025 Note Offering") pursuant to Rule 144A under the Securities Act. The 2031 Notes issued in the 2025 Note Offering include $75.0 million aggregate principal amount of 2031 Notes sold to the initial purchasers (the "2031 Notes Initial Purchasers") pursuant to the exercise in full of the 2031 Notes Initial Purchasers' option to purchase additional 2031 Notes. We received net proceeds from the 2025 Note Offering of approximately $563.0 million, after deducting the 2031 Notes Initial Purchasers' discount and offering costs. We used approximately $48.3 million of the net proceeds from the 2025 Note Offering to pay for the repurchase of 1,405,411 shares of BridgeBio's common stock and used a portion of the net proceeds from the 2025 Note Offering to repay all outstanding borrowings under, and terminate, the Financing Agreement, as defined below, and pay any fees related thereto.

On March 1, 2024, our subsidiaries, Eidos, BridgeBio International GmbH and BridgeBio Europe B.V. (collectively, "the Seller Parties"), entered into an exclusive license agreement (the "Bayer License Agreement") with Bayer Consumer Care AG, a wholly-owned subsidiary of Bayer AG ("Bayer"), to develop and commercialize acoramidis as a treatment for transthyretin amyloidosis in the EU and all member and extension states of the European Patent Organization (the "Licensed Territory"). Under the terms of the Bayer License Agreement, the Seller Parties granted Bayer an exclusive license on March 26, 2024 to certain of the Seller Parties' intellectual property rights to develop, manufacture and commercialize acoramidis (previously known as AG10) in the Licensed Territory. In consideration for the license grant, the Seller Parties are entitled to receive an upfront payment of $135.0 million, up to $150.0 million in regulatory and sales milestone payments through 2026, and additional payments up to $450.0 million subject to the achievement of certain sales milestones under the Bayer License Agreement. To date, the upfront payment and the regulatory and sales milestones achieved under the Bayer License Agreement total $285.0 million. In addition, the Seller Parties are entitled to receive royalties according to a tiered structure starting in the low-thirties percent on net sales by Bayer of acoramidis in the Licensed Territory, subject to reduction under certain circumstances as provided in the Bayer License Agreement.

On January 17, 2024, we and our subsidiaries, Eidos, BridgeBio Europe B.V. and BridgeBio International GmbH (collectively, the "Seller Parties"), entered into a Funding Agreement (the "Funding Agreement") with LSI Financing 1 Designated Activity Company and CPPIB Credit Europe S.à r.l. (together and with any future permitted assignees of a seller party, the "Funding Agreement Purchasers"), and Alter Domus (US) LLC, as the collateral agent. In connection with the Royalty Purchase Agreement described above, the Funding Agreement was amended on June 27, 2025. All terms and conditions of the Funding Agreement remain substantially unchanged. Refer to *Liquidity and Capital Resources* section for additional details regarding this agreement.

On January 17, 2024, we entered into a Financing Agreement with each of the guarantors, which was amended on February 12, 2024 (the "Financing Agreement") and June 20, 2024 (the Financing Agreement, as amended by the Second Amendment, the "Amended Financing Agreement"), with the lenders party thereto (the "Lenders") and Blue Owl Capital Corporation, as administrative agent for the Lenders (the "Administrative Agent"). On February 28, 2025, we fully repaid the Amended Financing Agreement for $467.0 million, which consisted of $450.0 million for the outstanding principal, $9.0 million for the prepayment fee, and $8.0 million in accrued interest using the proceeds from the 2031 Notes and recognized a loss on extinguishment of debt of $21.2 million. Refer to Note 8 of our notes to the condensed consolidated financial statement section for additional details regarding this agreement and transaction. Refer to *Liquidity and Capital Resources* section for additional details regarding this agreement.

In September 2019, Eidos entered into an exclusive license agreement with Alexion Pharma International Operations Limited Company, a subsidiary of Alexion Pharmaceuticals, Inc. (together, "Alexion") (the "Eidos-Alexion License Agreement"), to develop, manufacture, and commercialize in Japan the compound known as acoramidis (previously known as AG10) and any of its various chemical forms and any pharmaceutical products containing acoramidis. Under the Eidos-Alexion License Agreement, Eidos received an upfront nonrefundable payment of $25.0 million and became eligible to receive a regulatory milestone payment of $30.0 million. Following pricing approval from the National Health Insurance in Japan in May 2025, the regulatory milestone was fully achieved and recognized as license and services revenue. Under the Eidos-Alexion License Agreement, Eidos is eligible to receive royalties in the low-teens percent on net sales by Alexion of acoramidis in Japan.

Due to the inherently unpredictable nature of nonclinical and clinical development, and given our novel therapeutic approaches and the stage of development of our product candidates, we cannot determine and are unable to estimate with certainty the timelines we will require and the costs we will incur for the development of our product candidates. Clinical and nonclinical development timelines and costs, and the potential of development success, can differ materially from expectations due to a variety of factors.

We continuously evaluate our restructuring initiatives to streamline our operations and are committed to a restructuring program designed to drive operational changes, improve efficiencies and achieve cost savings to advance our corporate strategy and development programs. Our restructuring initiatives could include, among other components, consolidation and rationalization of our facilities, reprioritization of development programs and the reduction in our workforce. Our estimate of the costs is subject to certain assumptions and actual results may differ from those estimates or assumptions. We may also incur additional costs that are not currently foreseeable as we continue to evaluate our restructuring alternatives to drive operational changes in business processes, efficiencies and cost savings.

Results of Operations

The following table summarizes the results of our operations for the periods indicated:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
	(in thousands)		(in thousands)	
Total revenues, net	$ 353,171	$ 120,700	$ 791,362	$ 347,898
Total cost of revenues	$ 20,450	$ 6,563	$ 45,435	$ 12,855
Research and development	$ 143,506	$ 112,874	$ 419,590	$ 335,536
Selling, general and administrative	$ 200,854	$ 137,621	$ 551,011	$ 373,140
Loss from operations	$ (11,639)	$ (145,199)	$ (224,674)	$ (383,849)
Interest income	$ 13,105	$ 6,239	$ 26,010	$ 15,522
Interest expense	$ (13,255)	$ (11,739)	$ (39,475)	$ (41,467)
Noncash interest expense on deferred royalty obligations (1)	$ (42,282)	$ (36,410)	$ (123,500)	$ (86,460)
Net loss from equity method investments	$ (7,312)	$ (15,834)	$ (32,030)	$ (51,579)
Loss on extinguishment of debt	$ —	$ —	$ —	$ (21,155)
Other income, net	$ 2,116	$ 16,461	$ 11,956	$ 31,240
Net loss	$ (60,496)	$ (184,937)	$ (382,942)	$ (538,303)
Net loss attributable to redeemable convertible noncontrolling interests and noncontrolling interests	$ 3,786	$ 2,194	$ 9,973	$ 6,235
Preferred stock dividends and accretion	$ 26,293	$ —	$ 26,293	$ —
Net loss attributable to common stockholders of BridgeBio	$ (83,003)	$ (182,743)	$ (399,262)	$ (532,068)

(1) Including related party amounts of $(2,942) and $(13,878) for the period from July 1, 2026 to August 16, 2026 and for the period from January 1, 2026 to August 16, 2026, respectively, and $(5,383) and $(5,560) for the three and nine months ended September 30, 2025, respectively (as described in Note 9).

Cash, Cash Equivalents and Marketable Securities

The following table summarizes our cash, cash equivalents and marketable securities as of the following periods:

	September 30, 2026	December 31, 2025
	(in thousands)	
Cash and cash equivalents	$ 1,533,363	$ 570,119
Marketable securities	5,492	17,363
Total cash, cash equivalents and marketable securities	$ 1,538,855	$ 587,482

Revenues, Net

The following table summarizes our revenues for the following periods:

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2026	2025	Change	2026	2025	Change
	(in thousands)			(in thousands)		
Net product revenue	$ 253,346	$ 108,111	$ 145,235	$ 656,382	$ 216,351	$ 440,031
License and services revenue	79,314	8,311	71,003	89,537	125,441	(35,904)
Royalty revenue	20,511	4,278	16,233	45,443	6,106	39,337
Total revenues, net	$ 353,171	$ 120,700	$ 232,471	$ 791,362	$ 347,898	$ 443,464

Total revenues, net increased by $232.5 million for the three months ended September 30, 2026, compared to the same period in 2025, which consisted of an increase of $145.3 million in net product revenue, an increase of $71.0 million in license and services revenue, and an increase of $16.2 million in royalty revenue. Total revenues, net increased by $443.5 million for the nine months ended September 30, 2026, compared to the same period in 2025, which consisted of an increase of $440.0 million in net product revenue, an increase of $39.4 million in royalty revenue, and a decrease of $35.9 million in license and services revenue.

Net product revenue from Attruby increased for the three and nine months ended September 30, 2026, compared to the same periods in 2025, primarily due to continued commercial expansion driven by patient demand.

License and services revenue increased for the three months ended September 30, 2026, compared to the same period in 2025, primarily due to the recognition of a $75.0 million sales milestone under the Bayer License Agreement, which was achieved during the three months ended September 30, 2026. License and services revenue decreased for the nine months ended September 30, 2026, compared to the same period in 2025, primarily due to $105.0 million recognized for regulatory milestone achievements following approval of Beyonttra in the EU and pricing approval of Beyonttra in Japan in 2025 compared to the $75.0 million recognized for sales milestone achievement under the Bayer License Agreement during the three months ended September 30, 2026.

Royalty revenue increased for the three and nine months ended September 30, 2026, compared to the same periods in 2025, primarily due to royalties earned from net product sales of Beyonttra in the EU, following EC approval in February 2025, and in Japan, following pricing approval in May 2025.

Following the FDA approval of Attruby in November 2024, we commercialized Attruby in the U.S. and anticipate our future revenue to primarily be generated from recurring net product revenue from Attruby and future commercial products, if approved. In addition, the level of license and services revenue that we recognize depends in part upon the estimated recognition period of the upfront payments allocated to continuing performance obligations, the achievement of milestones and other contingent events, the level of effort incurred for research and development contracted services, and the impact of entering into new licensing and collaboration agreements, if any. Furthermore, following the regulatory approvals of Beyonttra in the EU, Japan, and in the UK in 2025, we anticipate significant future royalty revenue to be generated from the commercial sales of Beyonttra by our commercial partners, Bayer and Alexion.

Operating Costs and Expenses

Cost of Revenues

The following table summarizes our cost of revenues for the following periods:

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2026	2025	Change	2026	2025	Change
	(in thousands)			(in thousands)		
Cost of goods sold	$ 12,317	$ 4,028	$ 8,289	$ 30,577	$ 8,910	$ 21,667
Cost of license, services, and royalty revenue	8,133	2,535	5,598	14,858	3,945	10,913
Total cost of revenues	$ 20,450	$ 6,563	$ 13,887	$ 45,435	$ 12,855	$ 32,580

Total cost of revenues increased by $13.9 million for the three months ended September 30, 2026, compared to the same period in 2025 primarily due to an increase of $8.3 million in cost of goods sold and an increase of $5.6 million in cost of license, services, and royalty revenue. Total cost of revenues increased by $32.6 million for the nine months ended September 30, 2026, compared to the same period in 2025 primarily due to an increase of $21.7 million in cost of goods sold and an increase of $10.9 million in cost of license, services, and royalty revenue.

Cost of goods sold for the three and nine months ended September 30, 2026 and 2025 consists of contract manufacturing costs, transportation and freight-in, and indirect overhead costs (including salary and benefits related and stock-based compensation expenses) associated with the commercial manufacturing and distribution of Attruby, and third-party royalties associated with our net product revenue.

Cost of license, services, and royalty revenue for the three and nine months ended September 30, 2026 and 2025, consists mainly of third-party royalties and license fees associated with commercial sales of Beyonttra, contract manufacturing costs relating to product supply of Beyonttra to our collaboration partners, and amortization of intangible assets for milestones achieved upon FDA approval from our license and collaboration agreements. We began incurring royalties and manufacturing costs associated with commercial sales of Beyonttra upon its approval in the EU, Japan, and the UK in 2025.

Research and Development Expenses

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

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2026	2025	Change	2026	2025	Change
	(in thousands)			(in thousands)		
Research and development	$ 143,506	$ 112,874	$ 30,632	$ 419,590	$ 335,536	$ 84,054

Research and development expenses increased by $30.6 million and $84.1 million for the three and nine months ended September 30, 2026, respectively, compared to the same periods in 2025. The increases are primarily driven by the development of late-stage programs.

The increase of $30.6 million for the three months ended September 30, 2026 was primarily driven by an $18.2 million increase in external costs, a $9.8 million increase in personnel-related expenses due to headcount growth, and a $2.6 million increase in stock-based compensation expenses.

The increase of $84.1 million for the nine months ended September 30, 2026 was primarily driven by a $56.8 million increase in external costs, a $22.4 million increase in personnel-related expenses due to headcount growth, and a $4.9 million increase in stock-based compensation expenses.

Research and development costs consist primarily of external costs, such as fees paid to consultants, contractors, CMOs, and contract research organizations ("CROs"), as well as purchase of APIs in connection with our nonclinical, contract manufacturing and clinical development activities; internal costs such as personnel and facility costs, and are tracked on a program-by-program basis. License fees and other costs incurred after a product candidate has been designated and that are directly related to the product candidate are included in the specific program expense. License fees and other costs incurred prior to designating a product candidate are included in early-stage development and research programs, which are presented in the following table in "Other development programs" and "Other research programs," respectively.

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,	
	2026	2025	2026	2025
	(in thousands)		(in thousands)	
Acoramidis for the treatment of ATTR-CM and primary prevention in asymptomatic carriers of a pathogenic TTR variant	$ 33,782	$ 31,978	$ 101,695	$ 84,639
Infigratinib for achondroplasia and hypochondroplasia	34,089	30,756	105,082	88,881
BBP-418 for LGMD2I/R9	24,971	14,253	67,232	39,705
Encaleret for ADH1	27,048	16,046	71,555	44,633
Other development programs	3,292	357	16,815	22,323
Other research programs	20,324	19,484	57,211	55,355
Total	$ 143,506	$ 112,874	$ 419,590	$ 335,536

Selling, General and Administrative Expenses

The following table summarizes our selling, general and administrative expenses for the following periods:

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2026	2025	Change	2026	2025	Change
	(in thousands)			(in thousands)		
Selling, general and administrative	$ 200,854	$ 137,621	$ 63,233	$ 551,011	$ 373,140	$ 177,871

Selling, general and administrative expenses increased by $63.2 million and $177.9 million for the three and nine months ended September 30, 2026, respectively, compared to the same periods in 2025.

The increase of $63.2 million for the three months ended September 30, 2026 was primarily driven by a $30.8 million increase in external costs, a $29.7 million increase in personnel-related expenses due to headcount growth, and a $2.7 million increase in stock-based compensation expenses, reflecting continued investment in the ongoing commercialization of Attruby and pre-commercial activities for our late-stage product candidates.

The increase of $177.9 million for the nine months ended September 30, 2026 was primarily driven by a $104.7 million increase in external costs, a $63.1 million increase in personnel-related expenses due to headcount growth, and a $10.1 million increase in stock-based compensation expenses, reflecting continued investment in the ongoing commercialization of Attruby and pre-commercial activities for our late-stage product candidates.

Other Income (Expense), Net

Interest Income

The following table summarizes our interest income during the periods indicated:

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2026	2025	Change	2026	2025	Change
	(in thousands)			(in thousands)		
Interest income	$ 13,105	$ 6,239	$ 6,866	$ 26,010	$ 15,522	$ 10,488

Interest income has historically consisted of interest income earned on our cash, cash equivalents and marketable securities. Generally, increases and decreases in interest income during the three and nine months ended September 30, 2026 and 2025 are attributable to changes in the interest-bearing average balances of our cash, cash equivalents, marketable securities, and fluctuations in interest rates.

Interest Expense

The following table summarizes our interest expense during the periods indicated:

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2026	2025	Change	2026	2025	Change
	(in thousands)			(in thousands)		
Interest expense	$ (13,255)	$ (11,739)	$ (1,516)	$ (39,475)	$ (41,467)	$ 1,992

Interest expense consists primarily of interest expense incurred under our 2033 Notes issued in January 2026, our 2031 Notes issued in February 2025, our 2029 Notes issued in January 2021, and our 2027 Notes issued in March 2020. Our outstanding term loan principal balance under our Amended Financing Agreement was fully repaid in February 2025 upon receipt of proceeds from the 2031 Notes. Refer to Note 8 to our condensed consolidated financial statements.

Noncash Interest Expense on Deferred Royalty Obligations

The following table summarizes our noncash interest expense on deferred royalty obligations during the periods indicated:

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2026	2025	Change	2026	2025	Change
	(in thousands)			(in thousands)		
Noncash interest expense on deferred royalty obligations	$ (42,282)	$ (36,410)	$ (5,872)	$ (123,500)	$ (86,460)	$ (37,040)

Noncash interest expense on deferred royalty obligations increased by $5.9 million and $37.0 million for the three and nine months ended September 30, 2026, respectively, compared to the same periods in 2025. The increase for the nine months ended September 30, 2026 was primarily due to an increase of $16.0 million in noncash interest expense recognized under the Royalty Purchase Agreement, reflecting a full nine months of accretion in 2026 as compared with approximately three months following the execution of the agreement on June 27, 2025. The increase for the three months ended September 30, 2026 and the remaining increase for the nine months ended September 30, 2026 of $5.3 million and $20.3 million, respectively, were primarily driven by an increase in accretion expense under the Funding Agreement associated with our higher deferred royalty obligation balance and an increase in the effective interest rate from 21.3% as of September 30, 2025 to 22.2% as of September 30, 2026. The increase in the effective interest rate reflects a prospective adjustment resulting from updated projections of future global acoramidis net sales, revised upward to reflect the strong commercial performance of Attruby in the U.S. and the initiation of Beyonttra sales in Europe, Japan, and the UK, particularly during the second half of 2025.

Net Loss from Equity Method Investments

The following table summarizes our share in net loss of equity method investments during the periods indicated:

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2026	2025	Change	2026	2025	Change
	(in thousands)			(in thousands)		
Net loss from equity method investments	$ (7,312)	$ (15,834)	$ 8,522	$ (32,030)	$ (51,579)	$ 19,549

We account for our investments in GondolaBio and Legacy BBOT (now referred to as "BBOT" as the new combined company as more fully discussed in Note 5 to our condensed consolidated financial statements) using the equity method of accounting. For the three months ended September 30, 2026, we recorded net loss from the equity method investments in GondolaBio and BBOT of nil and $7.1 million, respectively. For the nine months ended September 30, 2026, we recorded net loss from the equity method investments in GondolaBio and BBOT of $6.4 million and $25.0 million, respectively. For the three months ended September 30, 2025, we recorded net loss from equity method investments in GondolaBio and Legacy BBOT of $7.1 million and $8.7 million, respectively. For the nine months ended September 30, 2025, we recorded net loss from equity method investments in GondolaBio and Legacy BBOT of $23.0 million and $28.6 million, respectively.

Loss on Extinguishment of Debt

In February 2025, upon receipt of proceeds from the 2031 Notes, we fully repaid the term loan under the Amended Financing Agreement and recognized a loss on extinguishment of debt of $21.2 million on our condensed consolidated statements of operations. Refer to Note 8 to our condensed consolidated financial statements.

Other Income, Net

The following table summarizes our other income, net during the periods indicated:

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2026	2025	Change	2026	2025	Change
	(in thousands)			(in thousands)		
Other income, net	$ 2,116	$ 16,461	$ (14,345)	$ 11,956	$ 31,240	$ (19,284)

The decrease for the three months ended September 30, 2026, compared to the same period in 2025, was primarily driven by $7.8 million of nonrecurring noncash income from an equity method investment recognized in the prior period, a $4.2 million decrease in other income resulting from the change in fair value of the embedded derivative liability component of our deferred royalty obligation under the Funding Agreement, and a $1.6 million decrease in other income recognized under the respective transition services agreements with GondolaBio and BBOT (as described in Note 5 to our condensed consolidated financial statements).

The decrease for the nine months ended September 30, 2026, compared to the same period in 2025, was primarily driven by $7.8 million of nonrecurring noncash income from an equity method investment recognized in the prior period, a $4.9 million decrease in net gains on foreign currency transactions, a $4.0 million decrease in other income resulting from the change in fair value of the embedded derivative liability component of our deferred royalty obligation under the Funding Agreement, and a $2.9 million decrease in other income recognized under the respective transition services agreements with GondolaBio and BBOT (as described in Note 5 to our condensed consolidated financial statements).

Preferred Stock Dividends and Accretion

The following table summarizes our preferred stock dividends and accretion during the periods indicated:

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2026	2025	Change	2026	2025	Change
	(in thousands)			(in thousands)		
Preferred stock dividends and accretion	$ 26,293	$ —	$ 26,293	$ 26,293	$ —	$ 26,293

On July 1, 2026 (the "Preferred Stock Closing Date"), the Company issued shares of a newly designated series of convertible preferred stock (see Note 13). The Company accounts for its Series A Cumulative Convertible Participating Preferred Stock, par value $0.001 per share (the "Preferred Stock") as permanent equity. Dividends on the Preferred Stock accrue and accumulate on a daily basis at an initial annual rate of 7.00% of the accumulated amount per share, initially the $1,000 per share original issue price, whether or not declared by the Company's Board of Directors, and are subject to contractual increases in the dividend rate over time and upon specified events. Dividends are payable quarterly in cash or in kind at the Company's election.

The Preferred Stock has similar characteristics of an "Increasing Rate Security" as described by SEC Staff Accounting Bulletin Topic 5.Q, *Increasing Rate Preferred Stock*. The Preferred Stock's initial carrying value was recorded at a discount to its liquidation preference (i.e., the difference between the issuance price and estimated call price) due to being issued with an increasing rate dividend, in addition to its issuance costs. Such discount is considered an unstated dividend cost and is amortized over the expected redemption period using the effective interest method, by charging the imputed dividend cost against additional paid-in capital in the absence of retained earnings and increasing the carrying amount of the Preferred Stock by a corresponding amount. The amortization in each period is the amount which, together with the stated dividend in the period, results in a constant rate of effective cost with regard to the carrying amount of the Preferred Stock. For the period from the Preferred Stock Closing Date to September 30, 2026, the Company recognized dividends of $26.3 million, which includes accretion of the implied discount of $9.9 million.

Liquidity and Capital Resources

We have historically financed our operations primarily through the sale of our equity securities, issuance of convertible notes, debt borrowings, royalty monetization, cash proceeds from net product revenue and royalties, and upfront and milestone payments received from license and collaboration arrangements. As of September 30, 2026, we had outstanding debt of approximately $2.5 billion related to our convertible senior notes, consisting of $548.4 million related to our 2027 Notes (which matures on March 15, 2027 and is classified as a current liability), $742.4 million related to our 2029 Notes, $566.0 million related to our 2031 Notes, and $620.5 million related to our 2033 Notes, in each case net of unamortized debt discount and issuance costs, and deferred royalty obligations of $920.1 million.

On July 1, 2026, we issued and sold an aggregate of 933,900 shares of Series A Cumulative Convertible Participating Preferred Stock (the "Preferred Stock") for aggregate gross proceeds of $933.9 million, pursuant to an Investment Agreement with affiliates of Sixth Street Partners, LLC and HCRx. The Preferred Stock ranks senior to our common stock, accrues cumulative dividends at an initial rate of 7.00% per annum (payable in cash or in kind at our election, subject to escalation over time as described in Note 13), and is convertible into shares of our common stock at an initial conversion price of $137.79 per share. This financing strengthened our liquidity position, and our cash, cash equivalents, and marketable securities were $1.5 billion as of September 30, 2026. Refer to Note 13 to our condensed consolidated financial statements for additional details.

Since inception, we have incurred significant operating losses. For the nine months ended September 30, 2026 and 2025, we incurred net losses of $382.9 million and $538.3 million, respectively. We incurred net cash outflow from operations of $312.6 million and $389.5 million for the same periods, respectively. We had an accumulated deficit as of September 30, 2026 and December 31, 2025 of $4.2 billion and $3.8 billion, respectively. While we have historically undertaken a restructuring initiative to drive operational change in business processes, efficiencies and cost savings, we expect to continue to incur operating and net losses over the next several years as we continue to fund our drug development and discovery efforts, as well as costs related to commercial launch readiness for our late-stage programs. In particular, to the extent we advance our programs into and through later-stage clinical trials without a partner, we will incur substantial expenses. In addition, we may not be able to generate significant revenues from product sales of any of our product candidates, even if any of our product candidates are approved for commercial sale. Further, we may not realize the anticipated efficiencies and other benefits of our past and any future restructuring initiatives. Our current business plan is also subject to significant uncertainties and risks as a result of, among other factors, our ability to generate net product revenue sufficient to achieve profitability, which will depend heavily on the successful development and eventual commercialization of our product candidates at our consolidated entities as well as our ability to partner in the development of certain late-stage clinical programs.

Our short-term and long-term liquidity requirements include contractual payments related to our 2027 Notes, 2029 Notes, 2031 Notes, and 2033 Notes (refer to Note 8 to our condensed consolidated financial statements), our deferred royalty obligations, net under the Funding Agreement and Royalty Purchase Agreement (refer to Note 9 to our condensed consolidated financial statements), obligations under our real estate leases (refer to Note 12 to our condensed consolidated financial statements), accounts payable and accrued liabilities.

We also have performance-based milestone compensation arrangements with certain employees, whose vesting is contingent upon meeting various regulatory, development and sales milestones, with fixed monetary amounts known at inception that can be settled in the form of cash or equity at our sole election, upon achievement of each contingent milestone (refer to Note 7 to our condensed consolidated financial statements).

Additionally, we have certain contingent payment obligations under various license and collaboration agreements in which we are required to make milestone payments upon successful completion and achievement of certain intellectual property, clinical, regulatory and sales milestones. We also enter into agreements in the normal course of business with CROs and other vendors for clinical trials and with vendors for nonclinical studies and other services and products for operating purposes, which are generally cancelable upon written notice with potential termination charges.

We continue to evaluate our research and development pipelines and restructure our business to streamline costs and expenses. We also continue to explore business opportunities to partner, divest or delay certain research and development programs to drive operational changes in our business processes, efficiencies and cost savings to advance our corporate strategy and development programs. We expect that these initiatives, including restructuring, will reduce our operating expenses.

We expect our cash, cash equivalents, and marketable securities, together with increasing cash collections from product sales of Attruby and collections from our licensing and collaboration agreements with our strategic partners, will fund our operations for at least the next 12 months from the date of filing of this Quarterly Report on Form 10-Q based on current operating plans and financial forecasts. If our current operating plans or financial forecasts change, as a result of general market and economic conditions, inflationary pressures, supply chain issues, our commercialization of Attruby/Beyonttra, and timing of commercialization of our product candidates we may require additional funding sooner in the form of public or private equity offerings, debt financings or additional collaborations and licensing arrangements. However, future financing may not be available in amounts or on terms acceptable to us, if at all.

In addition, we are closely monitoring ongoing developments in connection with economic conditions, inflationary pressures, evolving regulatory and policy landscapes, supply chain issues, our commercialization of Attruby/Beyonttra, and timing of commercialization of our product candidates which may negatively impact our financial and operating results. We will continue to assess our operating costs and expenses and our cash and cash equivalents and marketable securities and, if circumstances warrant, we will make appropriate adjustments to our operating plan.

Sources of Liquidity

Revenue from Attruby Sales

We currently generate material revenues from one commercial product, Attruby, which received FDA approval in November 2024, for the treatment of transthyretin amyloidosis. Product sales of Attruby represent an important source of our liquidity and cash inflows beginning in 2025. As commercialization efforts continue to expand domestically and internationally, and as market adoption increases, we expect product sales of Attruby to provide a growing and recurring source of operating cash flow to support our commercial activities and research and development.

Revenue from licensing and collaboration agreements

On March 1, 2024, our subsidiaries, Eidos, BridgeBio International GmbH and BridgeBio Europe B.V. (collectively, “the Seller Parties”), entered into the Bayer License Agreement with Bayer to develop and commercialize acoramidis as a treatment for transthyretin amyloidosis in the EU and all member states of the European Patent Organization (the “Licensed Territory”). Under the terms of the Bayer License Agreement, the Seller Parties granted Bayer an exclusive license on March 26, 2024 to certain of the Seller Parties’ intellectual property rights to develop, manufacture and commercialize acoramidis (previously known as AG10) in the Licensed Territory. In consideration for the license grant, the Seller Parties are entitled to receive an upfront payment of $135.0 million, up to $150.0 million in regulatory and sales milestone payments through 2026, and additional payments up to $450.0 million subject to the achievement of certain sales milestones under the Bayer License Agreement. To date, the upfront payment and the regulatory and sales milestones achieved under the Bayer License Agreement total $285.0 million. In addition, the Seller Parties are entitled to receive royalties according to a tiered structure starting in the low-thirties percent on net sales by Bayer of acoramidis in the Licensed Territory, subject to reduction under certain circumstances as provided in the Bayer License Agreement.

On February 7, 2024, our subsidiary, QED Therapeutics, Inc. ("QED"), and Kyowa Kirin Co., Ltd. ("Kyowa Kirin" or "KKC") entered into a license and collaboration agreement pursuant to which QED granted Kyowa Kirin an exclusive license to develop, manufacture, and commercialize infigratinib for achondroplasia, hypochondroplasia, and other skeletal dysplasias in Japan in accordance with the terms therein (the "KKC License Agreement"). In consideration for the license grant, QED is entitled to receive an upfront payment of $100.0 million and development and sales milestone payments up to $81.4 million. To date, we have received $100.0 million relating to the upfront payment. In addition, QED is entitled to receive royalties up to the mid-twenties percent on net sales of infigratinib in Japan.

In September 2019, Eidos entered into the Eidos-Alexion License Agreement with Alexion to develop, manufacture, and commercialize in Japan the compound known as acoramidis (previously known as AG10) and any of its various chemical forms and any pharmaceutical products containing acoramidis. Under the Eidos-Alexion License Agreement, Eidos received an upfront nonrefundable payment of $25.0 million, and in June 2025, Eidos received a regulatory milestone payment of $30.0 million following pricing approval from the National Health Insurance in Japan. Under the Eidos-Alexion License Agreement, Eidos is eligible to receive royalties in the low-teens percent on net sales by Alexion of acoramidis in Japan.

Deferred Royalty Obligations, net

Royalty Interest Purchase and Sale Agreement

On June 27, 2025 (the "Closing Date"), we and Eidos entered into a Royalty Interest Purchase and Sale Agreement (the "Royalty Purchase Agreement") with Acoramidis Royalty SPV, LP ("ARS"), an affiliate of HealthCare Royalty Management, LLC ("HCRx"), as a purchaser and the purchaser representative (in such capacity, the "Purchaser Representative"), and LSI Financing Fund, LP, an affiliate of Blue Owl Capital Corporation, as a purchaser (together with ARS as a purchaser and any future permitted assignees of a purchaser, the "Royalty Agreement Purchasers"). Subsequent to the Closing Date, on July 30, 2025, KKR & Co. Inc. ("KKR") acquired a majority ownership interest in HCRx. At that time, KKR beneficially owned more than five percent of the Company's outstanding common stock, and HCRx accordingly became a related party. On August 17, 2026, KKR sold a portion of its shares of our common stock and is no longer a beneficial owner of more than five percent of our outstanding shares of common stock. Accordingly, KKR and HCRx ceased to be related parties of the Company as of August 17, 2026.

Pursuant to the Royalty Purchase Agreement, Eidos sold to the Royalty Agreement Purchasers certain of Eidos' right to receive certain royalty payments ("Purchased Royalty Payment") on net sales of certain products containing acoramidis (the "Licensed Products") made in the EU and all member and extension states of the European Patent Organization (the "Licensed Territory") under (i) an exclusive license agreement, dated as of March 1, 2024, by and among Bayer (as described in Note 10 to our condensed consolidated financial statements), Eidos and our other subsidiaries party thereto, as amended from time to time (the "Bayer License Agreement") and (ii) an amended and restated license agreement, effective as of June 30, 2023, by and between Eidos and our other subsidiary, BridgeBio International GmbH. As consideration for the sale of the Purchased Royalty Payment, the Royalty Agreement Purchasers agreed to pay Eidos $300.0 million in cash (the "Purchase Price"), which was funded in full on the Closing Date. The Royalty Agreement Purchasers' rights to the Purchased Royalty Payment are subject to (a) an annual cap equal to 60% of all royalty payments paid by Bayer to Eidos and its affiliates under the Bayer License Agreement on the first $500.0 million of annual net sales of Licensed Products in the Licensed Territory under the Bayer License Agreement and (b) an initial hard cap equal to 145% of the Purchase Price.

In addition, we and our subsidiary, Eidos, granted the Purchaser Representative, for the benefit of the Royalty Agreement Purchasers, a security interest in specific assets related to the Purchased Royalty Payment. The Royalty Purchase Agreement also contains certain representations and warranties, indemnification obligations, events of default and other provisions that are customary for transactions of this nature.

Upon the occurrence of a change of control of the Company, the successor entity has an option to either (a) assume the obligations of the Company and/or Eidos under the Royalty Purchase Agreement or (b) pay the Royalty Agreement Purchasers an amount equal to the then-applicable hard cap, less total payments already made to the Royalty Agreement Purchasers, plus any other amounts payable under the Royalty Purchase Agreement (the "Change of Control Payment"), upon payment of which no further payments will be due to the Royalty Agreement Purchasers or the Purchaser Representative under the Royalty Purchase Agreement.

If an event of default occurs and is continuing, Eidos is required to immediately pay the Change of Control Payment to the Royalty Agreement Purchasers.

Refer to Note 9 to our condensed consolidated financial statements for other details.

Funding Agreement

On January 17, 2024, we and Eidos, BridgeBio Europe B.V. and BridgeBio International GmbH (collectively, the "Seller Parties") entered into a Funding Agreement (the "Funding Agreement") with LSI Financing 1 Designated Activity Company and CPPIB Credit Europe S.à r.l. (together and with any future permitted assignees of a seller party, the "Funding Agreement Purchasers"), and Alter Domus (US) LLC, as the collateral agent.

Pursuant to the Funding Agreement, the Funding Agreement Purchasers agreed to pay us $500.0 million (net of certain transaction expenses) (the "Investment Amount") upon the first FDA approval of acoramidis, subject to certain conditions relating to the FDA approval and other customary conditions (such date of payment, the "Funding Date").

In return, we granted the Funding Agreement Purchasers the right to receive payments (the "Royalty Interest Payments") equal to 5% of the global net sales of acoramidis (the "Net Sales"). Under certain conditions relating to the sales performance of acoramidis, the rate of the Royalty Interest Payments may adjust to a maximum rate of 10% in 2027. Each Royalty Interest Payment will become payable to the Funding Agreement Purchasers on a quarterly basis after the Funding Date. In addition, the Seller Parties granted the collateral agent, for the benefit of the Funding Agreement Purchasers, a security interest in specific assets related to acoramidis.

The Funding Agreement Purchasers' rights to the Royalty Interest Payments and ownership interest in Net Sales will terminate upon the earlier of the Funding Agreement Purchasers' receipt of (a) Royalty Interest Payments equal to $950.0 million (the "Cap Amount") and (b) a buy-out payment ("Buy-Out Payment") in an amount determined in accordance with the Funding Agreement but that will not exceed the Cap Amount. In the event that a change of control (as customarily defined in the Funding Agreement) occurs on or after the effective date of the Funding Agreement, the Purchasers may elect to require the Seller Parties to make the Buy-Out Payment and the Funding Agreement will be terminated upon payment in-full of the Seller Parties' obligations under the Funding Agreement (including the Buy-Out Payment and all reimbursable expenses). The Funding Agreement will also terminate upon customary events.

Following the FDA approval of Attruby in November 2024, and in accordance with the Funding Agreement, we received net cash proceeds of $472.5 million after deducting debt discount and issuance costs paid of $27.5 million in December 2024.

Under the Funding Agreement, the Seller Parties are required to comply with various covenants, including using commercially reasonable efforts to obtain regulatory approval for and commercialize acoramidis, providing the Funding Agreement Purchasers with certain clinical, commercial, regulatory and intellectual property updates and certain financial statements, and providing notices upon the occurrence of certain events, each as agreed under the Funding Agreement. The Funding Agreement also contains certain representations and warranties, indemnification obligations, put-option events and other provisions that are customary for transactions of this nature.

In connection with the Royalty Purchase Agreement described above, the Funding Agreement was amended on June 27, 2025. All terms and conditions of the Funding Agreement remain substantially unchanged.

Refer to Note 9 to our condensed consolidated financial statements for other details.

Debt

As of September 30, 2026, we had borrowings under the 2027 Notes, 2029 Notes, 2031 Notes, and 2033 Notes, which are discussed below.

2027 Notes, net

In March 2020, we issued an aggregate principal amount of $550.0 million of our 2027 Notes, pursuant to an Indenture dated March 9, 2020 (the "2027 Notes Indenture"), between us and U.S. Bank National Association, as trustee (the "2027 Notes Trustee"), in a private offering to qualified institutional buyers (the "2020 Note Offering"), pursuant to Rule 144A under the Securities Act. The 2027 Notes issued in the 2020 Note Offering include $75.0 million in aggregate principal amount of 2027 Notes sold to the initial purchasers (the "2027 Notes Initial Purchasers") resulting from the exercise in full of their option to purchase additional 2027 Notes.

The 2027 Notes are senior, unsecured obligations of BridgeBio and accrue interest payable semiannually in arrears on March 15 and September 15 of each year, beginning on September 15, 2020, at a rate of 2.50% per year. The 2027 Notes will mature on March 15, 2027, unless earlier converted or repurchased. Upon conversion, the 2027 Notes are convertible into cash, shares of our common stock or a combination of cash and shares of our common stock, at our election.

We received net proceeds from the 2020 Note Offering of approximately $537.0 million, after deducting the 2027 Initial Purchasers' discount and offering expenses. We used approximately $49.3 million of the net proceeds from the 2020 Note Offering to pay for the cost of the Capped Call Transactions, and approximately $75.0 million to pay for the repurchases of shares of our common stock.

A holder of 2027 Notes may convert all or any portion of its 2027 Notes at its option at any time prior to the close of business on the business day immediately preceding December 15, 2026 only under certain circumstances.

On or after December 15, 2026 until the close of business on the second scheduled trading day immediately preceding the maturity date, a holder may convert all or any portion of its 2027 Notes at any time.

We may not redeem the 2027 Notes prior to the maturity date, and no sinking fund is provided for the 2027 Notes. If we undergo a fundamental change (as defined in the 2027 Notes Indenture), holders may require us to repurchase for cash all or any portion of their 2027 Notes at a fundamental change repurchase price equal to 100% of the principal amount of the 2027 Notes to be repurchased, plus any accrued and unpaid interest to, but excluding, the fundamental change repurchase date. The 2027 Notes Indenture contains customary terms and covenants, including that upon certain events of default occurring and continuing, either the 2027 Notes Trustee or the holders of not less than 25% in aggregate principal amount of the 2027 Notes then outstanding may declare the entire principal amount of all the 2027 Notes plus accrued special interest, if any, to be immediately due and payable. The 2027 Notes are our general unsecured obligations and rank senior in right of payment to all of our indebtedness that is expressly subordinated in right of payment to the 2027 Notes; equal in right of payment with all of our liabilities that are not so subordinated; effectively junior to any of our secured indebtedness to the extent of the value of the assets securing such indebtedness; and structurally junior to all indebtedness and other liabilities (including trade payables) of our subsidiaries.

The 2027 Notes are convertible for a limited period from October 1, 2026 through December 14, 2026, as an early conversion condition based on the price of BridgeBio's common stock, as described above, was satisfied. On or after December 15, 2026 until the close of business on the second scheduled trading day immediately preceding the maturity date, a holder may convert all or any portion of its 2027 Notes at any time. The 2027 Notes, which mature on March 15, 2027, were classified as current liabilities as of September 30, 2026.

Refer to Note 8 to our condensed consolidated financial statements for other details.

2029 Notes, net

In January and February 2021, we issued an aggregate principal amount of $747.5 million of our 2029 Notes, pursuant to an Indenture dated January 28, 2021 (the "2029 Notes Indenture"), between us and U.S. Bank National Association, as trustee (the "2029 Notes Trustee"), in a private offering to qualified institutional buyers (the "2021 Note Offering"), pursuant to Rule 144A under the Securities Act.

The 2029 Notes accrue interest payable semiannually in arrears on February 1 and August 1 of each year, beginning on August 1, 2021, at a rate of 2.25% per year. The 2029 Notes will mature on February 1, 2029, unless earlier converted, redeemed or repurchased. The 2029 Notes are convertible into cash, shares of our common stock or a combination of cash and shares of our common stock, at our election.

We received net proceeds from the 2021 Note Offering of approximately $731.4 million, after deducting the 2029 Notes Initial Purchasers' discount (there were no direct offering expenses borne by us for the 2029 Notes). We used approximately $61.3 million of the net proceeds from the 2021 Note Offering to pay for the cost of the 2021 Capped Call Transactions and approximately $50.0 million to pay for the repurchase of shares of our common stock.

A holder of 2029 Notes may convert all or any portion of its 2029 Notes at its option at any time prior to the close of business on the business day immediately preceding November 1, 2028 only under certain circumstances.

On or after November 1, 2028 until the close of business on the second scheduled trading day immediately preceding the maturity date, a holder may convert all or any portion of its 2029 Notes at any time.

We may not redeem the 2029 Notes prior to February 6, 2026. We may redeem for cash all or any portion of the 2029 Notes, at our option, on a redemption date occurring on or after February 6, 2026 and on or before the 41st scheduled trading day immediately before the maturity date, under certain circumstances. No sinking fund is provided for the 2029 Notes. If we undergo a fundamental change (as defined in the 2029 Notes Indenture), holders may require us to repurchase for cash all or any portion of their 2029 Notes at a fundamental change repurchase price equal to 100% of the principal amount of the 2029 Notes to be repurchased, plus any accrued and unpaid interest to, but excluding, the fundamental change repurchase date. The 2029 Notes Indenture contains customary terms and covenants, including that upon certain events of default occurring and continuing, either the 2029 Notes Trustee or the holders of not less than 25% in aggregate principal amount of the 2029 Notes then outstanding may declare the entire principal amount of all the 2029 Notes plus accrued special interest, if any, to be immediately due and payable. The 2029 Notes are our general unsecured obligations and rank senior in right of payment to all of our indebtedness that is expressly subordinated in right of payment to the 2029 Notes; equal in right of payment with all of our liabilities that are not so subordinated, including our 2027 Notes, 2031 Notes and 2033 Notes; effectively junior to any of our secured indebtedness to the extent of the value of the assets securing such indebtedness; and structurally junior to all indebtedness and other liabilities (including trade payables) of our subsidiaries.

Refer to Note 8 to our condensed consolidated financial statements for other details, including our future minimum payments under the 2029 Notes.

2031 Notes, net

On February 28, 2025, we issued an aggregate of $575.0 million principal amount of our 2031 Notes pursuant to the 2031 Notes Indenture dated February 28, 2025 between us and the 2031 Notes Trustee in a private offering to qualified institutional buyers pursuant to Rule 144A under the Securities Act.

The 2031 Notes accrue interest payable semiannually in arrears on March 1 and September 1 of each year, beginning on September 1, 2025, at a rate of 1.75% per year. The 2031 Notes will mature on March 1, 2031, unless earlier converted, redeemed or repurchased. The 2031 Notes are convertible into cash, shares of our common stock or a combination of cash and shares of our common stock, at our election.

We received net proceeds from the 2025 Note Offering of approximately $563.0 million, after deducting the 2031 Notes Initial Purchasers' discount and offering costs. We used approximately $48.3 million to pay for the repurchase of shares of our common stock and used a portion of the net proceeds from the 2025 Note Offering to repay all outstanding borrowings under, and terminate, the Financing Agreement, and pay any fees related thereto.

A holder of 2031 Notes may convert all or any portion of its 2031 Notes at its option at any time prior to the close of business on the business day immediately preceding December 2, 2030 in multiples of $1,000 only under certain circumstances.

We may not redeem the 2031 Notes prior to March 6, 2028. We may redeem for cash all or any portion of the 2031 Notes, at our option, on a redemption date occurring on or after March 6, 2028 and on or before the 41st scheduled trading day immediately before the maturity date, under certain circumstances. No sinking fund is provided for the 2031 Notes. If we undergo a fundamental change (as defined in the 2031 Notes Indenture), holders may require us to repurchase for cash all or any portion of their 2031 Notes at a fundamental change repurchase price equal to 100% of the principal amount of the 2031 Notes to be repurchased, plus any accrued and unpaid interest to, but excluding, the fundamental change repurchase date. The 2031 Notes Indenture contains customary terms and covenants, including that upon certain events of default occurring and continuing, either the 2031 Notes Trustee or the holders of not less than 25% in aggregate principal amount of the 2031 Notes then outstanding may declare the entire principal amount of all the 2031 Notes plus accrued special interest, if any, to be immediately due and payable. The 2031 Notes are our general unsecured obligations and rank senior in right of payment to all of our indebtedness that is expressly subordinated in right of payment to the 2031 Notes; equal in right of payment with all of our liabilities that are not so subordinated, including our 2027 Notes, 2029 Notes and 2033 Notes; effectively junior to any of our secured indebtedness to the extent of the value of the assets securing such indebtedness; and structurally junior to all indebtedness and other liabilities (including trade payables) of our subsidiaries.

Refer to Note 8 to our condensed consolidated financial statements for other details, including our future minimum payments under the 2031 Notes.

2033 Notes, net

On January 21, 2026, we issued an aggregate of $632.5 million principal amount of our 2033 Notes pursuant to the 2033 Notes Indenture between us and the 2033 Notes Trustee in a private offering to qualified institutional buyers pursuant to Rule 144A under the Securities Act.

The 2033 Notes are senior, unsecured obligations of BridgeBio and accrue interest payable semiannually in arrears on February 1 and August 1 of each year, beginning on August 1, 2026, at a rate of 0.75% per year. The 2033 Notes will mature on February 1, 2033, unless earlier converted, redeemed or repurchased. The 2033 Notes are convertible into cash, shares of BridgeBio's common stock or a combination of cash and shares of BridgeBio's common stock, at our election.

We received net proceeds from the 2026 Note Offering of approximately $619.3 million, after deducting the 2033 Notes Initial Purchasers' discount and offering costs. We used approximately $82.5 million of the net proceeds from the 2026 Note Offering to pay for the repurchase of 1,081,825 shares of BridgeBio's common stock from certain purchasers of the 2033 Notes in privately negotiated transactions. We intend to use the remainder of the net proceeds from the 2026 Note Offering to settle future conversion obligations in respect of or repay at maturity a portion of our 2027 Notes, on or before the maturity date of the 2027 Notes and for general corporate purposes, which may include working capital, capital expenditures and/or debt repayment.

A holder of 2033 Notes may convert all or any portion of its 2033 Notes at its option at any time prior to the close of business on the business day immediately preceding November 1, 2032 only under certain circumstances.

We may not redeem the 2033 Notes prior to February 6, 2030. We may redeem for cash all or any portion of the 2033 Notes, at our option, on a redemption date occurring on or after February 6, 2030 and on or before the 21st scheduled trading day immediately before the maturity date, under certain circumstances. No sinking fund is provided for the 2033 Notes. If we undergo a fundamental change (as defined in the 2033 Notes Indenture), holders may require us to repurchase for cash all or any portion of their 2033 Notes at a fundamental change repurchase price equal to 100% of the principal amount of the 2033 Notes to be repurchased, plus any accrued and unpaid interest to, but excluding, the fundamental change repurchase date. The 2033 Notes Indenture contains customary terms and covenants, including that upon certain events of default occurring and continuing, either the 2033 Notes Trustee or the holders of not less than 25% in aggregate principal amount of the 2033 Notes then outstanding may declare the entire principal amount of all the 2033 Notes plus accrued special interest, if any, to be immediately due and payable. The 2033 Notes are our general unsecured obligations and rank senior in right of payment to all of our indebtedness that is expressly subordinated in right of payment to the 2033 Notes; equal in right of payment with all of our liabilities that are not so subordinated, including our 2027 Notes, 2029 Notes and 2031 Notes; effectively junior to any of our secured indebtedness and obligations, including our obligations under our Funding Agreement, to the extent of the value of the assets securing such indebtedness; and structurally junior to all indebtedness and other liabilities (including trade payables) of our subsidiaries, including obligations under our Royalty Purchase Agreement.

Refer to Note 8 to our condensed consolidated financial statements for other details, including our future minimum payments under the 2033 Notes.

Public Offerings

In May 2026, we filed a shelf registration statement on Form S-3 (the "2026 Shelf") with the SEC in relation to the registration of common stock, preferred stock, debt securities, warrants and units or any combination thereof. We also concurrently entered into an Equity Distribution Agreement (the "2026 ATM Agreement") with Goldman Sachs & Co. LLC and Leerink Partners LLC (collectively, the "2026 ATM Sales Agents"), with respect to an "at-the-market" offering program under which we may issue and sell, from time to time at our sole discretion and pursuant to a prospectus supplement, shares of our common stock, par value $0.001 per share, having an aggregate offering price of up to $500.0 million through the 2026 ATM Sales Agents. Under the 2026 ATM Agreement, we have agreed to pay the 2026 ATM Sales Agents a customary commission of up to 3.0% of the aggregate gross proceeds from all sales of the common stock. As of September 30, 2026, $500.0 million remained available to be sold pursuant to the 2026 ATM Agreement under the 2026 Shelf.

Series A Cumulative Convertible Participating Preferred Stock

On July 1, 2026, we entered into an Investment Agreement (the "Investment Agreement") with Chinotto Investments, LLC (the "Sixth Street Purchaser") and HCRx Investments HoldCo, L.P. (the "HCR Purchaser") (collectively, the "Purchasers"), providing for the issuance and sale of Series A Cumulative Convertible Participating Preferred Stock, par value $0.001 per share (the "Preferred Stock"). Pursuant to the Investment Agreement, the Purchasers purchased an aggregate of 933,900 shares of Preferred Stock at a purchase price of $1,000 per share, for an aggregate purchase price of $933.9 million, consisting of 800,000 shares purchased by the Sixth Street Purchaser for an aggregate purchase price of $800.0 million and 133,900 shares purchased by the HCR Purchaser for an aggregate purchase price of $133.9 million. The Preferred Stock is convertible into shares of our common stock at an initial conversion price of $137.79 per share, subject to adjustment as set forth in the certificate of designations for the Preferred Stock.

Refer to Note 13 to our condensed consolidated financial statements for additional details.

Cash Flows

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

	Nine Months Ended September 30,		
	2026	2025	Change
	(in thousands)		
Net cash used in operating activities	$ (312,550)	$ (389,490)	$ 76,940
Net cash provided by (used in) investing activities	11,761	(10,133)	21,894
Net cash provided by financing activities	1,264,137	361,475	902,662
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 963,348	$ (38,148)	$ 1,001,496

Net Cash Flows Used in Operating Activities

Net cash used in operating activities was $312.6 million for the nine months ended September 30, 2026, and consisted of our net loss of $382.9 million and net cash outflow of $211.2 million related to changes in operating assets and liabilities, partially offset by noncash adjustments totaling $281.5 million. The noncash adjustments totaling $281.5 million primarily included $123.5 million in noncash interest expense on deferred royalty obligations, $117.2 million in stock-based compensation expense, $32.0 million in net loss from equity method investments, $5.7 million in amortization of debt discount and issuance costs, partially offset by $7.1 million in change in fair value of the embedded derivative associated with the deferred royalty obligation under the Funding Agreement. The net cash outflow of $211.2 million related to changes in operating assets and liabilities was attributed mainly to an increase of $235.6 million in accounts receivable, net primarily related to receivables from net product and license revenues, an increase of $35.6 million in inventories due to a continuing build-up of Attruby inventory to support anticipated demand, an increase of $26.9 million in prepaid expenses and other current assets primarily due to timing of payments and operational fluctuations, a decrease of $9.0 million in accrued compensation and benefits, and a decrease of $6.6 million in deferred revenue primarily related to the Bayer License Agreement and KKC License Agreement; partially offset by increases of $52.0 million in accounts payable, $13.6 million in accrued research and development, and $48.4 million in other liabilities primarily due to timing of payments.

Net cash used in operating activities was $389.5 million for the nine months ended September 30, 2025, and consisted of our net loss of $538.3 million, noncash adjustments totaling $249.5 million, and net cash outflow of $100.7 million related to changes in operating assets and liabilities. The noncash adjustments totaling $249.5 million primarily included $98.4 million in stock-based compensation expense, $86.5 million in noncash interest expense on deferred royalty obligations, net loss from equity method investments of $51.6 million, $21.2 million in loss on extinguishment of debt from the repayment of the term loan under the Amended Financing Agreement, $4.5 million in amortization of debt discount and issuance costs; partially offset by $11.1 million in change in fair value of the embedded derivative associated with the deferred royalty obligation under the Funding Agreement, and $7.8 million in noncash income from an equity method investment. The net cash outflow of $100.7 million related to changes in operating assets and liabilities was attributed mainly to an increase of $111.8 million in accounts receivable, net primarily related to receivables for net product revenues, an increase of $23.4 million in inventories, an increase of $17.5 million for prepaid expenses and other current assets, partially offset by an increase in other liabilities of $53.0 million.

Net Cash Flows Provided by (Used in) Investing Activities

Net cash provided by investing activities was $11.8 million for the nine months ended September 30, 2026, attributable primarily to maturities of marketable securities of $76.5 million partially offset by purchases of marketable securities of $63.9 million.

Net cash used in investing activities was $10.1 million for the nine months ended September 30, 2025, attributable primarily to purchases of marketable securities of $10.9 million and the aggregate payments made for intangible assets of $8.5 million, partially offset by maturities of marketable securities of $8.0 million and a special cash dividend from investment in equity securities of $2.3 million.

Net Cash Flows Provided by Financing Activities

Net cash provided by financing activities was $1.3 billion for the nine months ended September 30, 2026, and consisted primarily of $932.6 million in net proceeds from the issuance of the Preferred Stock, $632.5 million in proceeds from the issuance of the 2033 Notes, and $30.0 million in proceeds from stock option exercises and employee stock purchase plan purchases (net of repurchases); partially offset by the $252.5 million in repurchase of common stock in relation to the issuance of our 2033 Notes and our stock repurchase program, $13.2 million payment of issuance costs and discounts associated with the 2033 Notes, $62.5 million repayments of deferred royalty obligations, and $2.7 million payment of preferred stock dividends.

Net cash provided by financing activities was $361.5 million for the nine months ended September 30, 2025, and consisted primarily of $575.0 million in proceeds from the issuance of 2031 Notes, $300.0 million in gross cash proceeds from the royalty obligation under the Royalty Purchase Agreement, and $14.1 million in proceeds from stock option exercises and employee stock purchase plan purchases (net of repurchases), partially offset by the $459.0 million repayment of the term loan under the Amended Financing Agreement, $48.3 million in repurchase of common stock, $12.0 million payment of issuance costs and discounts associated with the 2031 Notes, $6.9 million repayments of deferred royalty obligations, and $3.0 million payment of issuance costs associated with the royalty obligation under the Royalty Purchase Agreement.

Critical Accounting Policies 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 generally accepted accounting principles in the United States ("U.S. GAAP"). 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 Results of Operations" included in our Annual Report on Form 10-K for the year ended December 31, 2025, as filed with the SEC.

Recent Accounting Pronouncements

There have been no significant changes in recently adopted or issued accounting pronouncements from those disclosed in the section titled "Financial Statements and Supplementary Data" included in our Annual Report on Form 10-K for the year ended December 31, 2025, as filed with the SEC.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As of September 30, 2026, we held cash, cash equivalents and marketable securities of $1.5 billion. Our cash equivalents consist of amounts invested in money market funds, agency discount notes, commercial paper, and high investment grade fixed income securities that are primarily invested in U.S. government securities and treasury bills. Our marketable securities consisted of high investment grade fixed income securities that were invested in U.S. treasury bills and agency discount notes. 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. We do not believe that our cash, cash equivalents and marketable securities have a significant risk of default or illiquidity.

As of September 30, 2026, our 2027 Notes, 2029 Notes, 2031 Notes, and 2033 Notes had principal balances of $550.0 million, $747.5 million, $575.0 million, and $632.5 million, respectively, which bear fixed interest rates that are not subject to variability as a result of changes in interest rates.

Inflationary factors, such as increases in the cost of our raw materials, clinical supplies, interest rates and overhead costs may adversely affect our operating results. We do not believe that inflation has had a material impact on our financial position or results of operations during the periods presented. Significant adverse changes in inflation and prices in the future could result in material losses.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our periodic and current reports that we file under the Securities Exchange Act of 1934, as amended, or the Exchange Act, with the U.S. Securities and Exchange Commission, or the SEC, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our chief executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer (our principal executive officer and principal financial officer, respectively), evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2026, and our Chief Executive Officer and our Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of that date. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

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.

PART II—OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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

ITEM 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 condensed consolidated financial statements and the related notes. If any of the following risks actually occur, it could harm our business, prospects, operating results and financial condition and future prospects. In such event, the market price of our common stock could decline, and you could lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations. This 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 Commercialization

Our business is substantially dependent on the commercial success of Attruby and Beyonttra. The continued commercial success of this product, along with our product candidates, if approved, will depend upon the degree of market acceptance by physicians, patients, healthcare payors, and others in the medical community.

Our business depends heavily on our ability to successfully commercialize Attruby and Beyonttra. The commercial success of Attruby and Beyonttra or our product candidates, if approved, will depend upon their degree of market acceptance by physicians, patients, third-party payors, and others in the medical community. Our product candidates, if approved, 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 Attruby and Beyonttra or any other of our 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 the FDA or comparable regulatory authorities;
- 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, including generics of competing products;
- publicity concerning these products or competing products and treatments;
- the strength of marketing and distribution support;

- favorable third-party coverage and sufficient reimbursement or other assistance for patients who are uninsured or underinsured; and
- the prevalence and severity of any side effects or adverse effects ("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 products are 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 our sales and marketing capabilities for Attruby and Beyonttra, and our future product candidates, if approved, are not effective or we are unable to establish sales and marketing capabilities or enter into and maintain our agreements with third parties to sell and market Attruby and Beyonttra or any future product candidates approved for commercial sale, we may be unsuccessful in our commercial efforts.

To achieve and maintain commercial success for Attruby and Beyonttra and any other approved product for which we retain sales and marketing responsibilities, we must continue to develop a sales and marketing organization or outsource these functions to third parties. In the future, we may choose to grow our 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 U.S., as we have done with Bayer and Alexion in the case of Beyonttra, although there is no guarantee we will be able to enter into similar arrangements in the future 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. We may also fail to obtain or maintain the necessary regulatory approvals, distribution licenses or other registrations that are required to ship an approved product to a customer or commercial partner, or our contract manufacturers may fail to supply us or our commercial partners with our required or forecasted amounts of finished product, active pharmaceutical ingredients or raw materials to meet commercial demand on a timely basis, or at all.

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;
- manufacturing, supply chain or distribution disruptions that delay or prevent the launch and continued commercialization of any approved products by us or a commercial partner;
- the failure to obtain the necessary regulatory approvals, state licenses, wholesale distribution licenses or other registrations that are required to ship an approved product to a customer or commercial partner;
- 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, if approved, 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. Even if we enter into a commercial partnership with a third party, we may have manufacturing, supply chain or distribution disruptions that delay or prevent the commercial launch of an approved product by our partner. There is also a risk that one of our commercial partners decides to terminate our agreement due to a change in its business priorities or financial condition, or due to other circumstances may no longer be able to fulfill its obligations under our agreement, which would negatively impact our ability to sell our products in certain markets and to generate revenues from product sales. If we do not continue to build on our commercialization capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing Attruby and Beyonttra and our product candidates, if approved.

Our profitability will depend significantly on our ability to sell enough product at competitive prices and on the availability of adequate coverage and reimbursement through governmental or private third-party payors. 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 U.S., 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 those product candidates may obtain marketing approval. See the section titled, "*Business - Government Regulation - Coverage and Reimbursement*" in our Annual Report on Form 10-K for the year ended December 31, 2025 filed with the SEC on February 24, 2026.

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. Through December 2025, the approved list price of Attruby in the U.S. was $18,759.12 for a 28-day supply, which was subsequently increased to $19,790.00 in January 2026. A significant percentage of patients rely on government programs, such as Medicare and Medicaid, for their coverage of drug and other medical care, so the availability of federal and state coverage of Attruby is critical to the success of our commercialization efforts for Attruby in the U.S. Sales of Attruby or any product candidates, if approved, that we may identify will depend substantially, both domestically and abroad, on the extent to which the costs of such drugs 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, it may not allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment.

Additionally, we may develop companion diagnostic tests for use with Attruby and Beyonttra and our product candidates. 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 or 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.

Our future growth may depend, in part, on our ability to penetrate foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

We have partnered with Bayer and Alexion to commercialize Beyonttra in Europe and Japan, respectively, and we plan to commercialize Attruby and Beyonttra in other foreign markets. We may also commercialize in foreign markets any future drugs we develop for which we obtain commercial rights through additional partnerships with third parties or directly by ourselves. In addition, we may agree to supply drug product or API to a commercial partner in other foreign markets similar to our agreement with Bayer. In doing so, we would be subject to additional risks and uncertainties, including:

- the burden of complying with complex and changing foreign regulatory, tax, accounting, compliance and legal requirements;
- different medical practices and customs in foreign countries affecting acceptance in the marketplace;
- import, export or other distribution licensing requirements;
- the potential failure of obtaining and maintaining required licenses with foreign regulatory authorities that are required to ship API or distribute our drug product to customers or commercial partners like Bayer and Alexion;
- longer accounts receivable collection times;
- longer lead times for shipping;
- language barriers for technical training;
- reduced protection of intellectual property rights in some foreign countries, and related prevalence of bioequivalent or generic alternatives to therapeutics;
- foreign currency exchange rate fluctuations;
- potential resource constraints, including with respect to patients' ability to obtain reimbursement for our products in foreign markets; and
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute.

Any of these factors could impair our ability to commercialize Attruby and Beyonttra and any future drugs we may develop or for which we obtain commercial rights outside the U.S., which could have a material adverse effect on our business and results of operations.

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 U.S. 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, 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. See the section titled, "*Business - Government Regulation - Other Regulatory Matters*" in our Annual Report on Form 10-K for the year ended December 31, 2025 filed with the SEC on February 24, 2026.

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, the 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 U.S. will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

Third party patient assistance programs that receive financial support from companies have become the subject of enhanced government and regulatory scrutiny. Government enforcement agencies have shown increased interest in pharmaceutical companies' product and patient assistance programs, including reimbursement support services, and a number of investigations into these programs have resulted in significant civil and criminal settlements. The U.S. government has established guidelines that suggest that it is lawful for pharmaceutical manufacturers to make donations to charitable organizations who provide co-pay assistance to Medicare patients, provided that such organizations, among other things, are bona fide charities, are entirely independent of and not controlled by the manufacturer, provide aid to applicants on a first-come basis according to consistent financial criteria and do not link aid to use of a donor's product. However, donations to patient assistance programs have received some negative publicity and have been the subject of multiple government enforcement actions, related to allegations regarding their use to promote branded pharmaceutical products over other less costly alternatives. Specifically, in recent years, there have been multiple settlements resulting out of government claims challenging the legality of their patient assistance programs under a variety of federal and state laws. It is possible that we may make grants to independent charitable foundations that help financially needy patients with their premium, co-pay, and co-insurance obligations. If we choose to do so, and if we or our vendors or donation recipients are deemed to fail to comply with relevant laws, regulations or evolving government guidance in the operation of these programs, we could be subject to damages, fines, penalties, or other criminal, civil, or administrative sanctions or enforcement actions. We cannot ensure that our compliance controls, policies, and procedures will be sufficient to protect against acts of our employees, business partners, or vendors that may violate the laws or regulations of the jurisdictions in which we operate. Regardless of whether we have complied with the law, a government investigation could impact our business practices, harm our reputation, divert the attention of management, increase our expenses, and reduce the availability of foundation support for our patients who need assistance. Further, it is possible that changes in insurer policies regarding co-pay coupons and/or the introduction and enactment of new legislation or regulatory action could restrict or otherwise negatively affect these patient support programs, which could result in fewer patients using affected products, and therefore could have a material adverse effect on our sales, business, and financial condition. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the current U.S. presidential administration may reverse or otherwise change these measures, both the current U.S. presidential administration and Congress have indicated that they will continue to seek new legislative measures to control drug costs. We cannot predict how the implementation of and any further changes to this rule will affect our business.

Failure to comply with health and other personal 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 U.S., numerous federal and state laws and regulations, including federal health information privacy laws, state data breach notification laws, state health information privacy laws, U.S. state consumer privacy laws (e.g., the California Consumer Privacy Act), 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 the Health Information Technology for Economic and Clinical Health Act of 2009 ("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.

In addition, a number of U.S. states have passed or are considering comprehensive privacy laws that may impact our business.

The uncertainty surrounding the implementation of recent and emerging state privacy laws, regulations and standards increases the risk to our business. 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.

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

The U.S. 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 any products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business. See the section titled, "*Business - Government Regulation - Current and Future Legislation*" in our Annual Report on Form 10-K for the year ended December 31, 2025 filed with the SEC on February 24, 2026.

In addition, the Creating and Restoring Equal Access to Equivalent Samples Act ("CREATES Act"), was enacted in 2019 requiring sponsors of approved NDAs and BLAs to provide enough product samples on commercially reasonable, market-based terms to entities developing generic drugs and biosimilar biological products. The law establishes a private right of action allowing developers to sue application holders that refuse to sell them product samples needed to support their applications. If we are required to provide product samples or allocate additional resources to respond to such requests or any legal challenges under this law, our business could be adversely impacted.

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 Attruby and Beyonttra and our product candidates, if approved. 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. For example, the current administration is pursuing a range of strategies to reduce drug costs in the U.S., including voluntary most-favored-nation pricing agreements with manufacturers, the GENEROUS (GENErating cost Reductions fOr U.S. Medicaid) Model, a voluntary model that launched in January 2026, implementing most-favored-nation pricing in Medicaid, and pharmaceutical trade measures. The administration is also pursuing traditional regulatory pathways to impose drug pricing policies and published two proposed regulations in December 2025, the Global Benchmark for Efficient Drug Pricing ("GLOBE") for Medicare Part B and the Guarding U.S. Medicare Against Rising Drug Costs ("GUARD") for Medicare Part D. On October 2, 2026, CMS finalized the GLOBE regulation, effective November 30, 2026 and set to begin January 1, 2027, as a mandatory CMS Innovation Center payment model under Section 1115A of the Social Security Act. GUARD remains a proposed regulation that has not been finalized. GLOBE, along with GUARD, if finalized, implements a mandatory payment model under which manufacturers of eligible drugs would be required to pay rebates to the federal government on a portion of their units that are reimbursed by Medicare, with the rebate amount based on most-favored-nation pricing. Imposing a rebate in the U.S. that is based on drug prices outside the U.S. would mark a drastic and unprecedented shift in the U.S. pharmaceutical market, and while the impact of the GLOBE and GUARD regulations, if GUARD is finalized, cannot yet be fully determined, it is likely to be significant depending on the final language and whether any exemptions from the regulations apply. Even regulatory proposals or executive actions that are ultimately deemed unlawful could negatively impact the U.S. pharmaceutical sector and our business. 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 Attruby and Beyonttra and our product candidates, if approved;
- our ability to receive or set a price that we believe is fair for our future 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 Attruby and our product candidates, if approved.

Healthcare reform efforts have been and may continue to be subject to scrutiny and legal challenge. In 2021, the U.S. Supreme Court dismissed the latest judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. As another example, revisions to regulations under the federal anti-kickback statute would remove protection for traditional Medicare Part D discounts offered by pharmaceutical manufacturers to pharmacy benefit managers and health plans. Pursuant to court order, the removal was delayed and subsequent legislation imposed a moratorium on implementation of the rule until January 2032. The IRA drug price negotiation program has also been challenged in litigation filed by various pharmaceutical manufacturers and industry groups.

Individual states have also been increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs. We expect that additional state and federal healthcare reform measures will be adopted in the future, particularly in light of the current presidential administration, any of which could limit the amounts that federal and state governments will pay for healthcare products and services.

If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate program or other governmental pricing programs, we could be subject to additional reimbursement requirements, penalties, sanctions and fines, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We participate in the Medicaid Drug Rebate program, the 340B drug pricing program, and the VA's FSS pricing program. Under the Medicaid Drug Rebate program, we are required to pay a rebate to each state Medicaid program for our covered outpatient drugs that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program as a condition of having federal funds being made available to the states for our drugs under Medicaid and Medicare Part B. Those rebates are based on pricing data reported by us on a monthly and quarterly basis to CMS, the federal agency that administers the Medicaid Drug Rebate program. These data include the average manufacturer price and, in the case of innovator products, the best price for each drug which, in general, represents the lowest price available from the manufacturer to any entity in the U.S. in any pricing structure, calculated to include all sales and associated rebates, discounts and other price concessions. Our failure to comply with these price reporting and rebate payment obligations could negatively impact our financial results.

The ACA made significant changes to the Medicaid Drug Rebate program. CMS issued a final regulation, which became effective on April 1, 2016, to implement the changes to the Medicaid Drug Rebate program under the ACA. The issuance of the final regulation has increased and will continue to increase our costs and the complexity of compliance, has been and will continue to be time-consuming to implement, and could have a material adverse effect on our results of operations, particularly if CMS challenges the approach we take in our implementation of the final regulation.

Federal law requires that any company that participates in the Medicaid Drug Rebate program also participate in the Public Health Service's 340B drug pricing program for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B program requires participating manufacturers to agree to charge statutorily defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs. These 340B covered entities include a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients. The 340B ceiling price is calculated using a statutory formula based on the average manufacturer price and Medicaid rebate amount for the covered outpatient drug as calculated under the Medicaid Drug Rebate program, and in general, products subject to Medicaid price reporting and rebate liability are also subject to the 340B ceiling price calculation and discount requirement. Any additional future changes to the definition of average manufacturer price and the Medicaid rebate amount under the ACA, other legislation, or in regulation could affect our 340B ceiling price calculations and negatively impact our results of operations.

The Health Resources and Services Administration ("HRSA"), which administers the 340B program, issued a final regulation regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities, which became effective on January 1, 2019. We also are required to report our 340B ceiling prices to HRSA on a quarterly basis. Implementation of the civil monetary penalties regulation and the issuance of any other final regulations and guidance could affect our obligations under the 340B program in ways we cannot anticipate. In addition, legislation may be introduced that, if passed, would further expand the 340B program to additional covered entities or would require participating manufacturers to agree to provide 340B discounted pricing on drugs used in the inpatient setting.

Pricing and rebate calculations vary across products and programs, are complex, and are often subject to interpretation by us, governmental or regulatory agencies and the courts. In the case of our Medicaid pricing data, if we become aware that our reporting for a prior quarter was incorrect, or has changed as a result of recalculation of the pricing data, we are obligated to resubmit the corrected data for up to three years after those data originally were due. Such restatements and recalculations increase our costs for complying with the laws and regulations governing the Medicaid Drug Rebate program and could result in an overage or underage in our rebate liability for past quarters. Price recalculations also may affect the ceiling price at which we are required to offer our products under the 340B program or could require us to issue refunds to 340B covered entities.

Significant civil monetary penalties can be applied if we are found to have knowingly submitted any false pricing information to CMS, or if we fail to submit the required price data on a timely basis. Such conduct also could be grounds for CMS to terminate our Medicaid drug rebate agreement, in which case federal payments may not be available under Medicaid or Medicare Part B for our covered outpatient drugs. Significant civil monetary penalties also can be applied if we are found to have knowingly and intentionally charged 340B covered entities more than the statutorily mandated ceiling price. We cannot assure you that our submissions will not be found by CMS or HRSA to be incomplete or incorrect.

To be eligible to have our products paid for with federal funds under the Medicaid and Medicare Part B programs and purchased by certain federal agencies and grantees, as noted above, we participate in the VA's FSS pricing program. As part of this program, we are obligated to make our products available for procurement on an FSS contract under which we must comply with standard government terms and conditions and charge a price that is no higher than the statutory Federal Ceiling Price ("FCP"), to four federal agencies (the VA, U.S. Department of Defense, or DOD, Public Health Service, and the U.S. Coast Guard). The FCP is based on the Non-Federal Average Manufacturer Price ("Non-FAMP"), which we calculate and report to the VA on a quarterly and annual basis. Pursuant to applicable law, knowing provision of false information in connection with a Non-FAMP filing can subject a manufacturer to significant penalties for each item of false information. These obligations also contain extensive disclosure and certification requirements.

We also participate in the Tricare Retail Pharmacy program, under which we pay quarterly rebates on utilization of innovator products that are dispensed through the Tricare Retail Pharmacy network to Tricare beneficiaries. The rebates are calculated as the difference between the annual Non-FAMP and FCP. We are required to list our covered products on a Tricare Agreement in order for these products to be eligible for DOD formulary inclusion. If we overcharge the government in connection with our FSS contract or Tricare Agreement, whether due to a misstated FCP or otherwise, we are required to refund the difference to the government. Failure to make necessary disclosures and/or to identify contract overcharges can result in allegations against us under the FCA and other laws and regulations. Unexpected refunds to the government, and responding to a government investigation or enforcement action, would be expensive and time-consuming, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Federal legislative and regulatory efforts to implement reference pricing or most-favored-nation pricing models could impact our product revenues and materially harm our business.

The costs of prescription pharmaceuticals have also been the subject of considerable discussion in the United States. To date, there have been several recent U.S. congressional inquiries, as well as proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products.

The Trump Administration has issued executive orders and supported proposed regulatory initiatives in 2025 that could have a significant impact on the prices that we, or any collaborators, may receive for any approved products. On May 12, 2025, the current administration issued an executive order calling on pharmaceutical manufacturers to voluntarily reduce the prices of medicines in the U.S. and directing the Secretary of Health and Human Services ("HHS") to communicate most-favored-nation ("MFN") price targets to pharmaceutical manufacturers to align prices with those in comparably developed nations and, in the event significant progress towards MFN pricing is not delivered, to propose rulemaking to impose MFN pricing.

Since the May 12, 2025 order, the current administration has continued to exert pressure on drug manufacturers to implement MFN pricing, including by encouraging manufacturers to enter into voluntary MFN agreements and implementing trade measures. In August 2026, we entered into a voluntary MFN agreement with the Administration, which will expand state Medicaid access to Attruby via the GENEROUS Model. We expect any pricing commitment for future medicines under the agreement to exclude medicines approved exclusively for orphan indications. If under the MFN agreement, or subject to other policy developments, our currently marketed or future medicines become subject to additional MFN pricing obligations, this may affect our pricing and commercialization strategies. Further, in November 2025, the Centers for Medicare & Medicaid Services ("CMS") introduced the GENEROUS Model, a voluntary Medicaid payment initiative under which participating drug manufacturers may voluntarily offer supplemental rebates to participating state Medicaid programs that are intended to provide such Medicaid programs with an MFN price for the manufacturers' products. The GENEROUS Model launched in January 2026, and CMS has announced that all state Medicaid programs, along with the District of Columbia and Puerto Rico, have applied to participate in the model. Additionally, in December 2025, CMS announced proposals for new mandatory demonstration payment models through two proposed rules under its Center for Medicare and Medicaid Innovation ("CMMI") authority, the GLOBE for Medicare Part B and the GUARD for Medicare Part D. On October 2, 2026, CMS finalized the GLOBE regulation, effective November 30, 2026, as a mandatory CMS Innovation Center payment model under Section 1115A of the Social Security Act. As finalized, GLOBE will require manufacturers of specified single source drugs and sole source biologics, within designated therapeutic classes and that have incurred more than $100.0 million of Medicare Part B spending over a 12-month period, to pay incremental rebates based on an alternative, internationally benchmarked calculation of the existing Medicare Part B drug inflation rebate. The GLOBE model will begin on January 1, 2027 with the collection of voluntary manufacturer-submitted international drug net pricing data, and will be tested over five performance years, running from April 1, 2027 through March 31, 2032. The associated payment period will run from April 1, 2027 through March 31, 2034. GLOBE excludes orphan-only drugs, cell and gene therapy products, plasma-derived products, and drugs with an effective Medicare-negotiated maximum fair price. GUARD remains a proposed regulation that has not been finalized and, as proposed, would similarly mandate manufacturer rebates for qualifying sole source drugs where the Medicare net price exceeds an MFN benchmark derived from international reference pricing methodologies, with its performance period proposed to begin in 2027. The GLOBE model has been subject to legal challenge, and both the GLOBE model and the proposed GUARD model may face additional legal challenges, which could delay implementation or modify their impact on manufacturer pricing and revenue.

If the GLOBE model is implemented as finalized and the GUARD model is finalized as proposed under CMMI authority and if exemptions do not apply to our products, we could be required to pay additional rebates on products reimbursed by Medicare for the covered populations during the applicable model periods. In addition, if MFN pricing or similar reference pricing policies are enacted or implemented in the U.S. outside of the CMMI framework and applied more broadly, we could be required to pay rebates on product utilization by a broader portion of U.S. patients to align with prices in certain reference countries. We currently derive the substantial portion of our revenue from U.S. sales, and any requirement to pay additional rebates in the U.S. to match international reference prices would impact our overall net product revenue.

MFN pricing models in the U.S. could also affect our international pricing strategy and future decisions on reimbursement and commercialization in certain jurisdictions. If our U.S. pricing becomes tied to international reference prices, especially in light of our licensing agreements with Bayer and Alexion, we may face decisions regarding pricing in foreign markets that could result in reduced patient access internationally, affect our relationships with foreign regulatory authorities and payers, or impact our ability to obtain or maintain reimbursement approvals in ex-U.S. markets. The GLOBE model and the proposed GUARD model remain subject to potential legal challenges, and the proposed GUARD model remains subject to change, potential finalization, or expansion through additional rulemaking or sub regulatory guidance, creating uncertainty for our overall pricing strategy. It remains to be seen whether and how these drug pricing initiatives will apply to our products, how they will affect the broader pharmaceutical industry, and whether similar reform measures may be adopted in the future.

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

We face competition in the U.S. for Attruby and may face competition for our product candidates if approved, from therapies sourced from foreign countries that have placed price controls on pharmaceutical products. In the U.S., the Medicare Modernization Act contains provisions that may change U.S. importation laws and expand pharmacists' and wholesalers' ability to import lower priced versions of an approved drug and competing products from Canada, where there are government price controls. The FDA also issued a final guidance document outlining a pathway for manufacturers to obtain an additional National Drug Code ("NDC") for an FDA-approved drug that was originally intended to be marketed in a foreign country and that was authorized for sale in that foreign country. See the section titled, "*Business - Government Regulation - Current and Future Legislation*" in our Annual Report on Form 10-K for the year ended December 31, 2025 filed with the SEC on February 24, 2026 for more information regarding legislative and regulatory changes and proposed changes regarding the healthcare system directed at broadening the availability of healthcare, improving the quality of healthcare, and containing or lowering the cost of healthcare. If certain of these changes are implemented, importation of drugs from Canada may materially and adversely affect the price we receive for any of our product candidates. The regulatory and market implications of the final rule and guidance are unknown at this time. Proponents of drug reimportation may attempt to pass legislation that would directly allow reimportation under certain circumstances. Legislation or regulations allowing the reimportation of drugs, if enacted, could decrease the price we receive for any products that we may develop and adversely affect our future revenues and prospects for profitability. We will continue to monitor developments and their potential effect on our business.

We face significant competition in an environment of rapid technological and scientific change, and there is a possibility that our competitors may achieve commercial success or 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 face competition for Attruby and Beyonttra and 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.

Our approved product faces competition from other products approved for the same indication, and 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 some of our lead clinical-stage product candidates are pursuing. If any competitors for our 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, nonclinical 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 product candidates uneconomical or obsolete and we may not be successful in marketing those product candidates, once approved, 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 the section titled, "*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, 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 our products and product candidates may be limited or may not be amenable to treatment with our products or product candidates, and new patients may become increasingly difficult to identify or gain access to, which would adversely affect our results of operations and our business. Further, even if we obtain significant market share for our product candidates under development in our key value driver programs, 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. In particular, Attruby is not the first treatment on the market for ATTR-CM, and its market share and potential to generate revenues may be limited.

Risks Related to the Development of Our Product Candidates

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 nonclinical, 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 nonclinical and clinical product candidate development;
- delays in reaching a consensus with regulatory agencies as to the design or implementation of our clinical trials;
- delays in reaching agreement on acceptable terms with prospective contract research organizations ("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 ("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 Investigational New Drug application ("IND") or IND amendment, clinical trial application ("CTA") or CTA amendment, or equivalent application or amendment; or as a result of a new safety finding that presents unreasonable risk to clinical trial participants or 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 third parties that raise regulatory or safety concerns about risk to patients of the treatment, or if the FDA or other governmental authority 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 ("GCP"), requirements, or regulatory guidelines in other countries;
- occurrence of 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 or failing to meet a specified endpoint, which may result in our deciding, or regulators requiring us, to conduct additional clinical trials or to abandon product development programs;
- delays in clinical trial enrollment or clinical trial initiation resulting from any global health emergency;
- 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, conduct or complete clinical trials could result in additional costs to us or impair our ability to generate revenue. In addition, if we make manufacturing or formulation changes to our product candidates, we may be required to or we may elect to conduct additional nonclinical studies or clinical trials to bridge data obtained from our modified product candidates to data obtained from nonclinical and clinical research conducted using earlier versions of these product candidates. Clinical trial delays could also shorten any periods during which our product candidates 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 an ongoing or planned clinical trial is suspended or terminated by us, by the data safety monitoring board ("DSMB"), 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. We have in the past received, and may receive in the future, partial or full clinical hold notices from the FDA or other regulatory authorities, which have required, and may in the future require, us to conduct additional studies, generate additional data, amend our clinical trial protocols and/or delay or halt the initiation or continuation of our clinical trials. We may be required or may voluntarily determine to place one or more of our product candidates on clinical hold in the future for various reasons, which could delay or otherwise impair our clinical development efforts and ability to obtain regulatory approval for any such product candidate. Additionally, the FDA may determine, upon review of an IND submission, that we have not provided sufficient information needed to assess the risks to subjects of the proposed studies, or that our IND submission is otherwise insufficient to support initiation of a clinical trial. There is no guarantee that the FDA will agree that our responses are sufficient, and we may be required to conduct additional nonclinical studies or manufacturing steps before the FDA allows our proposed clinical trials to proceed.

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 from such product candidates, if approved. 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.

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 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 nonclinical studies and clinical trials ourselves. The results of nonclinical studies and clinical trials in one set of patients or disease indications, or from nonclinical 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, nonclinical and clinical data are often susceptible to various interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in nonclinical 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, despite 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 U.S. to market and sell these product candidates. Our failure to obtain marketing approval for our product candidates for commercially viable indications, or at all, would substantially harm our business, prospects, financial condition and results of operations.

Additionally, some clinical trials of our product candidates performed to date were designed as 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 trials 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.

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 each 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, 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 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 or product candidate, limit the commercial potential of a product candidate, if approved, or result in other significant negative consequences that could 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 use of our product candidates. 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 of our product candidates 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 nonclinical 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 nonclinical studies or clinical trials. AEs that we may observe in our ongoing and future nonclinical studies and clinical trials of our product candidates could require us to delay, modify or abandon our development plans for the affected product candidate or other product candidates that share properties of the affected product candidate. Many product candidates that initially show promise in early-stage testing may later be found to cause side effects that prevent further development. As we work to advance existing product candidates and to identify new product candidates, we cannot be certain that later testing or trials of product candidates that initially showed promise in early testing will not be found to cause similar or different unacceptable side effects that prevent their further development.

It is possible that as we test our product candidates in larger, longer and more extensive clinical trials, or as the use of our product candidates, if they receive regulatory approval, becomes more widespread, 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, 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, to change the requirements for approval of any of our product candidates.

In addition to side effects caused by a product candidate, the administration process or related procedures also can cause adverse side effects. If any such AEs occur, our clinical trials of a product candidate 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 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 we can demonstrate that all future 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 ("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 healthcare 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 or product candidate;
- regulatory authorities may require additional warnings or statements on the label;
- regulatory authorities may refuse to approve label expansion for additional indications of such product or product candidate;
- we may be required by the FDA to implement a REMS;
- we may be required to change the way a product or product candidate is distributed, administered or conduct additional clinical trials;
- we may be subject to regulatory investigations and enforcement actions;
- we may decide to remove such product or product candidate from the marketplace;
- 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 or product candidate, if approved, and may harm our business, financial condition and prospects significantly.

Certain of our product candidates are 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.

The inclusion of critically ill patients in our clinical trials may result in deaths or other adverse medical events due to underlying disease or to other therapies or medications that such patients may receive. Any of these events could prevent us from advancing our product candidates through clinical development, and from obtaining regulatory approval, and would impair our ability to commercialize our product candidates. Any inability to advance our product candidates through clinical development may harm our business, financial condition, results of operations and prospects.

Preliminary, interim or topline 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 have and may in the future publish or report preliminary, interim or topline data from our clinical trials, such as the release of our topline results from PROPEL 3, our Phase 3 study of oral infigratinib in children with achondroplasia. Preliminary, interim or topline data from clinical trials may not be indicative of the final results of the trial and are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and/or more patient data become available. The results of nonclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trial, and favorable data from interim analysis do not ensure the final results of a trial will be favorable. Preliminary, interim or topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary, interim or topline data we previously published. As a result, preliminary, interim or topline data should be viewed with caution until the final data are available. Material adverse changes between preliminary, interim or topline data and final data could significantly harm our business, financial condition, results of operations and prospects.

Risks Related to Regulatory Review and Approval of our Product Candidates

Although we have obtained marketing authorization for Attruby, we have multiple product candidates in our development pipeline that are still in nonclinical 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 pipeline 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. 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 nonclinical 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.

Our product candidates require additional development; management of nonclinical, clinical and manufacturing activities; and regulatory approval. In addition, we will need to obtain adequate manufacturing supply; complete the build-out of a commercial organization; commence product candidate-specific marketing efforts; and obtain reimbursement before we generate any significant revenue from commercial product sales from such product candidates, if ever. Some 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 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 are not able to successfully commercialize an approved drug or if we do not receive additional regulatory approvals for our product candidates, we and our subsidiaries may not be able to continue operations, which may result in us winding down and dissolving the subsidiary, selling or out-licensing the technology or pursuing an alternative strategy.

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

We cannot commercialize a product until the appropriate regulatory authorities have reviewed and approved the product candidate. Approval by the FDA and comparable foreign regulatory authorities is lengthy and unpredictable, and depends upon numerous factors, including substantial discretion of the regulatory authorities. Approval policies, regulations or the type and amount of nonclinical or clinical data necessary to gain approval may change during the course of a product candidate's development and may vary among jurisdictions, which may cause delays in the approval or the decision not to approve an application. In addition, the U.S. Supreme Court's July 2024 decision to overturn prior established case law giving deference to regulatory agencies' interpretations of ambiguous statutory language has introduced uncertainty regarding the extent to which the FDA's regulations, policies and decisions may become subject to increasing legal challenges, delays, and/or changes. 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. Although Attruby and Beyonttra received regulatory approval for commercial sale in the U.S., EU, UK, Brazil, Australia and Japan, we cannot be certain that any of our product candidates will receive regulatory approval or if approved, will be successfully commercialized.

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 nonclinical 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 a new drug application ("NDA"), biologics license application ("BLA"), or other submission for regulatory approval in the U.S. 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.

In addition, even if an NDA, BLA, or other submission for regulatory approval, is filed and accepted for review, the FDA or comparable regulatory authorities may delay their review or approval process or may decline to grant regulatory approval for a variety of reasons. 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 U.S. or elsewhere, which would significantly harm our business, prospects, financial condition and results of operations.

Our clinical trials may fail to demonstrate substantial evidence of the safety and efficacy 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 our product candidates, we must demonstrate through lengthy, complex and expensive nonclinical 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 future marketing approvals.

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. Success in clinical trials in a particular indication does not ensure that a product candidate will be successful in other indications. Similarly, approval of a product candidate in a particular indication does not ensure that the product candidate will be successful in other indications. 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. 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.

We conduct clinical trials for product candidates outside the U.S., and the FDA and comparable foreign regulatory authorities may not accept data from such trials.

We have conducted and plan to conduct clinical trials outside the U.S., including in Europe. The acceptance by the FDA or comparable foreign regulatory authority of study data from clinical trials conducted outside the U.S. or another jurisdiction may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the U.S., 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; (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations; and (iii) the data may be considered valid without the need for an on-site inspection by the FDA or, if the FDA considers such as inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. 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 U.S. or the applicable jurisdiction, and the FDA has discussed proposals to increase user fees for marketing applications containing certain foreign clinical data. In addition, the FDA recently signaled increased scrutiny of foreign clinical trial data submitted in support of marketing applications, indicating plans for increased foreign site inspections and increased transparency of inspection results. 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 any of our current pipeline product candidates in the U.S., we may never obtain approval to commercialize any of these product candidates outside of the U.S., which would limit our ability to realize their full market potential.

In order to market any products outside of the U.S., 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 U.S., including additional nonclinical 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 U.S., 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, once approved is also subject to approval.

Seeking and maintaining 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. While we previously had two products approved for sale in the U.S., we only have one product approved for sale in international markets, and we have only limited 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 any approved products will be harmed.

Even though we may apply for orphan drug designation for our product candidates, we may not be able to obtain such designations or maintain the benefits associated with orphan drug status, including orphan drug market exclusivity.

Our business strategy focuses on the development of product candidates for the treatment of genetic diseases, which may be eligible for FDA or European Commission orphan drug designation. Regulatory authorities in some jurisdictions, including the U.S. and European Union, may designate drugs or biologics for relatively small patient populations as orphan drugs. 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.

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 orphan drug exclusivity can be overcome if a subsequent applicant demonstrates clinical superiority over our product.

We have obtained from the FDA orphan drug designations, including for: Attruby for the treatment of transthyretin amyloidosis; low-dose infigratinib for the treatment of achondroplasia; encaleret for the treatment of autosomal dominant hypocalcemia (including ADH type 1 and ADH type 2); and BBP-812 for the treatment of Canavan Disease. We have obtained from the European Commission, orphan medicinal product designation for: acoramidis for the treatment of ATTR amyloidosis; low-dose infigratinib for the treatment of achondroplasia; BBP-418 for the treatment of limb-girdle muscular dystrophy; BBP-812 for the treatment of Canavan Disease; and encaleret as a treatment for hypoparathyroidism (inclusive of ADH1). We may seek orphan drug designation for other product candidates. Even if we obtain orphan drug designation, exclusive marketing rights in the U.S. 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, 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. In addition, although we may seek orphan drug designation for other product candidates, we may never receive such designations. Any failure to obtain, maintain or otherwise recognize the benefits of orphan drug designation for our product candidates could have a material adverse effect on our prospects.

On February 3, 2026, Congress passed the Consolidated Appropriations Act of 2026. The RARE Act codified the FDA's longstanding regulatory interpretation that orphan drug exclusivity applies only to the specific approved use or indication of a drug or biological product, rather than to all uses within a designated rare disease or condition.

The FDA may further reevaluate the Orphan Drug Act and its regulations and policies. We do not know if, when, or how the FDA may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted.

The FDA has granted rare pediatric disease designation to BBP-418 for the treatment of LGMD2I, BBP-812 for the treatment of Canavan Disease and infigratinib for the treatment of achondroplasia. However, a marketing application for these products that have been granted this designation or any other product candidate, if approved, may not meet the eligibility criteria for a PRV.

The FDA has granted rare pediatric disease designation to BBP-418 for the treatment of LGMD2I, BBP-812 for the treatment of Canavan Disease and infigratinib for the treatment of achondroplasia. 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 PRV at the time the application is approved. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), we will need to request a rare pediatric disease PRV in our original NDA for these designated products, which we did in the NDA submission for BBP-418 for the treatment of LGMD2I. Vouchers for rare pediatric disease drugs are awarded for qualifying applications when the drug receives approval. The FDA may determine that an NDA for these product candidates, if approved, does not meet the eligibility criteria for a PRV, including for the following reasons:

- achondroplasia, LGMD2I or Canavan Disease 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 the product is designated (for example, if BBP-418 is approved for an indication based on specific genetic alterations that would be inclusive of, but not limited to, BBP-418).

The Consolidated Appropriations Act of 2026 reauthorized the FDA's authority to award priority review vouchers to sponsors of new products intended to treat rare pediatric diseases through September 30, 2029. Under current law, after September 30, 2029, the FDA may not award any rare pediatric disease priority review vouchers, although the FDA's authority to do so could be extended by Congress in the future. Accordingly, there is no guarantee that we will be granted PRVs for any of our existing or future product candidates.

Accelerated approval by the FDA, even if granted for any of our product candidates, may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our product candidates will receive marketing approval.

We may seek approval of our product candidates using the FDA's accelerated approval pathway. This pathway may not lead to a faster development, regulatory review or approval process and does not increase the likelihood that our product candidates will receive marketing approval. A product may be eligible for accelerated approval if it treats a serious or life-threatening condition, generally provides a meaningful advantage over available therapies, and demonstrates an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. As a condition of approval, the FDA may require that a sponsor of a product receiving accelerated approval perform adequate and well-controlled post-marketing confirmatory clinical trials. These confirmatory trials must be completed with due diligence. Under the Food and Drug Omnibus Reform Act of 2022 ("FDORA"), the FDA is permitted to require, as appropriate, that a post-approval confirmatory trial or trials be underway prior to approval or within a specified time period after the date accelerated approval was granted. FDORA also requires sponsors to send updates to the FDA every 180 days on the status of such studies, including progress toward enrollment targets, and the FDA must promptly post this information publicly. Furthermore, under FDORA, the FDA is empowered to take action, such as issuing fines, against companies that fail to conduct with due diligence any post-approval confirmatory trial or submit timely reports to the agency on their progress. In addition, for products under consideration for accelerated approval, the FDA currently requires, unless otherwise requested by the agency, pre-approval of promotional materials prior to dissemination or publication, which could adversely impact the timing of the commercial launch of the product. Thus, even if we seek to utilize the accelerated approval pathway, we may not be able to obtain accelerated approval and, even if we do, we may not experience a faster development or regulatory review or approval process for that product. In addition, receiving accelerated approval does not assure that the product's accelerated approval will eventually be converted to a traditional approval.

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

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

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

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

We may also seek RMAT designation for one or more of our product candidates. This program is intended to facilitate efficient development and expedite review of regenerative medicine therapies, which are intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition and qualify for RMAT designation. A BLA for a product candidate that has received RMAT designation may be eligible for priority review or accelerated approval through use of surrogate or intermediate endpoints reasonably likely to predict long-term clinical benefit, or reliance upon data obtained from a meaningful number of sites. Benefits of RMAT designation also include early interactions with the FDA to discuss any potential surrogate or intermediate endpoint to be used to support accelerated approval.

Although some of our product candidates were granted fast track designation by the FDA, we may elect not to pursue any of breakthrough therapy, fast track or RMAT designations for our other product candidates, and the FDA has broad discretion whether or not to grant these designations.

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

Additionally, certain oncology product candidates may be eligible for review under the Real-Time Oncology Review ("RTOR"), which is an initiative of the FDA's Oncology Center of Excellence designed to expedite the delivery of safe and effective cancer treatments to patients. Although this program allows the FDA to review data earlier, before an applicant formally submits a complete application, acceptance into the RTOR pilot does not guarantee or influence approvability of the application, which is subject to the usual benefit-risk evaluation by FDA reviewers, and it does not affect the FDA's Prescription Drug User Fee Act timelines. Although early approvals have occurred with applications selected for RTOR, this may not be the case for our application even if it is selected for RTOR. If at any time the FDA determines our participation in RTOR, if selected, is no longer appropriate, the FDA may rescind our acceptance and instruct us to follow routine submission procedures for marketing approval.

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 product candidates.

In connection with the clinical development of our product 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. 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 product 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 nonclinical 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 and therapeutics 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 product candidates, or experience delays in doing so, the development of these therapeutic product candidates may be adversely affected, these therapeutic product candidates may not obtain marketing approval, and we may not realize the full commercial potential of any of these therapeutics that have or may 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 (collectively, the "ACA"), includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 ("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 nonclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity, and potency of the other company's product.

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. 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 any of our product candidates, our products may become subject to competition from such biosimilars, which would impair our ability to successfully commercialize and generate revenues from sales of such products.

Attruby and Beyonttra and our current product candidates, if approved, 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.

Attruby and Beyonttra and our current product candidates, if approved, will be subject to ongoing regulatory requirements and review by the FDA and other applicable regulatory authorities 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 U.S. 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 ("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 ("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. Furthermore, under the Drug Supply Chain Security Act, for certain commercial prescription drug products, manufacturers and other parties involved in the supply chain must also meet chain of distribution requirements and build electronic, interoperable systems for product tracking and tracing and for notifying the FDA of counterfeit, diverted, stolen, and intentionally adulterated products or other products that are otherwise unfit for distribution in the U.S. In addition, the distribution of prescription pharmaceutical products, including samples, is subject to the Prescription Drug Marketing Act ("PDMA"), which regulates the distribution of drugs and drug samples at the federal level, and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution. Prescription drug products must also meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. If we are not able to comply with post-approval regulatory requirements, we could have the marketing approvals for any approved products withdrawn by regulatory authorities and our ability to market such products could be limited, which could adversely affect our ability to achieve or sustain profitability and we could be subject to substantial penalties. As a result, the cost of compliance with post-approval regulations may have a negative effect on our operating results and financial condition.

Any regulatory approvals that we may receive for our product candidates, are or 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. 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. Additionally, under FDORA, sponsors of approved drugs and biologics must provide six months' notice to the FDA of any changes in marketing status, such as the withdrawal of a drug, and failure to do so could result in the FDA issuing a publicly available non-compliance letter to the sponsor.

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, if approved 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 those products.

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 or untitled 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;
- impose restrictions on the labeling of products;
- impose restrictions on product distribution or use, such as a REMS;
- 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, our operating results will be adversely affected and our stock price may decline. 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 or suspend, withdraw or modify regulatory approval of our products.

The FDA and other agencies actively enforce the laws and regulations governing the promotion of prescription products, including those prohibiting the promotion of off-label uses.

The FDA and other governmental and regulatory agencies, including the U.S. Department of Justice, strictly regulate and closely 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. While the FDA permits the dissemination of truthful and non-misleading information about an approved product, a sponsor may not promote a product unlawfully or 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 our products unlawfully or for 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 products, including for 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.

In September 2025, the FDA announced increased scrutiny of advertising and promotional practices, with a particular focus on direct-to-consumer ("DTC") advertising and reportedly sent thousands of letters to pharmaceutical companies to remove misleading ads, including a large number of untitled and warning letters citing allegedly misleading claims. For example, we received one of these untitled letters citing a DTC broadcast advertisement for Attruby. This heightened enforcement environment increases the risk that our promotional materials, even if we believe them to be compliant, could be challenged by the FDA or by consumers or plaintiffs' counsel, which could lead us to modify or withdraw certain promotional materials. If we cannot successfully manage the promotion of our products or product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

Notwithstanding regulations related to product promotion, the FDA and other regulatory authorities allow companies to engage in truthful, non-misleading, and non-promotional scientific exchange concerning their products. We intend to engage in medical education activities and communicate with healthcare providers in compliance with all applicable laws and regulatory guidance.

Existing regulatory policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates.

In June 2024, the U.S. Supreme Court overruled the Chevron doctrine, which gives deference to regulatory agencies' statutory interpretations in litigation against federal government agencies, such as the FDA, where the law is ambiguous. This decision may result in more lawsuits against the FDA to challenge longstanding decisions and policies of the FDA, which could undermine the FDA's authority, lead to uncertainties in the industry, and disrupt the FDA's normal operations, any of which could delay the FDA's review of our regulatory submissions. We cannot predict the full impact of this decision, future judicial challenges brought against the FDA, or the nature or extent of government regulation that may arise from future legislation or administrative action. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, and we may not achieve or sustain profitability.

Risks Related to Our Reliance on Third Parties

We rely entirely on third parties for the manufacturing of commercial supplies of Attruby and Beyonttra and for supplies of our product candidates that we may develop. 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 Attruby and Beyonttra on a commercial scale or to manufacture drug supplies of our product candidates for our ongoing clinical trials or any future clinical trials that we may conduct, and we lack the resources to manufacture our product candidates, if approved, on a commercial scale. We rely, and expect to continue to rely, on third-party manufacturers for the manufacturing of commercial supplies of Attruby and Beyonttra and our product candidates, if approved. We also rely on third-party manufacturers for the clinical manufacturing supply of our product candidates. Although we have entered into long-term supply arrangements and 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 commercial product, product candidate, or the raw material components thereof, for continued commercial sales or for an ongoing clinical trial due to the need to replace a third-party manufacturer could considerably delay or curtail commercial sales of a product or the clinical development and potential regulatory approval of our product candidates, which could harm our business and results of operations.

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 to produce such materials and products. The facilities used by our contract manufacturers to manufacture our products and 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 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, if approved, our product candidates.

On March 27, 2020, in response to the COVID-19 pandemic, the U.S. passed into law the CARES Act, which enhanced the FDA's authority with respect to drug shortage measures. Under the CARES Act, we must have in place a risk management plan that identifies and evaluates the risks to the supply of approved drugs for certain serious diseases or conditions for each establishment where the drug or active pharmaceutical ingredient is manufactured. The risk management plan will be subject to FDA review during an inspection. If we experience shortages in the supply of Attruby or any of our product candidates that receive marketing approval, our results could be materially impacted.

Our products and product candidates may compete with other marketed drugs and product candidates and marketed drugs for access to manufacturing facilities. In addition, 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 products and 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 are manufactured by single-source suppliers or CMOs pursuant to development and manufacturing contracts, quality agreements and purchase orders.

We do not currently have any other suppliers for the drug substance or drug product for these product candidates and, although we believe that there are alternate sources of supply that could satisfy our clinical requirements and are in the process of establishing agreements with alternate suppliers, we cannot assure you that we will be successful in identifying alternate sources and establishing relationships with such sources, or that we will be able to avoid significant delays or disruptions in the development of our product candidates due to our current reliance on single-source suppliers.

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

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

Additionally, we may not be able to enter into or maintain supply arrangements with alternative suppliers on commercially reasonable terms, or at all. A delay in the supply of our commercial products to the market or 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 increase our expenses, impair our ability to generate revenues and have a material adverse impact on our business.

The drug product for Attruby and Beyonttra is currently supplied by one primary supplier. We have entered into a master agreement with an alternative supplier of drug product and have taken delivery of commercial drug product manufactured by this secondary supplier. We expect these tablets to enter our finished goods inventory later this year following completion of packaging. However, we may encounter unexpected delays in the further processing, packaging, release, or supply of commercial drug product from this or other suppliers.

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 products for commercial sale or product candidates for clinical trials, including our existing CMOs for Attruby and Beyonttra and 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 U.S. 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 applicable product candidates 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 trial 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. In some cases, the technical skills required to manufacture our product candidates may be unique or proprietary to the original CMO and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change CMOs for any reason, we will be required to verify that the new CMO maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product or product candidate according to the specifications previously submitted to or approved by the FDA or another regulatory authority. The delays associated with the verification of a new CMO could negatively affect our ability to develop product candidates or once approved, to commercialize those product candidates in a timely manner or within budget. In addition, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies, which could require the conduct of additional clinical trials. Accordingly, 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. For example, Eidos is party to an exclusive license agreement with Bayer to develop and commercialize Beyonttra as a treatment for ATTR-CM in the European Union and all member states of the European Patent Organization; Eidos is also a party to a license agreement with Alexion Pharma International Operations Limited Company ("Alexion") pursuant to which we depend on Alexion for the commercialization of Beyonttra in Japan; QED is party to an exclusive license with Kyowa Kirin to develop, manufacture, and commercialize infigratinib for achondroplasia, hypochondroplasia, and other skeletal dysplasias in Japan. In addition, we may rely even more on strategic collaborations for R&D of other product candidates, and we may sell or license other product offerings through strategic partnerships with pharmaceutical and biotechnology companies.

If we enter into R&D collaborations during the early phases of product development, success will in part depend on the performance of research collaborators. We will not directly control the amount or timing of resources devoted by research collaborators to activities related to product candidates. Research collaborators may not commit sufficient resources to our R&D programs. If any research collaborator fails to commit sufficient resources, the nonclinical 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 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 such products. Such collaborators may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for any future product candidate.

Management of our relationships with collaborators will require:

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

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

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

We depend upon third-party collaboration partners for financial and human resources for the commercialization of Attruby and Beyonttra in certain territories outside the U.S. and may enter into additional collaborations, licenses and similar arrangements for the clinical development and commercialization of some of our product candidates. 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 our products or product candidates that are the subject of collaborations;
- collaborators may shift their priorities and resources away from the development and commercialization of our product candidates or may elect to discontinue 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, a lack of available funding or other external factors, such as a business combination or downsizing of its company or business unit that diverts or limits resources or creates competing priorities;

- collaborators may delay commercial sales or clinical trials, provide insufficient funding for a development program, stop a clinical trial, abandon a commercial product or product candidate, repeat or conduct new clinical trials or require a new formulation of a marketed product for continued commercialization or 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 developing or commercializing our product candidates on our own or 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 products or product candidates or the requirement to expend additional time and resources to seek an alternative collaboration partner;
- 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 actual or projected 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.

We expect to rely on third parties to conduct our clinical trials and some aspects of our research and nonclinical 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 nonclinical 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 will delay our 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 with 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 commercial sales of Attruby and Beyonttra or the clinical development or marketing approval of any product candidates we may develop resulting in additional losses and depriving us of potential product revenue.

Risks Related to the Novel Nature of our Product Candidates

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 have caused and may cause future production interruptions, including restrictions on certain manufacturing operations and shortages in on-site personnel at our CMOs' manufacturing facilities, 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, including historical disruptions related to the COVID-19 pandemic, which could reoccur in connection with any future global pandemic or health emergency.

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 certain of our biologic product candidates 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 do not distribute a lot until the relevant authority 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. Problems in our manufacturing process could also restrict our ability to meet potential future market demand for any products that may be approved.

Certain of our product candidates are based on adeno-associated virus ("AAV") gene therapy technology for which there is limited clinical or regulatory experience to date, making 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, the 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, the 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 U.S., 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 the development of gene therapy products have changed frequently and may continue to change in the future. In 2016, the FDA established the Office of Tissues and Advanced Therapies ("OTAT"), within its Center for Biologics Evaluation and Research ("CBER"), to consolidate the review of gene therapy and related products, and to advise CBER on its review. In September 2022, the FDA announced retitling of OTAT to the Office of Therapeutic Products ("OTP"), and elevation of OTP to a "Super Office" to meet its growing cell and gene therapy workload. In addition, under guidelines issued by the National Institutes of Health ("NIH") gene therapy clinical trials are also subject to review and oversight by an institutional biosafety committee ("IBC") a local institutional committee that reviews and oversees research utilizing recombinant or synthetic nucleic acid molecules at that institution. Before a clinical trial can begin at any institution, that institution's institutional review board ("IRB"), and its IBC assesses the safety of the research and identifies any potential risk to public health or the environment. 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. Moreover, serious adverse events or developments in clinical trials of gene therapy product candidates conducted by others may cause the FDA or other regulatory bodies to initiate a clinical hold on our clinical trials or otherwise change the requirements for approval of any of our product candidates. Although the FDA decides whether individual cell and gene therapy protocols may proceed, the review process and determinations of other reviewing bodies can impede or delay the initiation of a clinical trial, even if the FDA has reviewed the trial and approved its initiation.

Similarly, the EMA conducts the scientific evaluation of marketing authorization applications for gene therapies in the European Union and the EMA or other relevant authorities 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, if approved, 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, the imposition of a clinical hold, limit the commercial potential or result in significant negative consequences.

Public attitudes may be influenced by claims that gene therapy as a novel 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. In addition, the FDA has imposed an increased number of clinical holds on gene therapy candidates in recent years. 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. There has also been a case report of a tumor presumed to have been introduced by integration of portions of the transgene into cellular DNA. While new AAV vectors have been developed to reduce some of 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, increasingly reported side effects of AAV gene therapy include, but are not limited to: a t-cell immunological response, often seen affecting the liver or complement mediated immune responses (particularly Thrombotic Microangiopathy) which can affect the kidneys, blood compartment / bone marrow, among other systems, and which can be lethal. Any actual or perceived negative effects of our AAV gene therapy product candidates or those under development by third parties could impair our ability to continue the development of these product candidates and have an adverse effect on our prospects.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain sufficient intellectual property protection for Attruby and Beyonttra and our product candidates, including low-dose infigratinib, BBP-418, and encaleret, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize products or product candidates similar or identical to ours, and our ability to successfully commercialize our product candidates 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 U.S. and other countries with respect to our product candidates and technology. We seek to protect our proprietary position by filing patent applications in the U.S. and abroad related to our product candidates.

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 U.S., 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 U.S. 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, 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 U.S. 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 products. 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 U.S. Patent and Trademark Office ("USPTO") and from time to time have been or may 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 from time to time our issued patents have been or may be challenged in the courts or patent offices in the U.S. 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 product candidates might expire before or shortly after such product 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 under certain circumstances. For example, the government may 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 U.S. 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 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 our product candidates that we successfully develop and commercialize. 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 condition, 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 Attruby or any 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. In particular, 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 infigratinib under which we are required to use commercially reasonable efforts to develop infigratinib, and to obtain regulatory approval for and commercialize at least one therapeutic product incorporating infigratinib in the U.S. 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 Attruby and we may be required to cease our development and commercialization of Attruby. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, 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 condition, 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 U.S., involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits in the courts, and interferences, oppositions, *inter partes* review, and other 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 Attruby and Beyonttra, low-dose infigratinib, BBP-418, encaleret 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 our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates 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 our product candidates, 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 or product candidate unless we obtained a license under the applicable patents, or until such patents expire.

Similarly, if any third-party patents 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 or 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 rights.

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

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 our 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 U.S., 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 products or new product candidates, patents protecting such products or candidates might expire before or shortly after such products or 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, or in applicable cases maintain, patent term extension or non-patent exclusivity in the U.S. 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 products or 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 U.S. 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 the term of any such extension is less than we request, the period during which we will have the right to exclusively market any products that may be approved, 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, an application 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 an application to obtain a patent term extension is filed, or an extension 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 (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 our current 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 ("ANDA") filed with the FDA to obtain permission to sell a generic version of such product.

Depending upon the timing and specifics of marketing approval of our products, the FDA and other applicable regulatory authorities may grant certain non-patent exclusivities. Although we intend to seek new chemical entity exclusivity, and potentially other exclusivities, for product candidates we are developing, we may not be successful in doing so. Moreover, these non-patent exclusivities, if granted, are limited and other companies may be able to submit marketing applications and receive approval earlier than we anticipate.

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 product candidates 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 U.S. 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 U.S., 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, 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 enter into 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 litigation or other proceedings.

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 U.S., 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. From time to time, third parties have raised and may in the future raise validity challenges before administrative bodies in the U.S. 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 products or 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 or other third party were to prevail on an 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 U.S. 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 entity 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 U.S. can be less extensive than those in the U.S. 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 U.S. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the U.S., or from selling or importing products made using our inventions in and into the U.S. 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 U.S. 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 U.S. 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 U.S., the first to invent the claimed invention was entitled to a patent, while outside the U.S., the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith America Invents Act (the "America Invents Act"), enacted in September 2011, the U.S. 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 U.S. 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 U.S. 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 federal 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 federal 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. 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 rights in the future.

Risks Related to Our Business and Industry

Disruptions to the operations of the FDA, the SEC and other government agencies, or comparable regulatory authorities caused by funding shortages or global health concerns, in addition to substantial uncertainty regarding the current Administration's initiatives and staffing cuts and how these might impact the FDA, its implementation of laws, regulations, policies and guidance, and its personnel, 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, including timely reviews, 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, the ability to hire and retain key personnel and accept payment of user fees, the availability of personnel and other resources, and statutory, regulatory and policy changes that may otherwise affect the FDA's ability to perform routine functions. As a result, average review times at the agency have fluctuated in recent years. 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, including substantial leadership departures, personnel cuts, and policy changes, 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. Changes and cuts in FDA staffing have been reported by some within the pharmaceutical industry as creating instances of delays in the FDA's responsiveness or in its ability to review IND submissions or applications, issue regulations or guidance, or implement or enforce regulatory requirements in a timely fashion or at all.

Similar consequences would also result in the event of another significant shutdown of the federal government. For example, over the last several years, the U.S. government has shut down several times, including the most recent shutdown that began on October 1, 2025 and lasted for 43 days, and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. If a prolonged government shutdown occurs, or if geopolitical or global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or such other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business, including INDs placed on clinical holds or delayed new drug approvals. Similarly, a prolonged government shutdown or disruption to the operations of the USPTO could prevent the timely review of our patent applications, which could delay the issuance of any U.S. patents to which we might otherwise be entitled. Further, in our operations as a public company, future government shutdowns or substantial leadership, personnel, and policy changes could impact our ability to access the public markets and obtain necessary capital to properly capitalize and continue our operations. If the FDA is constrained in its ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

With the change in the U.S. Presidential Administration in 2025, there continues to be substantial uncertainty as to whether and how the current administration will seek to modify or revise the requirements and policies of the FDA and other regulatory agencies with jurisdiction over our product candidates and any products for which we obtain approval. This uncertainty could present new challenges as we navigate development and approval of our product candidates. Some of these efforts have manifested to date in the form of personnel cuts and measures that could impact the FDA's ability to hire and retain key personnel, which could result in delays or limitations on our ability to obtain guidance from the FDA on our product candidates in development and obtain the requisite regulatory approvals in the future. There remains general uncertainty regarding future activities. The current administration could issue or promulgate executive orders, regulations, policies or guidance that adversely affect us or create a more challenging or costly environment to pursue the development of new therapeutic products. Alternatively, state governments may attempt to address or react to changes at the federal level with changes to their own regulatory frameworks in a manner that is adverse to our operations. If we become negatively impacted by future governmental orders, regulations, policies or guidance as a result of the current administration or otherwise, there could be a material adverse effect on us and our business.

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.

If we were to lose Dr. Neil Kumar, our founder and Chief Executive Officer, 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 personnel will be critical to our success as we continue to scale up our organization for commercialization. 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, 2026, we had 1,081 full-time employees and 4 part-time employees. While we believe our structure enables us to reduce certain infrastructure costs, the small size of our central team, consisting of employees engaged in providing administrative, research and development and other services across our entire organization, 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 of 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.

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, 2026, we had 1,081 full-time employees and 4 part-time employees across all of our affiliates and controlled entities. 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 commercialization of our product candidates, if approved, and 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 if approved, 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, regardless of the treatment modality or the particular target indication within this space. Because we have limited financial and personnel resources, we may forego 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 related to the commercial sales of approved medicines. 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;
- 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 successfully commercialize our product candidates or medicines.

Although we maintain product liability insurance, including coverage for clinical trials that we sponsor and for our commercial product sales, 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 as we commercialize product candidates that may be approved. The market for insurance coverage is increasingly expensive, and the costs of insurance coverage will increase as our clinical programs and commercialization efforts 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 U.S. 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 U.S., we believe that 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 have adopted a code of business conduct and ethics applicable to our employees and directors, 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.

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

We currently market Attruby and Beyonttra outside of the U.S. through our collaboration partners. In addition, we are conducting clinical trials internationally through a global CRO, and our business strategy incorporates potential further international expansion targeting patient populations outside the U.S. If we receive regulatory approval for and commercialize any of our product candidates in patient populations outside the U.S., we may hire sales representatives and conduct physician and patient association outreach activities outside of the U.S. 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 tariffs and 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, global or widespread health emergencies (such as the COVID-19 pandemic), 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.

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, which could negatively affect the price of our common stock.

As a public company, we are required to maintain internal control over financial reporting and to report any material weaknesses in such internal controls. The Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act"), requires that we evaluate and determine the effectiveness of our internal control over financial reporting and, pursuant to Section 404(b) of the Sarbanes-Oxley Act ("Section 404") provide a management report on internal control over financial reporting. In addition, we are 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 be required to include in our periodic reports that will be filed with the SEC.

If we are unable to assert that our internal control over financial reporting is effective or 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 or sanctions by the stock exchange on which our securities are listed, the SEC, or other regulatory authorities, which could require additional financial and management resources.

We do 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.

Artificial intelligence presents risks and challenges that can impact our business including by posing security risks to our confidential information, proprietary information, and personal data.

Issues in the development and use of artificial intelligence ("AI"), combined with an uncertain regulatory environment, may result in reputational harm, liability, or other adverse consequences to our business operations. As with many technological innovations, AI presents risks and challenges that could impact our business. The use of certain AI technology can give rise to intellectual property risks, including compromises to proprietary intellectual property and intellectual property infringement. Additionally, government and supranational regulation related to AI is evolving and could increase the burden and cost of compliance, including through requirements related to transparency, accountability, risk management, human oversight, and data governance. For example, the EU's Artificial Intelligence Act ("AI Act") — the world's first comprehensive AI law — has entered into force on August 1, 2024, with additional provisions becoming effective on August 2, 2026. As currently enacted, this legislation, which may be amended as part of the EU's Digital Omnibus, imposes significant obligations on providers and deployers of high-risk artificial intelligence systems, and encourages providers and deployers of artificial intelligence systems to account for EU ethical principles in their development and use of these systems. The scope of requirements depends on legal and risk determinations that rely on novel legal provisions that have not yet been interpreted by courts or regulators, and non-compliance can lead to significant fines.

In the U.S., the regulatory environment is complex and uncertain. Over the past year, states have advanced, and in some cases passed, dozens of laws focusing on AI governance and regulation, including on deployment of AI in healthcare settings. At the federal level, the current Administration has endorsed a federal moratorium on the enforcement of state AI laws, including through a December 11, 2025, executive order on "Ensuring a National Policy Framework for Artificial Intelligence." So far, these efforts have not been successful at curtailing state action on AI regulation, contributing to a complicated legislative patchwork, which may be litigated in state and federal courts. In addition, there is continued uncertainty regarding the application of existing federal and state legal frameworks to uses and development of AI, and legal norms and market standards regarding AI continue to evolve. For example, various federal and state regulators have issued guidance and focused enforcement efforts on the use of AI in regulated sectors. The FDA, for example, issued draft guidance on the use of AI in regulatory decision-making for drug and biological products that centers on the context of use while establishing a credibility assessment framework for establishing and evaluating AI model outputs intended to support regulatory decision-making. If we develop or use AI systems that are governed by these laws or regulations, including as informed by regulatory guidance, we will need to meet higher standards of data quality, transparency, and human oversight, and we would need to adhere to specific and potentially burdensome and costly ethical, accountability, and administrative requirements.

The rapid evolution of AI may require the application of significant resources to design, develop, test and maintain our products and services to help ensure that AI is implemented in accordance with applicable law and regulation and in a socially responsible manner and to minimize any real or perceived unintended harmful impacts. The use of certain AI technologies can also give rise to intellectual property risks, including by disclosing or otherwise compromising confidential or proprietary intellectual property, or by undermining our ability to assert or defend ownership rights in intellectual property created with the assistance of AI tools.

Our vendors may in turn incorporate AI tools into their offerings, and the providers of these AI tools may not meet existing or rapidly evolving regulatory or industry standards, including with respect to privacy and data security. If we, our vendors, or our third-party partners experience an actual or perceived breach or privacy or security incident because of the use of AI, we may lose valuable intellectual property rights and confidential information and our reputation and the public perception of the effectiveness of our security measures could be harmed. Further, bad actors around the world use increasingly sophisticated methods, including the use of AI, to engage in illegal activities involving the theft and misuse of personal information, confidential information, and intellectual property. Any of these outcomes could damage our reputation, result in the loss of valuable property and information, and adversely impact our business.

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

Where we conduct clinical trials and enroll subjects in our clinical trials in the European Economic Area (the "EEA") or in the United Kingdom (the "UK"), we are subject to European data protection regulations which include additional privacy restrictions. The collection and use of data (including personal health data) in the EEA and UK are governed by the provisions of the EU GDPR and UK GDPR (together "GDPR" and each as defined in the section titled, "*Business - Government Regulation - EU and UK Data Collection*" in our Annual Report on Form 10-K for the year ended December 31, 2025 filed with the SEC on February 24, 2026). The GDPR imposes several stringent requirements on companies that process personal data, including requirements relating to the processing of special categories of personal data (such as health data), relying on a legal basis or condition for processing personal data, where required, obtaining consent of data subjects to whom the personal data relates, providing detailed information to data subjects about how their personal data is used, notification of data breaches to the competent national data protection authorities and implementing safeguards to protect the security and confidentiality of personal data. The GDPR also imposes strict rules on the transfer of personal data out of the EEA and UK to non-adequate territories such as the U.S.; any inability to transfer personal data from the EEA and UK to the U.S. in compliance with data protection laws may impede our ability to conduct trials and may adversely affect our business and financial position. Failure to comply with the requirements of the GDPR, and the related national data protection laws of the UK and EEA Member States may result in significant fines, other administrative penalties and private rights of action from data subjects and consumer associations. Compliance with the GDPR and any other data privacy and data security laws and regulations is a rigorous and time-intensive process and requires significant resources and an ongoing review of our technologies, systems and practices, as well as those of any third-party collaborators, service providers, contractors or consultants that process or transfer personal data. The GDPR and other changes in laws or regulations associated with the enhanced protection of certain types of sensitive data, such as healthcare data or other personal information from our clinical trials, could require us to change our business practices and put in place additional compliance mechanisms, may interrupt or delay our development, regulatory and commercialization activities and increase our cost of doing business, and could lead to government enforcement actions, private litigation and significant fines and penalties against us and could have a material adverse effect on our business, financial condition or results of operations.

Although the EU GDPR and the UK GDPR currently impose substantially similar obligations, it is possible that over time the UK GDPR could become less aligned with the EU GDPR, particularly with the introduction of the new UK Bill into the UK legislative process. In addition, EEA Member States have adopted national laws to supplement the EU GDPR, which may partially deviate from the EU GDPR, and the competent authorities in the EEA Member States may interpret EU GDPR obligations slightly differently from country to country, such that we do not expect to operate in a uniform legal landscape in the EEA and UK with respect to data protection regulations. The potential of the respective provisions and enforcement of the EU GDPR and UK GDPR further diverging in the future creates additional regulatory challenges and uncertainties for us. The lack of clarity on future UK laws and regulations and their interaction with EU laws and regulations could add legal risk, uncertainty, complexity and compliance cost to the handling of European personal data and our privacy and data security compliance, and could require us to amend our processes and procedures to implement different compliance measures for the UK and the EEA.

Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults, or non-performance by financial institutions or transactional counterparties, could adversely affect our current and projected business operations, financial condition and results of operations.

Actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past, such as in the case of the closure and subsequent placement into receivership with the Federal Deposit Insurance Corporation ("FDIC") of Silicon Valley Bank in March 2023, and may in the future lead to market-wide liquidity problems. In these cases, borrowers under credit agreements, letters of credit and certain other financial instruments with any financial institution that is placed into receivership by the FDIC may be unable to access undrawn amounts thereunder. If any of our lenders or counterparties to any such instruments were to be placed into receivership, we may be unable to access such funds, which could result in liquidity constraints or failures. In addition, if any of our collaboration partners, suppliers or other parties with whom we conduct business are unable to access funds pursuant to such instruments or lending arrangements with such a financial institution, such parties' ability to pay their obligations to us or to enter into new commercial arrangements requiring additional payments to us could be adversely affected.

Although we assess our banking and other business relationships as we believe necessary or appropriate, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect us, the financial institutions with which we have credit agreements or arrangements directly, or the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry or the supervision thereof. These factors could involve financial institutions or financial services industry companies with which we have financial or business relationships, but could also include factors involving financial markets or the financial services industry generally.

The results of events or concerns that involve one or more of these factors could include a variety of material and adverse impacts on our current and projected business operations and our financial condition and results of operations. These could include, but may not be limited to, the following:

- Delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets;
- Delayed or lost access to, or reductions in borrowings available under revolving existing credit facilities or other working capital sources and/or delays, inability or reductions in our ability to refund, roll over or extend the maturity of, or enter into new credit facilities or other working capital resources;
- Potential or actual breach of contractual obligations that require us to maintain letters of credit or other credit support arrangements;
- Potential or actual breach of financial covenants in our credit agreements or credit arrangements;
- Potential or actual cross-defaults in other credit agreements, credit arrangements or operating or financing agreements; or
- Termination of cash management arrangements and/or delays in accessing or actual loss of funds subject to cash management arrangements.

In addition, investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our financial and/or contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity and our current and/or projected business operations and financial condition and results of operations.

In addition, any further deterioration in macroeconomic conditions or the financial services industry could lead to losses or defaults by our collaboration partners, suppliers or other parties with whom we do business, which in turn, could have a material adverse effect on our current and/or projected business operations and results of operations and financial condition. Any bankruptcy or insolvency of a collaboration partner, supplier or other party with whom we do business, or the failure of any such party to make payments when due, or any breach or default by any such party, or the loss of any significant business relationships, could result in material losses to us and may have a material adverse impact on our business.

We have recorded significant restructuring charges from our corporate restructuring initiatives, including any associated workforce reductions or reorganizations, and may do so again in the future, which could have a material negative impact on our results of operations, may not result in the full anticipated savings, and may disrupt operations.

Historically, we have recorded significant restructuring charges related to our prior corporate restructuring initiatives. Specifically in 2024, we committed to restructuring initiatives designed to drive operational changes in our business processes, efficiencies, and cost savings to advance our corporate strategy and development programs. The restructuring initiatives included, among other components, consolidation and rationalization of our facilities, reprioritization of development programs and the reduction in our workforce. We may not fully realize the anticipated benefits, savings and improvements in our cost structure from this restructuring initiative or other restructuring efforts that we may undertake in the future, due to unforeseen difficulties, delays, or unexpected costs and the expenses of restructuring may be greater than anticipated. If we are unable to realize anticipated cost savings from our restructuring initiatives in the future, our operating results and financial condition may be adversely affected. Furthermore, our reprioritization of development programs may be disruptive to our operations. For example, our workforce reductions could yield unanticipated consequences, such as turnover beyond planned reductions or increased difficulties in conducting our day-to-day operations. Our workforce reductions could also harm our ability to attract and retain qualified personnel who are critical to our business and make it difficult for us to pursue, or prevent us from pursuing, new opportunities and initiatives due to insufficient personnel, or require us to incur additional and unanticipated costs to hire new personnel to pursue such opportunities or initiatives. Any failure to attract or retain qualified personnel could prevent us from successfully executing key business initiatives and adversely impact our business, financial condition, and results of operations.

Risks Related to Our Financial Position 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. Although we have been generating product revenue from Attruby since its approval, this 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. Although we are a commercial-stage biopharmaceutical company, we have a limited operating history as a commercial-stage company upon which you can evaluate our business and prospects. Our subsidiaries, on whose success we largely rely, are primarily early-stage biopharmaceutical companies. In November 2024, Attruby was approved for commercial sale in the U.S. In February 2025, Beyonttra was approved for commercial sale in the European Union. In addition, our pipeline of product candidates may require substantial additional development time, including additional clinical research, and resources before we would be able to apply for or receive additional regulatory approvals and begin generating revenue from sales of those product candidates, if approved.

We are not profitable and have incurred losses since our inception in April 2015. For the three and nine months ended September 30, 2026, we incurred net losses of $60.5 million and $382.9 million, respectively. For the three and nine months ended September 30, 2025, we incurred net losses of $184.9 million and $538.3 million, respectively. As of September 30, 2026, we had an accumulated deficit of $4.2 billion. In November 2024, Attruby was approved for commercial sale in the U.S. and in February 2025, Beyonttra was approved for commercial sale in the European Union. In addition, we previously had two products approved for commercial sale, NULIBRY and TRUSELTIQ™, but did not generate any significant revenues from product sales, and have until recently financed operations solely through the sale of equity securities, debt financings, royalty monetization, and the sale of certain assets. We continue to incur significant research and development ("R&D"), costs for the commercialization of Attruby and Beyonttra, and other expenses related to ongoing operations and expect to incur losses for the foreseeable future. In addition, we believe that potential delays in our ongoing and planned clinical trials and adjustments to certain of our study procedures for various reasons, such as challenges in enrollment, additional requirements imposed by regulatory authorities or investigative sites, or supply chain issues, could increase our expenditures or draw out our expenditures over a longer period of time than originally estimated. Additionally, changes to our selection of CROs for non-clinical laboratory activities and engagement with CMOs, to mitigate any potential impacts to our supply chain may increase our expenditures relative to initial expectations. We anticipate these losses will increase substantially in future periods.

Because of the numerous risks and uncertainties associated with drug development and commercialization, we are unable to predict the timing or amount of our expenses, or when we will be able to generate any meaningful revenue from our product candidates or achieve or maintain profitability, if ever. In addition, our expenses could increase beyond our current expectations if we are required by the FDA, or comparable foreign regulatory authorities, to conduct nonclinical studies or clinical trials in addition to those that we currently anticipate or to otherwise provide data beyond that which we currently believe is necessary to support an application for marketing approval or to continue clinical development, 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. We anticipate incurring significant costs associated with commercializing any future product candidates, if approved, and ongoing compliance efforts.

We may never be able to successfully commercialize any of our product candidates or achieve profitability. Revenue from the sale of any product will be dependent, in part, upon the size of the markets in the territories for which we have or may 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. 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 our stock price 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' deficit and working capital.

We may 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 and commercialization efforts.

Developing and commercializing biopharmaceutical products is expensive and time-consuming, and we may require substantial additional capital to conduct research, nonclinical 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 nonclinical 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, 2026, we had working capital of $1.1 billion, of which cash, cash equivalents and marketable securities amounted to $1.5 billion. We expect that our cash and cash equivalents, and marketable securities, and proceeds from Attruby product revenue will be sufficient to fund our operations through at least the next 12 months from the date of filing of this report. However, our operating plan may change as a result of many factors currently unknown to us, including our need for, and ability to raise, capital to support our research, development and commercialization plans, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings or other sources, such as royalty monetization, 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 establish internal commercialization capabilities or enter into collaborations with third parties for the commercialization of Attruby or any product candidate, if approved;
- our ability to satisfy the conditions required by the funding of the investment amount under the Funding Agreement;
- the time and cost necessary to complete ongoing and planned clinical trials, including our ongoing Phase 3 clinical trials of low-dose infigratinib, BBP-418, and encaleret;
- 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, clinical trials and other related activities, including the ability to enroll patients in a timely manner, for the ongoing and planned clinical trials set forth above, and potential future clinical trials;
- the costs of obtaining adequate clinical and commercial supplies of raw materials and drug products for our product candidates, including gene therapies such as 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 CMOs;
- our ability to successfully commercialize any product candidates that may be approved;
- the manufacturing, selling and marketing costs associated with any product candidates that may be approved, 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 any approved products, including the sales price and the availability of adequate third party reimbursement;
- the cash requirements of any future acquisitions or discovery of product candidates;
- the time and cost necessary to respond to technological and market developments;
- the costs of acquiring, licensing or investing in intellectual property rights, products, product candidates and businesses;
- our ability to continue to discover and develop additional product candidates, and the time and costs associated with identifying additional product candidates;
- our ability to attract, hire and retain qualified personnel; and
- the costs of maintaining, expanding and protecting our intellectual property portfolio.

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

We have incurred a significant amount of debt and may in the future incur additional indebtedness. Servicing our debt requires a significant amount of cash, and we may not have sufficient cash flow from our business to pay our substantial debt.

As of September 30, 2026, we and our subsidiaries had total consolidated indebtedness of $2.5 billion related to the Notes and deferred royalty obligations of $920.1 million. The Notes include $550.0 million of indebtedness outstanding under our unsecured 2.50% Convertible Senior Notes due 2027 (the "2027 Notes"), $747.5 million of indebtedness outstanding under our 2.25% Convertible Senior Notes due 2029 (the "2029 Notes"), $575.0 million of indebtedness outstanding under our 1.75% Convertible Senior Notes due 2031 (the "2031 Notes") and $632.5 million of indebtedness outstanding under our 0.75% Convertible Senior Notes due 2033 (the "2033 Notes"). Subject to the limitations in the terms of our existing and future indebtedness, we and our subsidiaries may incur additional indebtedness, secure existing or future indebtedness, or refinance our indebtedness. We may be required to use a substantial portion of our cash to pay interest and principal on our indebtedness. Our ability to make scheduled payments of the principal of, to pay interest on or to refinance our indebtedness, depends on our future performance and our ability to generate sufficient cash flow from our operations, which are subject to economic, financial, competitive and other factors beyond our control. Such payments will reduce the funds available to us for working capital, capital expenditures, and other corporate purposes and limit our ability to obtain additional financing for working capital, capital expenditures, expansion plans, and other investments, which may in turn limit our ability to implement our business strategy, heighten our vulnerability to downturns in our business, the industry, or in the general economy, limit our flexibility in planning for, or reacting to, changes in our business and the industry, and prevent us from taking advantage of business opportunities as they arise. Additionally, if we are unable to generate sufficient cash flow to service our indebtedness and fund our operations, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations.

Refer to the Risk Factor below in this Item 1A for further discussion related to our royalty monetization arrangements.

The conditional conversion feature of the Notes, if triggered, may adversely affect our financial condition and operating results.

In the event the conditional conversion feature of the Notes is triggered, holders of the Notes will be entitled to convert the notes at any time during specified periods at their option. If one or more holders elect to convert their Notes, we may satisfy our conversion obligation, at our election, in cash, shares of our common stock, or a combination of cash and shares of our common stock (other than paying cash in lieu of delivering any fractional share). To the extent we elect to settle any conversion in cash or in a combination of cash and shares, the cash portion of such settlement could reduce our liquidity. For example, the 2027 Notes and 2031 Notes are convertible for a limited period starting on October 1, 2026 and will remain convertible until December 31, 2026 because an early conversion condition based on the trading price of BridgeBio's common stock was satisfied. Separately, on or after December 15, 2026 until the close of business on the second scheduled trading day immediately preceding the maturity date, a holder may convert all or any portion of its 2027 Notes at any time.

We are parties to the Royalty Purchase Agreement and the Funding Agreement, which contain certain covenants and restrictions on our operations that, if violated, may adversely affect our financial condition and operating results. The Royalty Purchase Agreement requires us to direct 60% of BridgeBio's European royalties on the first $500.0 million of annual BEYONTTRA net sales to the purchasers until the applicable cap is reached. Under the Funding Agreement, an increase in the rate of royalty interest payments payable by us to the purchasers based on the net sales of Attruby under the Funding Agreement could impact our financial condition and operating results.

We are parties to two royalty monetization arrangements pursuant to which we have monetized a portion of future royalty streams on certain products in exchange for upfront capital. Such arrangements subject us to certain covenants and restrictions that we must comply with.

In June 2025, we and our subsidiary Eidos Therapeutics, Inc. ("Eidos") entered into a Royalty Interest Purchase and Sale Agreement (the "Royalty Purchase Agreement") with Acoramidis Royalty SPV, LP ("ARS"), an affiliate of HealthCare Royalty Management, LLC ("HCRx"), as a purchaser and the purchaser representative (in such capacity, the "Purchaser Representative"), and LSI Financing Fund, LP, an affiliate of Blue Owl Capital Corporation, as a purchaser (together with ARS as a purchaser and any future permitted assignees of a purchaser, the "Royalty Agreement Purchasers").

Pursuant to the Royalty Purchase Agreement, Eidos sold to the Royalty Agreement Purchasers certain of Eidos' right to receive certain royalty payments ("Purchased Royalty Payment") on net sales of certain products containing acoramidis (the "Licensed Products") made in the EU and all member and extension states of the European Patent Organization (the "Licensed Territory") under (i) our Bayer License Agreement and (ii) the amended and restated license agreement between Eidos and our other subsidiary, BridgeBio International GmbH. As consideration for the sale of the Purchased Royalty Payment, the Royalty Agreement Purchasers paid Eidos $300.0 million in cash (the "Purchase Price"), which was funded in full upon the closing of the transactions under the Royalty Purchase Agreement.

Under the Royalty Purchase Agreement, the Royalty Agreement Purchasers are entitled to the Purchased Royalty Payment, subject to (a) an annual cap equal to 60% of all royalty payments paid by Bayer to Eidos and its affiliates under the Bayer License Agreement on the first $500.0 million of annual net sales of Licensed Products in the Licensed Territory under the Bayer License Agreement and (b) an initial hard cap equal to 145% of the Purchase Price. In addition, we and our subsidiary, Eidos, granted the Purchaser Representative, for the benefit of the Royalty Agreement Purchasers, a security interest in specific assets related to the Purchased Royalty Payment.

In January 2024, we and our subsidiaries Eidos, BridgeBio Europe B.V. and BridgeBio International GmbH (together, the "Seller Parties") entered into a Funding Agreement (the "Funding Agreement") with LSI Financing 1 Designated Activity Company and CPPIB Credit Europe S.à r.l. (together and with any future permitted assignees of a seller party, the "Funding Agreement Purchasers"), and Alter Domus (US) LLC, as the collateral agent, to help support the commercial launch of Attruby. Under the Funding Agreement, the Funding Agreement Purchasers' obligation to pay us $500.0 million (in the aggregate, net of certain transaction expenses) (the "Investment Amount") was conditioned upon the first FDA approval of Attruby. In addition, pursuant to the Funding Agreement, the Seller Parties have granted to the collateral agent, for the benefit of the Funding Agreement Purchasers, a security interest in specific assets related to Attruby.

Under the Royalty Purchase Agreement and the Funding Agreement, we are required to comply with various affirmative and negative covenants. For example, under the Funding Agreement, we are required to use commercially reasonable efforts to obtain regulatory approval for and commercialize Attruby, provide the Funding Agreement Purchasers with certain clinical, commercial, regulatory and intellectual property updates and certain financial statements, and provide notices upon the occurrence of certain events. The Royalty Purchase Agreement includes covenants primarily relating to the preservation of the applicable royalty-generating agreements and the Royalty Agreement Purchasers' rights to receive the purchased royalty payments. Compliance with these covenants may limit our flexibility in operating our business and our ability to take actions that might otherwise be advantageous to us and our stockholders. If we are unable to comply with applicable obligations, the purchasers under the Royalty Purchase Agreement or the Funding Agreement, as applicable, may be entitled to exercise remedies against their respective collateral securing our obligations, including taking possession of assets under the Funding Agreement, which could have a material adverse effect on our business, financial condition and results of operations.

Under the Funding Agreement, following the Funding Agreement Purchasers' payment of the Investment Amount to us, the Funding Agreement Purchasers have the right to receive payments (the "Royalty Interest Payments") equal to 5% of the global net sales of Attruby ("Net Sales"). However, under certain conditions, including conditions relating to sales performance of Attruby by or on behalf of us, the rate of the Royalty Interest Payments may be increased to a maximum rate of 10% in 2027. Such increase(s) could result in additional payments by us to the Funding Agreement Purchasers and may materially impact our liquidity and profitability or otherwise affect our financial condition and operating results. The Funding Agreement Purchasers' rights to the Royalty Interest Payments and ownership interest in Net Sales will terminate upon the earlier of the Funding Agreement Purchasers' receipt of (a) Royalty Interest Payments equal to $950.0 million ("Cap Amount") and (b) a buy-out payment ("Buy-Out Payment") in an amount determined in accordance with the Funding Agreement but that will not exceed the Cap Amount.

The sale or issuance of our securities, including pursuant to "at-the-market" offering arrangements, may cause significant dilution and the sale of such securities, or the perception that such sales may occur, could cause the price of our common stock to fall.

In May 2026, we entered into an Equity Distribution Agreement with Goldman Sachs & Co. LLC and Leerink Partners LLC, which provides for the offer and sale of up to $500.0 million of our common stock in an "at-the-market" offering program. Sales under any equity distribution agreements or "at-the-market" offering arrangements, including those we may enter into in the future, could result in substantial dilution to the interests of other holders of our common stock. Additionally, the sale of a substantial number of shares of our common stock or other securities, or the anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales.

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

We may seek additional capital through any number of available sources, including, but not limited to, public and private equity offerings, debt financings, royalty monetization, 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 additional 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 to third parties, our equity interests 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 intellectual property rights, technologies or product candidates, or grant licenses on terms that are not favorable to us.

Our outstanding convertible preferred stock has rights, preferences and privileges that are not held by, and are preferential to, the rights of our common stock.

In July 2026, we issued an aggregate of 933,900 shares of Series A Cumulative Convertible Participating Preferred Stock, par value $0.001 per share (the "Preferred Stock"), to funds managed by Sixth Street Partners, LLC, and funds managed by HealthCare Royalty, pursuant to an investment agreement (the "Investment Agreement") dated July 1, 2026. The Preferred Stock ranks senior to our common stock with respect to the payment of dividends and rights on liquidation, dissolution or winding up. Holders of the Preferred Stock are also entitled to participate in dividends declared or paid on our common stock on an as-converted basis, and no dividends may be paid on our common stock unless the full participating dividends are paid at the same time to the holders of the Preferred Stock.

The Preferred Stock may initially be converted at any time at the option of the respective holders into an aggregate of 6,777,704 shares of our common stock. Any conversion of the Preferred Stock may significantly dilute the holders of our common stock. Unless we obtain stockholder approval in accordance with the listing requirements of Nasdaq, the maximum number of shares of common stock into which the Preferred Stock may be converted will be limited such that, upon any conversion of Preferred Stock, the number of shares of our common stock being issued upon conversion will not cause the holder thereof, when taken together with all other shares of our common stock beneficially owned by such holder at the time of conversion, to beneficially own shares of our common stock exceeding 19.9% of the total voting power of our common stock (on an as-converted basis). We are obligated under the Investment Agreement to seek stockholder approval to have such restriction removed. The conversion price of the Preferred Stock is initially $137.79 per share and will increase to $153.10 per share on and after the fifth anniversary of the original issuance date, and is subject to customary anti-dilution adjustments, including in the event of any stock split, stock dividend, recapitalization or similar event. In addition, we may require conversion of all outstanding shares of Preferred Stock on or after the third anniversary of the original issuance date if specified trading price and liquidity conditions are satisfied.

For additional details about the Preferred Stock, refer to Note 13 to our condensed consolidated financial statements.

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, 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;
- difficulties in retaining key employees and 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, any of which could have a material adverse effect on our business, prospects, financial condition and results of operations. For example, our acquisition in January 2021 of all of the outstanding shares of common stock of Eidos that were not previously owned by us or our subsidiaries (the "Eidos Merger") resulted in a reduction of our cash and dilutive issuances of our equity securities to the former Eidos stockholders. Any similar transactions in the future that require us to provide cash or stock consideration could harm our financial condition and negatively impact our existing stockholders.

Recent volatility in capital markets and lower market prices for our securities may affect our ability to access new capital through sales of shares of our common stock or issuance of indebtedness, which may harm our liquidity, increase our cost of capital, limit our ability to grow our business, pursue acquisitions or improve our operating infrastructure and restrict our ability to compete in our markets.

Our operations consume substantial amounts of cash, and we intend to continue to make significant investments to support our business growth, respond to business challenges or opportunities, develop new product candidates, retain or expand our current levels of personnel, improve our existing product candidates, enhance our operating infrastructure, and potentially acquire complementary businesses and technologies. Our future capital requirements may be significantly different from our current estimates and will depend on many factors, including the need to:

- finance unanticipated working capital requirements;
- continue the research and development of our existing product candidates and develop or enhance our technological infrastructure;
- pursue acquisitions, in-licenses or other strategic relationships; and
- respond to competitive pressures.

Accordingly, we may need to pursue additional equity, debt or other financings to meet our capital needs. With uncertainty in the capital markets and other factors, such financing may not be available on terms favorable to us or at all. If we raise additional funds through further issuances of equity or convertible debt securities, our existing stockholders could suffer significant dilution, and any new equity securities we issue could have rights, preferences, and privileges superior to those of holders of our common stock. In addition, any additional debt financing secured by us may also subject us to increased fixed payment obligations and covenants limiting or restricting our ability to take specific actions such as capital-raising activities, incurring additional debt, making capital expenditures or declaring dividends, and could involve additional restrictive covenants relating to our capital-raising activities and other financial and operational matters, which may make it more difficult for us to obtain additional capital and to pursue business opportunities, including potential acquisitions. If we raise additional capital through marketing and distribution arrangements or other collaborations, other royalty monetization, or strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. To meet our liquidity needs, we have previously relied, in part, on borrowed funds, and may do so again in the future. Recent and continued increases in interest rates could affect our ability to obtain working capital through borrowings such as bank credit lines and public or private sales of debt securities, which may result in lower liquidity, reduced working capital and other adverse impacts on our business. If we are unable to obtain adequate financing or financing on terms satisfactory to us, we could face significant limitations on our ability to invest in our operations and otherwise suffer harm to our business.

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 ("VIEs"). Investments in our existing and any future subsidiaries involve numerous risks, including, but not necessarily limited to:

- risk of conducting research and development activities in new therapeutic areas or treatment modalities in which we have little to no experience;
- diversion of financial and managerial resources from existing operations;
- our ability to negotiate a proposed acquisition, in-license or investment in a timely manner or at a price or on terms and conditions favorable to us;
- our ability to combine and integrate a potential acquisition into our existing business to fully realize the benefits of such acquisition;
- the impact of regulatory reviews on a proposed acquisition, in-license or investment; and
- the outcome of any legal proceedings that may be instituted with respect to a potential 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. In the future, we may engage in potential transactions that may divert our time and resources from our ongoing operations. In addition, from time to time we have pursued, and may in the future pursue, research and development programs through our wholly-owned subsidiaries and VIEs that we may ultimately determine not to advance, based on our ongoing assessment of the likelihood of success relative to the costs and risks associated with the program.

Risks Related to Our Common Stock

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

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

- our failure to successfully commercialize Attruby and Beyonttra, or any product candidate that we may develop or for which we acquire commercial rights;
- adverse results or delays in our clinical trials, particularly those of our late-stage product candidates, or nonclinical studies;
- inability for us to generate revenues, obtain additional funding, or to service our existing debt obligations, on reasonable terms or at all;
- reports of AEs or other negative results in clinical trials of third parties' product candidates that target our product candidates' target indications;
- 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, including any failure to obtain FDA clearance or approval with respect to such regulatory filing or submission;
- the termination of, or any other failure to develop successfully and commercialize our product candidates;
- announcements we make regarding our current product candidates, sales, dispositions or other divestitures of development programs or product candidates, acquisitions of potential new product candidates and companies and/or in-licensing;
- the termination of, or any other 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 our current and future products or product candidates;

- 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 partners 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;
- trading volume of our common stock;
- acts of war or periods of widespread civil unrest, including the increasingly volatile global economic conditions resulting from the conflicts in Ukraine and in the Middle East;
- general economic and market conditions, including inflationary pressures and stock market volatility; and
- continued increases in interest rates that increase the cost of our existing indebtedness and any potential new indebtedness.

In addition, companies trading in the stock market in general, and The Nasdaq Global Select Market ("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, including the effects of the ongoing conflicts in Ukraine and in the Middle East, widespread inflationary pressures and interest rate increases, any global health emergency such as the COVID-19 pandemic, and global economic conditions on the global economy, may negatively affect the market price of our common stock, regardless of our actual operating performance.

We have in the past been and could be subject to securities class action litigation and other types of stockholder litigation.

The stock market in general, and Nasdaq and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. In the past, we have been subject to stockholder litigation related to the Eidos Merger, and securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. We could also be subject to other types of litigation, which may involve claims of breach of fiduciary duties by our directors or officers for misuse/mismanagement of company assets/resources or conflicts of interest. Any such litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which would harm our business, operating results, or financial condition. Additionally, the dramatic increase in the cost of directors' and officers' liability insurance may cause us to opt for lower overall policy limits or to forgo insurance that we may otherwise rely on to cover significant defense costs, settlements, and damages awarded to plaintiffs.

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 Third Amended and Restated 2021 Stock Option and Incentive Plan (the "A&R 2021 Plan"), we are authorized to grant stock options and other stock-based awards to our employees, directors and consultants. In addition, pursuant to our Amended and Restated 2019 Inducement Equity Plan, we are authorized to grant stock options and other stock-based awards to prospective officers and employees who are not currently employed by us or one of our subsidiaries. If our board of directors elects in the future to increase the number of shares available for future grant and, in the case of the A&R 2021 Plan, if our stockholders approve of any such further increase, our stockholders may experience additional dilution, and our stock price may fall.

Any sales of a significant portion of our total outstanding shares, including shares of common stock underlying resale registration statements filed on behalf of certain of our stockholders, into the market 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 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.

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. Sales of a substantial number of shares of our common stock underlying the resale registration statements on Form S-3/ASR filed on November 2, 2023 and July 24, 2026 in the public market by the selling stockholders named in these registration statements, or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities or other securities convertible into or exchangeable for equity securities, regardless of whether there is any relationship between such sales and the performance of our business. We may also file registration statements in the future that register a substantial number of shares of our common stock where if any additional shares are sold pursuant to these registration statements, or if it is perceived that they will be sold, in the public market, the market price of our common stock could decline. We have also filed registration statements on Form S-8 registering the issuance of shares of common stock issued or reserved for future issuance under our equity compensation and equity inducement plans. Shares registered under these registration statements on Form S-8 can be freely sold in the public market upon issuance and once vested, subject to volume limitations applicable to affiliates. In addition, certain of our directors, executive officers, employees and affiliates have established or may in the future establish programmed selling plans under Rule 10b5-1 of the Securities Exchange Act of 1934, as amended, for the purpose of effecting sales of our common stock. 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, 2026, our beneficial stockholders, directors, and executive officers beneficially own 40.9% of our outstanding common stock. These stockholders will have the ability to influence us through their ownership positions. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders, acting together, may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. In turn, this may have an adverse effect on the market price of our common stock. 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. In certain circumstances, these stockholders' interests as stockholders may differ or even conflict with the interests of our other 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 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 will be the sole and exclusive forum for any state law claim for (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a claim of breach of or based on a fiduciary duty owed by any of our current or former directors, officers or employees 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 amended and restated certificate of incorporation or amended and restated bylaws; (iv) any action to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or amended and restated bylaws; or (v) any action asserting a claim governed by the internal affairs doctrine of the State of Delaware. Our amended and restated bylaws further provide that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the U.S. will be the sole and exclusive forum for resolving any complaint asserting a cause of action arising under the Securities 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.

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

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

- our ability to successfully commercialize Attruby and Beyonttra or any of our product candidates, if approved, and the timing and costs of our commercialization activities;
- our quarterly financial results, including net product revenue from sales of Attruby, license and services and royalty revenue from net sales of Beyonttra or revenue from any of our product candidates, if approved;
- the timing, results and cost of, and level of investment in, our clinical development activities for our current product candidates and any other product candidates we may identify and pursue, which may change from time to time;
- the cost of manufacturing Attruby and Beyonttra and our current product candidates 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 our ongoing and planned clinical trials in accordance with our current plans and to obtain regulatory approval for our current product candidates 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 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 Attruby and Beyonttra and our current product candidates 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;
- future tax regulation changes that impact effective tax rates;
- the success of our restructuring initiatives;
- the risk/benefit profile, cost and reimbursement policies with respect to Attruby and Beyonttra and our current product candidates or other product candidates that we may identify, if approved, and existing and potential future drugs that compete with our products and product candidates;
- changes in global economic and market conditions, including inflationary pressures, interest rate increases, supply chain shortages, tariffs, and stock market volatility; and
- acts of war, armed conflicts and political or civil unrest, including volatile global economic conditions resulting from the conflicts in Ukraine and the Middle East.

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 indefinitely if not utilized, subject to expiration of such carryforwards in the case of federal net operating loss carryforwards generated prior to 2018. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the "Code"), and corresponding provisions of state law, 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 ("NOLs") and other pre-change tax attributes to offset its post-change income or taxes may be limited. Our existing net operating losses or credits may be subject to limitations arising from previous ownership changes and if we undergo future ownership changes, many of which may be outside of our control, our ability to utilize our net operating losses or credits could be further limited by Sections 382 and 383 of the Code. Accordingly, we may not be able to utilize a material portion of our net operating losses or credits. In addition, the amount of post-2017 NOLs that we are permitted to deduct in taxable years beginning after December 31, 2024 is limited to 80% of our taxable income in such year.

Changes in tax laws or regulations may adversely affect our financial condition and results of operations.

Changes in tax laws or regulations, or changes in interpretations of existing tax laws and regulations, could adversely affect our financial condition and results of operations, possibly with retroactive effect. For example, on July 4, 2025, tax reform legislation included in the One Big Beautiful Bill Act (the "OBBBA") was enacted in the U.S. Key corporate tax provisions include the restoration of 100% bonus depreciation, immediate expensing for domestic research and experimental expenditures, changes to Section 163(j) interest limitations, updates to GILTI and FDII rules, amendments to energy credits, and expanded Section 162(m) aggregation requirements. Outside of the U.S., various governments and organizations are increasingly focused on tax reform and other legislative or regulatory action to increase tax revenue, including the base erosion and profit shifting ("BEPS") project that is being led by the Organization for Economic Co-operation and Development ("OECD") and other initiatives led by the OECD or the European Commission. With our international operations and potential expansion, these types of changes to the taxation of our activities could increase the amount of taxes imposed on our business, and adversely affect our financial condition and results of operations.

We have never paid 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 common stock and do not currently intend to pay any cash dividends on our common stock for the foreseeable future. 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 on our common stock, 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 have incurred and will continue to incur significant costs as a result of operating as a public company, and our management is required to devote substantial time to new compliance initiatives.

As a public company, we incur significant legal, tax, accounting and other expenses which are greater than those for private companies. We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Act, the listing requirements of the Nasdaq and other applicable securities laws and regulations. For example, the Exchange Act 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. These reporting requirements also continue to change, which has created uncertainty for public companies like us, and accommodating the evolving standards may require additional legal and financial compliance costs.

General Risk Factors

Significant political, trade, regulatory developments, and other circumstances beyond our control, including as a result of the current administration's tariff policy, could have a material adverse effect on our financial condition or results of operations.

We operate globally and plan to sell our products in countries throughout the world. Significant political, trade, or regulatory developments in the jurisdictions in which we sell our products, such as those stemming from U.S. federal elections, are difficult to predict and may have a material adverse effect on us. Similarly, changes in U.S. federal policy that affect the geopolitical landscape could give rise to circumstances outside our control that could have negative impacts on our business operations. For example, in April 2025, the U.S. imposed "reciprocal" tariffs, which were broad tariffs on imports from virtually all countries, with particularly high tariffs on imports from China. The U.S. Supreme Court invalidated the reciprocal tariffs on February 20, 2026; however, the current administration has imposed new historically elevated tariffs under different authorities, which remain subject to ongoing legal challenge, and has active investigations that may result in tariffs on certain countries or products. In response to higher U.S. tariffs, some countries have implemented retaliatory tariffs on U.S. goods, while others have negotiated agreements regarding U.S.-imposed tariffs. Historically, increased tariffs have led to more trade and political tensions and the status of these agreements between the U.S. and the various countries remains unclear. Moreover, starting in mid-2026, the U.S. has imposed special tariffs on certain imported pharmaceutical products, encompassing some of our products, ranging from 10% to 100% depending on the exporting country and the importing company. Political tensions as a result of trade policies could reduce trade volume, investment, technological exchange and other economic activities between major international economies, resulting in a material adverse effect on global economic conditions and the stability of global financial markets. Any changes in political, trade, regulatory, and economic conditions, including U.S. trade policies, could have a material adverse effect on our financial condition or results of operations.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could 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 that 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 U.S., political influences and inflationary pressures. For example, an overall decrease in or loss of insurance coverage among individuals in the U.S. due to high levels of unemployment, underemployment or the repeal of certain provisions of the ACA, may decrease the demand for healthcare services and pharmaceuticals. Additionally, the availability of healthcare services and resources can be constrained due to a public health emergency, such as during the COVID-19 pandemic. If fewer patients are seeking medical care because they do not have insurance coverage or are unable to obtain medical care for their conditions due to resource constraints on the healthcare system, 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 a public health emergency, such as the COVID-19 pandemic, or similar outbreaks, the current economic climate, and financial market conditions could adversely impact our business.

Further, military conflicts or wars (such as Russia's invasion of Ukraine or the armed conflicts in the Middle East) can damage or disrupt international commerce and the global economy. It is not possible to predict the broader or longer-term consequences of such conflicts, or the sanctions imposed to date, which could include further sanctions and counter-sanctions, embargoes, regional instability, retaliatory cyber-attacks, geopolitical shifts and adverse effects on macroeconomic conditions, security conditions, currency exchange rates and financial markets. The potential effects of such conflicts include but are not limited to changes in laws and regulations affecting our business, fluctuations in foreign currency markets, potential supply chain disruptions, inflationary pressures, and increased market volatility and uncertainty that could have an adverse impact on macroeconomic factors that affect our business, financial condition, stock price and results of operations.

Our internal computer systems, or those used by our third-party collaborators, contractors or consultants, may fail or suffer cybersecurity incidents or breaches, which could result in a material disruption of our development programs and business operations.

Despite the implementation of security measures, our internal computer systems and those of our CROs, CMOs, third-party logistics providers, third-party collaboration and commercialization partners, and other contractors and consultants may be vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, cybersecurity threats, war, and telecommunication and electrical failures. Like other companies in our industry, we have, from time to time, experienced threats to and security incidents related to our data and systems, including phishing attacks and attacks to the security of the systems of our third-party vendors and service providers. If a material event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and business operations. For example, the loss of clinical trial data from completed, ongoing or future clinical trials or commercialization information could result in delays in our regulatory approval or commercialization 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 commercialization activities. We depend on these third parties to implement adequate controls and safeguards to protect against and report cybersecurity incidents or breaches. If they fail to do so, we may suffer financial and other harm, including to our information, operations, performance, and reputation. To the extent that any disruption or cybersecurity incident breach were to result in a loss of, or damage to, our data or systems, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our product candidates could be delayed. We also rely on third-party service providers for aspects of our internal control over financial reporting, and such service providers may experience a material system failure or fail to carry out their obligations in other respects, which may impact our ability to produce accurate and timely financial statements, thus harming our operating results, our ability to operate our business, and our investors' view of us.

Cybersecurity threats, both on premises and in the cloud, are evolving and include, but are not limited to: malicious software, destructive malware, ransomware, social engineering attacks (including phishing attacks) and other attempts to gain unauthorized access to systems or data, disruption to operations, critical systems or denial of service attacks; unauthorized release of confidential, personal or otherwise protected information; corruption of data, networks or systems; harm to individuals; and loss of assets. In addition, we could be impacted by cybersecurity threats or other disruptions or vulnerabilities found in products or services we use that are provided to us by third-parties. Although we devote resources to protect our information systems, the techniques used by criminal elements to attack computer systems are sophisticated, change frequently and may originate from less regulated and remote areas of the world. As a result, we may not be able to address these techniques proactively or implement adequate preventative measures. These events, if not prevented or effectively mitigated, could damage our reputation, require remedial actions and lead to loss of business, regulatory actions, potential liability and other financial losses.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our privacy and data security obligations. Certain data breaches must also be reported to affected individuals, certain other stakeholders, and various government and/or regulatory agencies, 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 EU GDPR and relevant member state law in the EU and other foreign laws, and financial penalties may also apply. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences.

Cybersecurity liability insurance is difficult to obtain and may not cover any damages we would sustain based on any breach of our computer security protocols or other cybersecurity attack. 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.

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

Climate change, earthquakes, outbreak of disease, or other natural disasters, including extreme weather events and changing weather patterns such as storms, flooding, droughts, fires and temperature changes, which have become more common, 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, extreme weather risk, power outage, cybersecurity attack or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as the manufacturing facilities of our third-party CMOs, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. For example, we may experience delays in the supply of drug product for our clinical trials as a result of disruptions to the operations of the manufacturing facilities of some of our third-party CMOs. 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. In addition, as noted above, cybersecurity liability insurance is difficult to obtain and may not cover any damages we would sustain based on any breach of our computer security protocols or other cybersecurity attack. 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.

Climate change or legal, regulatory or market measures to address climate change may negatively affect our business and results of operations.

Climate change resulting from increased concentrations of carbon dioxide and other greenhouse gases in the atmosphere could present risks to our operations, including an adverse impact on global temperatures, weather patterns and the frequency and severity of extreme weather and natural disasters. Natural disasters and extreme weather conditions, such as a hurricane, tornado, earthquake, wildfire or flooding, may pose physical risks to our facilities and disrupt the operation of our supply chain. The impacts of the changing climate on water resources may result in water scarcity, limiting our ability to access sufficient high-quality water in certain locations, which may increase operational costs. Concern over climate change may also result in new or additional legal or regulatory requirements designed to reduce greenhouse gas emissions and/or mitigate the effects of climate change on the environment. If such laws or regulations are more stringent than current legal or regulatory obligations, we may experience disruption in, or an increase in the costs associated with sourcing, manufacturing and distribution of our product candidates, which may adversely affect our business, results of operations or financial condition. Further, the impacts of climate change have an influence on customer preferences, and failure to provide climate-friendly products could potentially result in loss of market share.

The increasing use of social media platforms presents new risks and challenges.

Social media is increasingly being used to communicate about our research, product candidates, investigational medicines, and the diseases our product candidates and investigational medicines are being developed to treat. Social media practices in the biopharmaceutical industry continue to evolve and regulations relating to such use are not always clear. This evolution creates uncertainty and risk of noncompliance with regulations applicable to our business, resulting in potential regulatory actions against us. For example, patients may use social media channels to comment on their experience in an ongoing blinded clinical study or to report an alleged adverse event. When such disclosures occur, there is a risk that we fail to monitor and comply with applicable adverse event reporting obligations or we may not be able to defend our business or the public's legitimate interests in the face of the political and market pressures generated by social media due to restrictions on what we may say about our development candidates, investigational medicines and approved products. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us on any social networking website. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face regulatory actions, or incur other harm to our business.

Our business operations may subject us to disputes, claims and lawsuits, which may be costly and time-consuming and could materially and adversely impact our financial position and results of operations.

From time to time, we may become involved in disputes, claims and lawsuits relating to our business operations. For example, we may, from time to time, face or initiate claims related to intellectual property matters, employment matters, or commercial disputes. Any dispute, claim or lawsuit may divert management's attention away from our business, we may incur significant expenses in addressing or defending any dispute, claim or lawsuit, and we may be required to pay damage awards or settlements or become subject to equitable remedies that could adversely affect our operations and financial results. Litigation related to these disputes may be costly and time-consuming and could materially and adversely impact our financial position and results of operations if resolved against us. In addition, the uncertainty associated with litigation could lead to increased volatility in our stock price.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

(a) Sales of Unregistered Securities

Except as previously disclosed in our Current Report on Form 8-K filed on July 2, 2026, we did not make any unregistered sales of equity securities during the period covered by this Quarterly Report on Form 10-Q.

(b) Use of Proceeds from Public Offering of Common Stock

None.

(c) Issuer Purchases of Company Equity Securities

In May 2026, our Board of Directors approved a stock repurchase program pursuant to which we may purchase up to $500.0 million of BridgeBio's outstanding common stock. Stock repurchases under the program may be made from time to time, in the open market, in privately negotiated transactions and otherwise, at the discretion of our management and in accordance with applicable federal securities laws, including Rule 10b-18 of the Securities Exchange Act of 1934, as amended, and other applicable legal requirements. The timing, pricing, and amounts of these repurchases will depend on a number of factors, including the market price of our common stock and general market and economic conditions. The stock repurchase program does not obligate us to repurchase any dollar amount or number of shares, and the program may be suspended or discontinued at any time.

The table below sets forth information regarding repurchases during the period covered by this Quarterly Report on Form 10-Q:

Period	Total number of shares purchased	Average price paid per share[1]	Total number of shares purchased as part of publicly announced plans or programs	Maximum dollar value of shares that may yet be purchased under the plans or programs (in thousands)
July 1–July 31, 2026	—	—	—	$ 372,514
August 1–August 31, 2026	—	—	—	$ 372,514
September 1–September 30, 2026	712,165	$66.68	712,165	$ 325,025
Total	712,165	$66.68	712,165	$ 325,025

(1) Excludes commissions and transaction costs.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

(a) Information Required to be Reported on Form 8-K

None.

(b) Material Changes to Nomination Procedures

None.

(c) Director and Officer Trading Plans and Arrangements

On September 4, 2026, Charles Homcy, our Chairman of Pharmaceuticals and Lead Director on our Board of Directors, adopted a trading plan (the "Homcy Trading Plan") intended to satisfy the affirmative defense conditions of Securities Exchange Act Rule 10b5-1(c). The Homcy Trading Plan provides for the potential sale of an aggregate of 120,000 shares of our common stock underlying the stock options held by Dr. Homcy. Dr. Homcy is not permitted to transfer, sell or otherwise dispose of any shares under the Homcy Trading Plan until the Earliest Sell Date, which is the later of (i) the 91st day after the adoption date of the Homcy Trading Plan; or (ii) the earlier of: (a) the third business day following the disclosure of the Company's financial results in a Form 10-Q or Form 10-K for the completed fiscal quarter in which the Homcy Trading Plan is adopted; or (b) the 121st day after the adoption date. The Homcy Trading Plan is expected to remain in effect until the earlier of (a) September 4, 2027; (b) the first date on which all trades have been executed or all trading orders relating to such trades set forth in Addendum A to the Homcy Trading Plan have expired; (c) as soon as practicable following the date on which Dr. Homcy gives written notice to Morgan Stanley Smith Barney LLC ("MSSB") to terminate the Homcy Trading Plan; (d) as soon as practicable following the date on which MSSB receives written notice of a termination of an additional contract, instruction or plan that is being treated as a single "plan" with the Homcy Trading Plan (or MSSB receives written notice of a modification of such additional contract, instruction or plan and the requirements for a modification of the Homcy Trading Plan are not or cannot be satisfied); (e) as soon as practicable following the date on which MSSB receives written notice of a legal, regulatory or contractual restriction applicable to the Company or to Dr. Homcy that would result in a modification or change to the amount, price or timing of the sale of shares under the Homcy Trading Plan but the requirements for a modification of the Homcy Trading Plan are not or cannot be satisfied; and (f) as soon as practicable following the date on which MSSB receives notice of certain events, including the public announcement of a tender or exchange offer with respect to the Company's common stock or that the Company is the target of a merger, acquisition, reorganization, recapitalization or comparable transaction as a result of which the Company's common stock will be converted into shares of another company, or the commencement of bankruptcy or insolvency proceeding with respect to the Company.

ITEM 6. EXHIBITS

Exhibit Number	Exhibit Title	Form	File No.	Exhibit	Filing Date
2.1	Agreement and Plan of Merger, dated as of October 5, 2020, by and among BridgeBio Pharma, Inc., Eidos Therapeutics, Inc., Globe Merger Sub I, Inc. and Globe Merger Sub II, Inc. (incorporated by reference to Exhibit 2.1 to BridgeBio's Current Report on Form 8-K filed with the Securities Exchange Commission on October 6, 2020).	8-K	001-38959	2.01	January 26, 2021
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	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Registrant	8-K	001-38959	3.1	June 23, 2025
3.3	Amended and Restated Bylaws of the Registrant, as currently in effect.	S-4	333-249944	3.2	November 6, 2020
3.4	Certificate of Designations, Preferences and Rights of Series A Cumulative Convertible Participating Preferred Stock of BridgeBio Pharma, Inc.	8-K	001-38959	3.1	July 2, 2026
4.1	Specimen Common Stock Certificate.	S-1	333-231759	4.1	June 24, 2019
4.2	Form of Registration Rights Agreement, dated June 26, 2019, among the Registrant and certain of its stockholders.	S-1	333-231759	4.3	June 24, 2019
4.3	Indenture, dated as of March 9, 2020, by and between BridgeBio Pharma, Inc. and U.S. Bank National Association, as Trustee.	8-K	001-38959	4.1	March 10, 2020
4.4	Form of Global Note, representing BridgeBio Pharma, Inc.'s 2.50% Convertible Senior Notes due 2027 (included as Exhibit A to the Indenture filed as Exhibit 4.1).	8-K	001-38959	4.2	March 10, 2020
4.5	Indenture, dated as of January 28, 2021, by and between BridgeBio Pharma, Inc. and U.S. Bank National Association, as Trustee.	8-K	001-38959	4.1	January 29, 2021
4.6	Form of Global Note, representing BridgeBio Pharma, Inc.'s 2.25% Convertible Senior Notes due 2029 (included as Exhibit A to the Indenture filed as Exhibit 4.1)	8-K	001-38959	4.2	January 29, 2021
4.7	Securities Purchase Agreement, dated September 25, 2023, by and among BridgeBio Pharma, Inc., and the purchasers party thereto.	8-K	001-38959	10.1	September 25, 2023
4.8†	Registration Rights Agreement, dated September 25, 2023, by and among BridgeBio Pharma, Inc. and the purchasers party thereto.	8-K	001-38959	10.2	September 25, 2023
4.9	Indenture, dated as of February 28, 2025, by and between BridgeBio Pharma, Inc. and U.S. Bank Trust Company, National Association, as Trustee.	8-K	001-38959	4.1	February 28, 2025

4.10	Form of Global Note, representing BridgeBio Pharma, Inc.'s 1.75% Convertible Senior Notes due 2031 (included as Exhibit A to the Indenture filed as Exhibit 4.1)	8-K	001-38959	4.2	February 28, 2025
4.11	Indenture, dated as of January 21, 2026, by and between BridgeBio Pharma, Inc. and U.S. Bank Trust Company, National Association, as Trustee.	8-K	001-38959	4.1	January 21, 2026
4.12	Form of Global Note, representing BridgeBio Pharma, Inc.'s 0.75% Convertible Senior Notes due 2033 (included as Exhibit A to the Indenture filed as Exhibit 4.1).	8-K	001-38959	4.1	January 21, 2026
4.13	Registration Rights Agreement, dated as of July 1, 2026, by and among BridgeBio Pharma, Inc. and the Purchasers identified therein.	8-K	001-38959	10.2	July 2, 2026
10.1†	Investment Agreement, dated as of July 1, 2026, by and among BridgeBio Pharma, Inc. and the Purchasers identified therein.	8-K	001-38959	10.1	July 2, 2026
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
31.3	Certification of Principal Accounting 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
32.3*	Certification of Principal Accounting 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	Inline XBRL Instance Document	—	—	—	Filed herewith
101.SCH	Inline XBRL Taxonomy Extension Schema Document	—	—	—	Filed herewith
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document	—	—	—	Filed herewith
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document	—	—	—	Filed herewith

101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document	—	—	—	Filed herewith
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document	—	—	—	Filed herewith
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101).	—	—	—	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.

† 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 because such information (i) is not material and (ii) is the type that the registrant treats as private or confidential.

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: October 29, 2026

By: /s/ Neil Kumar

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

Date: October 29, 2026

By: /s/ Thomas Trimarchi

Thomas Trimarchi, Ph.D.
President and Chief Financial Officer
(Principal Financial Officer)

Date: October 29, 2026

By: /s/ Maricel M. Apuli

Maricel M. Apuli
Chief Accounting Officer
(Principal Accounting Officer)

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Neil Kumar, certify that:

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

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

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

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: October 29, 2026

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, Thomas Trimarchi, 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: October 29, 2026

By: /s/ Thomas Trimarchi

Thomas Trimarchi, Ph.D.

President and Chief Financial Officer
(Principal Financial Officer)

Exhibit 31.3

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, Maricel M. Apuli, 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: October 29, 2026

By: /s/ Maricel M. Apuli

Maricel M. Apuli

Chief Accounting Officer
Principal Accounting Officer)

Exhibit 32.1

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

In connection with the Quarterly Report of BridgeBio Pharma, Inc. (the "Company") on Form 10-Q for the fiscal quarter ended September 30, 2026, 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 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 results of operations of the Company.

Date: October 29, 2026

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, 2026, 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 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 results of operations of the Company.

Date: October 29, 2026

By: /s/ Thomas Trimarchi

Thomas Trimarchi, Ph.D.

President and Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.3

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, 2026, 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 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 results of operations of the Company.

Date: October 29, 2026

By: /s/ Maricel M. Apuli

Maricel M. Apuli

Chief Accounting Officer
(Principal Accounting Officer)