

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2025

or

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

For the transition period from _____ to _____

Commission File No. 001-38959

BridgeBio Pharma, Inc.

(Exact name of registrant as specified in its charter)

Delaware

State or other jurisdiction of
incorporation or organization

3160 Porter Drive, Suite 250, Palo Alto, CA
(Address of principal executive offices)

84-1850815

(I.R.S. Employer
Identification No.)

94304
(Zip Code)

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.001 per share	BBIO	The Nasdaq Global Select Market

Securities registered pursuant to section 12(g) of the Act: **NONE**

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

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

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 726(b)) by the registered public accounting firm that prepared or issued its audit report.

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements.

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b).

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant based upon the closing price of the registrant's Common Stock on The Nasdaq Global Select Market on June 30, 2025 was approximately \$7.3 billion. Shares of the registrant's Common Stock held by each executive officer and director and by each other person who may be deemed an affiliate of the Registrant have been excluded from this computation. The determination of affiliate status for this purpose is not necessarily a conclusive determination for other purposes.

On February 12, 2026, there were 193,862,871 shares of the registrant's Common Stock issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Specified portions of the registrant's definitive Proxy Statement to be issued in conjunction with the registrant's 2025 Annual Meeting of Stockholders, which is expected to be filed not later than 120 days after the registrant's fiscal year ended December 31, 2025, are incorporated by reference into Part III of this Annual Report. Except as expressly incorporated by reference, the registrant's Proxy Statement shall not be deemed to be a part of this Annual Report on Form 10-K.

BRIDGEBIO PHARMA, INC.
2025 Form 10-K Annual Report

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In this Annual Report on Form 10-K, 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”) and Japan. 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 (ii) the EU, Japan, and the UK, as applicable, we use both names Attruby™ and Beyontra™ – e.g., “Our commercial organization focuses on supporting the appropriate use of Attruby and Beyontra in the markets where this product has been approved.”

Special Note Regarding Forward-Looking Statements

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

- the commercial success of AttrubyTM (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 product candidates, including the progress of, and results from and data readouts for, our ongoing Phase 2 and Phase 3 clinical trials of low-dose infigratinib for achondroplasia, our Phase 3 clinical trial of BBP-418 for LGMD2I, our ongoing Phase 3 clinical trial of encaleret for ADH1, and our ongoing Phase 1/2 clinical trial of BBP-812 for Canavan disease, and the clinical timeline for our new antibody deplete program for ATTR-CM, as well as the potential indications for each;
- our ability to continue planned preclinical and clinical development of our respective development programs, and the timing, cost and success of any such continued preclinical 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 submissions, including New Drug Applications (“NDAs”) to the U.S. Food and Drug Administration (the “FDA”), and similar submissions with foreign regulatory authorities, our Investigational New Drug applications (“INDs”), our potential receipt of U.S. approval and commencement of commercial launch for BBP-418, encaleret, and infigratinib, subject to such approval and our anticipated interaction with and feedback from 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 Israel and the Gaza Strip 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.

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

RISK FACTOR 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. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below under the heading "Risk Factors" and should be carefully considered, together with other information in this Annual Report on Form 10-K and our other filings with the U.S. Securities and Exchange Commission (the "SEC") before making investment decisions regarding our common stock.

- Our business is substantially dependent on the commercial success of Attruby and Beyontra. 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 Beyontra, 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 Beyontra 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 to implement reference pricing or most-favored-nation pricing models could impact our product revenues 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 preclinical or clinical development, which is a lengthy and expensive process with uncertain outcomes and the potential for substantial delays. We cannot give any assurance that any of our 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 Beyontra 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 Beyontra and our product candidates, including low-dose infigratinib, BBP-418, and encalaret, 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.

PART I

ITEM 1. BUSINESS

Overview

A New Type of Biopharmaceutical Company

BridgeBio Pharma, Inc. 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.

Since our founding 10 years ago, we have advanced multiple programs from discovery through regulatory approval and commercialization. To date, more than 8,500 patients have been treated with our approved medicines, and we have obtained U.S. Food and Drug Administration (the “FDA”) approval for three products. We believe our decentralized hub and spoke model enables us to achieve clinical proof-of-concept with speed and efficiency, demonstrated by an average investment per program of less than \$40.0 million to proof-of-concept data and less than \$10.0 million to reach Investigational New Drug (“IND”) submission. This efficiency allows us to work on a broad range of scientifically compelling therapies, including programs for underserved conditions which more traditional biopharmaceutical models might leave on the shelf but we believe can be developed on a Net Present Value (“NPV”)-positive basis in our portfolio.

In addition to our commercial products led by Attriby, we plan to pursue regulatory submissions for several advanced product candidates, including therapies for achondroplasia, limb-girdle muscular dystrophy type 2I/R9, and autosomal dominant hypocalcemia type 1, which have all recently released positive Phase 3 data. Since inception, we have generated 19 investigational new drug applications and contributed to more than 70 peer-reviewed scientific publications, reflecting our continued focus on advancing the understanding and treatment of genetic diseases.

What BridgeBio Is Today

Today, BridgeBio is a commercial-stage biopharmaceutical company with multiple approved products, a growing global commercial footprint, and a portfolio of late-stage development programs with regulatory pathways that we believe to be well-defined. Over the past year, we have demonstrated our ability to translate research and development (“R&D”) efforts into successful commercial execution.

Our largest commercial product, acoramidis, was approved by the FDA in November 2024 for the treatment of transthyretin amyloid cardiomyopathy and is being commercialized by BridgeBio in the United States (under the brand name Attriby™). Outside the United States, acoramidis is marketed as Beyontra™ and is commercialized through strategic collaboration partners, including Bayer in Europe and Alexion in Japan, as well as directly by BridgeBio in certain international markets.

Our achievements in 2025 demonstrate strong commercial momentum with the potential for Attriby to become a significant commercial asset over time.

In parallel, we are advancing multiple Phase 3 programs across rare and genetically defined diseases and are well advanced in commercial launch preparations following the recent positive data readouts from our infigratinib, BBP-418, and encalceret programs. We believe each of these programs has the potential to serve a significant patient population with best-in-class or first-in-class medicines. On a standalone basis, we believe the commercial expectations for each of these assets are promising and demonstrate the effect of our decentralized R&D engine. During 2026, we expect to progress each of these programs towards anticipated approvals in the United States and Europe and are actively preparing for the worldwide commercial launches of these products, if approved.

Lastly, our continued focus on early-stage development includes various expansion indications and we plan to initiate a registrational study of encalceret in chronic hypoparathyroidism and pediatric ADHD in 2026 alongside studying infigratinib for hypochondroplasia in 2027. We are also developing the next generation of transthyretin-mediated amyloidosis (“ATTR-CM”) treatment through a depletor program to explore the potential of disease reversal on ATTR-CM. Finally, we maintain our minority equity interests in GondolaBio, LLC and BridgeBio Oncology Therapeutics, Inc., which are separate companies spun out of BridgeBio and allows us to retain exposure to a broad pipeline of early-stage development opportunities, while remaining focused on advancing and commercializing our core portfolio.

Our Objective Function and How We Define Success

Our corporate objective at BridgeBio is to develop medicines that meaningfully improve patient outcomes and thereby maximize the positive impact we can have on the quality-adjusted life-years of the patients we serve as quickly as possible. We pursue this objective by advancing programs underpinned by clear genetic drivers, established disease mechanisms, and therapeutic approaches designed to address the underlying cause of disease.

We apply a consistent decision framework that considers biological validation, probability of technical success, development timelines, capital requirements, and expected risk-adjusted value. We evaluate performance at the portfolio level based on overall progress across development milestones, regulatory approvals, and commercialization, as well as our ability to reallocate resources as data emerge. This portfolio-based approach allows us to advance multiple programs in parallel and, over time, support a self-reinforcing “flywheel” of portfolio development.

The following graphic illustrates our approach to program selection:

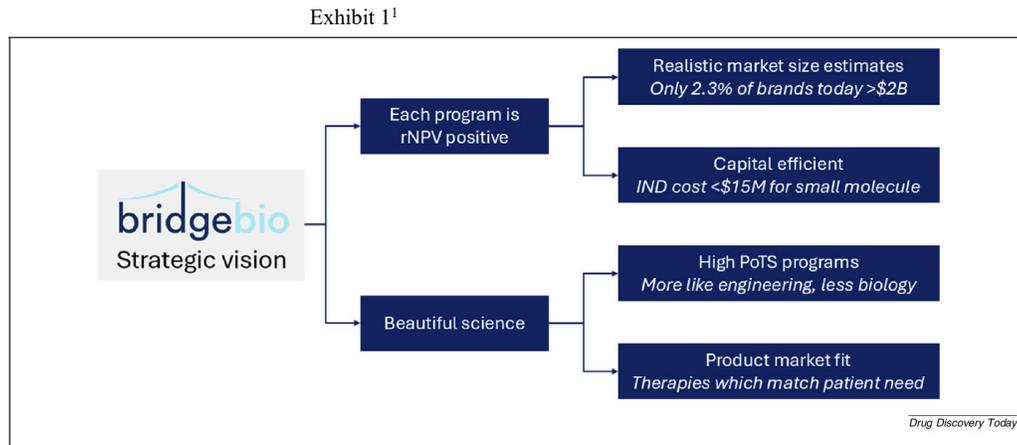


EXHIBIT 1
BridgeBio's two criteria for program selection inspired by Freedman (2013).^[p12] PoTS: probability of technical success; rNPV: risk-adjusted net present value.

As shown in Exhibit 1 above, we apply a quantitative approach to evaluating our programs and our Company as a whole, which typically includes the following factors:

- **Scientifically grounded program selection:** Each program is selected based on strong biological validation, including a clear understanding of disease mechanism and a therapeutic approach designed to address a well-defined genetic condition. We believe this focus supports more predictable development outcomes and a higher probability of technical success over time.
- **Focus on differentiated medicines:** We seek to develop medicines that have the potential to be first-in-class or best-in-class within their respective fields. In evaluating differentiation, we consider factors such as clinical outcomes, timing of therapeutic effect, safety profile, and overall treatment burden, using available clinical data and comparative assessments where appropriate.
- **Economic sustainability at the program level:** Each program is evaluated with the objective of supporting long-term economic sustainability on a risk-adjusted basis. We consider factors such as development timelines, capital requirements, and expected returns in determining whether to advance or continue investment in a program.
- **Capital efficiency as an operating principle:** We emphasize disciplined capital deployment throughout research and development, with a focus on managing costs through early development stages while maintaining flexibility to adjust investment based on emerging data.

¹ Shukla, C., Tendler, I., Kumar, N. and Lo, A.W. (2026) Genetic targets, financial creativity: BridgeBio's model for sustainable drug development. Drug Discovery Today, 31(1), pp. 1–7.

Our Hub-and-Spoke Operating Model

BridgeBio operates a decentralized, hub-and-spoke model designed to maximize our probability of success over time. This model is intended to allow multiple programs to advance concurrently while enabling capital and other resources to be allocated flexibly as data evolves, consistent with our approach to managing development risk over time.

Our “spokes” consist of program-specific teams responsible for research, development, and scientific leadership for individual conditions or product candidates. These teams are accountable for program strategy and day-to-day development decisions. Each spoke is structured as a dedicated, minimum viable development unit, concentrating only the capabilities required to advance a program efficiently while minimizing organizational complexity. Furthermore, within each spoke we focus scientific effort on the rate-limiting questions for program advancement, reducing non-essential experimentation and supporting faster progression to key development milestones.

Our “hub” consists of centralized functions that provide shared business and finance operations, clinical and regulatory expertise, and our commercial platform. This structure allows us to separate asset-level scientific development from enterprise-level execution, support disciplined capital allocation, and scale our commercial platform for existing and future commercial products.

By maintaining lean, asset-focused teams supported by shared services, the model allows BridgeBio to be “led by the science” while retaining financial discipline in program development and preserve our flexibility to advance or discontinue programs based on the latest data.

Portfolio Overview

The following portfolio tables summarize our products for which we have previously received regulatory approval and our commercial products and Phase 3 registrational programs, which include our most advanced assets and key value drivers in our portfolio.

The tables also include selected early-stage clinical development programs that may contribute to the long-term expansion of our portfolio, subject to clinical progress and regulatory outcomes.

Commercial Products	Indication	Status
Products marketed by BridgeBio		
Attruby (acoramidis)	Transthyretin Amyloidosis (ATTR – CM)	Approved
Products not marketed by BridgeBio		
Beyontra (acoramidis)	Transthyretin Amyloidosis (ATTR – CM)	Approved
Nulibry (fosdenopterin)	Molybdenum Cofactor Deficiency (MoCD) Type A	Approved
Truseltiq (infigratinib)	Cholangiocarcinoma	Approved (withdrawn)
Phase 3 Registrational and Selected Phase 2/3 Clinical Development Programs	Indication	Status
Infigratinib	Achondroplasia (ACH)	Positive Topline Readout
BBP-418	Limb-Girdle Muscular Dystrophy Type 2I/R9 (LGMD2I/R9)	Positive Interim Analysis Topline Readout
Encaleret	Autosomal Dominant Hypocalcemia Type 1 (ADH1)	Positive Topline Readout
Infigratinib	Hypochondroplasia (HCH)	Fully Enrolled Phase 2 study
Encaleret	Chronic Hypoparathyroidism (CHP)	Phase 3 study initiating in 2026

In addition, we maintain a broad set of early-stage development programs and strategic equity investments, as reflected in the following pipeline overview. Together, these clinical and pre-clinical assets may develop into a meaningful driver of future portfolio value and long-term growth potential, subject to clinical progress and regulatory outcomes.

A pipeline of products that sing across the BridgeBio ecosystem

Program	Indication	Pre-Clinical	Phase 1	Phase 2	Phase 3	Approved	Patients (US + EU)	Market Opportunity
Attruby (acoramidis)	Transthyretin Amyloidosis (ATTR-CM)					✓	500,000+	\$20B+
Nulibry (fosdenopterin)	Molybdenum Cofactor Deficiency (MoCD) Type A					✓	<100	Partnered
Truseltiq (infigratinib)	Cholangiocarcinoma					✓	37,000	Partnered
Infigratinib	Achondroplasia (ACH)					Topline Readout	55,000+	\$2B+
	Hypochondroplasia (HCH)				Observational Run-in Fully Enrolled		55,000+	\$2B+
BBP-418	Limb-Girdle Muscular Dystrophy Type 2I/R9 (LGMD2I/R9)					Topline Readout	7,000+	\$1B+
Encaleret	Autosomal Dominant Hypocalcemia Type 1 (ADH1)					Topline Readout	25,000+	\$1B+
	Chronic Hypoparathyroidism (HP)						200,000+	\$1B+
BBP-812	Canavan Disease				Phase 1/2 Pivotal		1,000	TBD
Evanesco (depleter)	Transthyretin Amyloidosis (ATTR-CM)						500,000+	\$20B+
ADPKD (small molecule)	Autosomal Dominant Polycystic Kidney Disease						300,000	TBD
BridgeBio Oncology Therapeutics	3 Oncology Programs (various indications)						Various	Various
GondolaBio	17 Rare Disease Programs (various indications)						Various	Various

As of December 31, 2025, BridgeBio has an 18.2% ownership stake in BridgeBio Oncology Therapeutics and a 27.5% ownership stake in GondolaBio. BridgeBio Oncology Therapeutics and GondolaBio are independent companies from BridgeBio. BridgeBio's interest in GondolaBio is subject to reduction as additional tranches of capital contributions are funded.

Key Highlights

- Attruby commercial and clinical momentum:** In 2025, Attruby generated significant commercial uptake in the United States, supported by continued prescription growth, expanding prescriber adoption, and additional clinical data demonstrating early and sustained reductions in mortality and cardiovascular outcomes in patients with ATTR-CM.
- Beyontra commercial momentum in Europe:** Beyontra demonstrated strong early uptake in Europe, led by Germany, where the product achieved an estimated new-to-brand prescription (“NBRx”) share of more than 50% within the first year of launch, reflecting the strong commercial potential of the product in Europe.
- Positive Phase 3 results for infigratinib in achondroplasia:** In February 2026, we presented topline results from the PROPEL 3 global pivotal study of oral infigratinib in children living with achondroplasia. PROPEL 3 successfully met all primary and secondary endpoints with no serious adverse events related to the drug study. Based on these results, we plan to submit a New Drug Application (“NDA”) to the FDA and a Marketing Authorization Application (“MAA”) to the European Medicines Agency (“EMA”) in the second half of 2026.
- Positive Phase 3 results for encaleret in ADH1:** In October 2025, we presented topline results from the Phase 3 CALIBRATE trial of encaleret in autosomal dominant hypocalcemia type 1, which demonstrated statistically significant normalization of serum and urinary calcium versus standard of care. We plan to submit an NDA to the FDA in the first half of 2026.
- Positive Phase 3 results for BBP-418 in LGMD2I/R9:** In October 2025, we presented Topline data from the Phase 3 FORTIFY study showed BBP-418 achieved its primary and key secondary endpoints in limb-girdle muscular dystrophy type 2I/R9. We plan to submit an NDA to the FDA in the first half of 2026.
- International approvals for Beyontra:** In the first half of 2025, Beyontra received approval for the treatment of transthyretin amyloid cardiomyopathy from the European Commission and the regulatory authorities in the United Kingdom and Japan.

Commercial Products

ATTRUBY

Summary

Attruby (acoramidis), previously known as AG10, is a next-generation oral small molecule near-complete transthyretin (“TTR”) stabilizer, and was approved by the FDA in 2024 for the treatment of cardiomyopathy of wild-type or ATTR-CM in adults to reduce cardiovascular death and cardiovascular-related hospitalization. Acoramidis has demonstrated differentiated clinical benefit in ATTR patients in the Phase 3 ATTRibute-CM study and its open label extension. Attruby is the first and only approved product with a label specifying near-complete stabilization of TTR.

In 2025, Attruby generated \$362.4 million in U.S. net product revenues. These results correspond with increasing patient adoption and prescriber utilization. As of February 20, 2026, we have achieved:

- 7,804 unique patient prescriptions² in the United States
- 1,856 prescribing healthcare professionals³, demonstrating the broad and deep penetration of the Attruby story
- An estimated >25% share of NBRx for Attruby

In February 2025, the European Commission approved acoramidis, under the brand name Beyontra, for the treatment of adults with ATTR-CM in Europe. In 2025 regulatory approvals for the marketing of Beyontra were also granted in the United Kingdom and Switzerland. We have licensed commercial rights in Europe to Bayer who are commercializing Beyontra in all EU member states, the United Kingdom, Switzerland and Turkey under our Exclusive License Agreement with Bayer signed in March 2024.

The European launch of Beyontra has delivered strong early uptake, highlighting the product’s significant commercial potential in the region. Germany has been the leading market, with Beyontra achieving an estimated NBRx share of more than 50% within the first year of launch.

In March 2025, the Japanese Ministry of Health, Labor and Welfare approved acoramidis, under the brand name Beyontra, for the treatment of adults with ATTR-CM in Japan. We have licensed commercial rights in Japan to Alexion, AstraZeneca Rare Disease, under the Exclusive License Agreement signed in September 2019 with our subsidiary, Eidos Therapeutics, Inc.

In 2025, Beyontra contributed \$105.0 million in license and services revenue following approvals in Europe and Japan. Additionally, we received \$11.4 million in royalty revenue primarily earned on net product sales of Beyontra in Europe and Japan. In 2026, we plan to continue our collaborations with Bayer and Alexion to drive continued growth in Europe and Japan, respectively.

Market Opportunity

We believe that the total market for ATTR therapeutic interventions will continue to grow for the foreseeable future as the population of diagnosed patients increases because of heightened disease awareness and the increased adoption of non-invasive diagnostic techniques. We believe the potential total global addressable market could exceed \$20.0 billion. The number of estimated diagnosed ATTR-CM patients in the United States has grown from fewer than 5,000 in 2019 to more than 50,000 in 2025. As such, we believe that there could be a significant population of either newly diagnosed or undiagnosed patients who have not previously been treated with a disease-modifying therapy and could be treated with acoramidis. We believe acoramidis will also be an important treatment option for patients inadequately managed by the current treatment. Further, we believe that acoramidis has the potential to be a best-in-class stabilizer for the treatment of ATTR-CM and that stabilization is likely to remain the preferred mechanism. We are also encouraged by the potential that depleters could offer for ATTR-CM patients with existing amyloidogenic TTR deposits and are exploring potential combination therapy regimens.

² Unique patient prescriptions represent the cumulative total number of distinct patients in the United States who have received at least one prescription for Attruby since launch, across all distribution channels.

³ Unique prescribing healthcare professionals represents the cumulative total number of distinct healthcare providers in the United States who have prescribed Attruby at least since launch.

Design Overview

ATTR is a disease caused by destabilization of TTR tetramers resulting in progressive amyloid deposition. TTR is a protein that occurs naturally in the form of a tetramer, consisting of four identical subunits, or monomers, and performs multiple physiologic roles, including the transport of thyroxine and retinol. In ATTR, TTR tetramers become destabilized due to a mutation in the TTR gene or as part of the natural aging process. Destabilized TTR dissociates into monomers, self-aggregates, and assembles into fibrils that are deposited, predominantly in the heart and nervous system, driving disease pathophysiology. TTR itself is not toxic – it is a normal and essential protein in humans, and humans cannot be born in the absence of the TTR gene. Higher serum TTR levels are associated with increased longevity and reduced cardiovascular and dementia risk in multiple independent studies. Higher serum levels also reflect greater TTR stability. The ATTR disease process begins only when TTR destabilizes to release its monomers, which may then re-aggregate and misfold into amyloid fibrils.

Cardiomyopathic ATTR is commonly categorized by its genotypic cause with wild-type ATTR cardiomyopathy (“ATTRwt-CM”), which results from an age-related process, and variant ATTR cardiomyopathy (“ATTRv-CM”). Both forms of the disease are progressive and fatal, though ATTRv-CM patients’ condition often presents at an earlier age and progress more rapidly than patients with wild-type disease, which translates into a worse prognosis in many such patients. ATTRwt-CM and ATTRv-CM patients generally present with symptoms later in life (older than 50) and have median life expectancies of two to five years from diagnosis if untreated. Progression of both forms of the disease can cause significant disability, impact productivity and quality of life, and create a significant economic burden due to the costs associated with patient need for supportive care. As the disease progresses, ATTRwt-CM and ATTRv-CM patients may experience recurrent hospitalizations and repeated interventions.

The worldwide estimated prevalence of ATTRwt-CM and ATTRv-CM is greater than 400,000 and 40,000, respectively. We believe that cardiomyopathic ATTR is significantly underdiagnosed today. For example, recent literature has suggested that between 10% to 13% of patients diagnosed with heart failure with preserved ejection fraction may have undiagnosed ATTR-CM. The heart failure with preserved ejection fraction segment represents approximately half of the 6.0 million to 7.0 million estimated people with heart failure in the United States. With the increasing availability of disease-modifying therapeutics, disease awareness is heightened, and the diagnosis rate will likely continue to grow.

We believe the population of diagnosed ATTR-CM patients is also growing rapidly due to the shift to an accurate and reliable non-invasive diagnostic imaging technique. Historically, a heart biopsy was required to make a diagnosis of ATTR-CM. Recently, however, it has been shown that scintigraphy with technetium-labeled radiotracers paired with single-photon emission computerized tomography (“SPECT”) imaging is a highly accurate, non-invasive, and cost-effective method for ATTR-CM diagnosis. We believe that both increased disease awareness and availability of this non-invasive diagnostic imaging technique allow for earlier diagnosis of ATTR-CM patients and the identification of previously misdiagnosed patients.

Design Criteria

Acoramidis is a commercially available, orally administered, small molecule TTR stabilizer that treats ATTR at its source. We designed acoramidis to meet two primary criteria – to preserve circulating native TTR and to reduce amyloid deposition by minimizing toxic monomer formation.

TTR is a protein that has been highly conserved throughout evolution, and which is abundant in the plasma with relatively rapid turnover requiring sustained metabolic energy expenditure. Thus, we seek to achieve maximal stabilization of the TTR tetramer rather than elimination.

Acoramidis has been shown in preclinical studies and clinical trials to prevent the dissociation of tetrameric TTR into monomers, and in preclinical studies, to reduce the rate of amyloid fibril formation. In addition, it has been shown to lead to increased circulating levels of tetrameric TTR. Acoramidis was designed to bind TTR in a way that causes TTR’s conformational structure to mimic that of the well-characterized T119M variant, a naturally occurring rescue mutation that super stabilizes the TTR tetramer. The T119M variant has been observed to prevent the dissociation of TTR tetramers into monomers; T119M tetramers dissociate 40-fold more slowly than wild-type tetramers in biochemical assays. Known as a trans-allelic trans-suppressor, individuals who coinherit the T119M rescue mutation along with a TTR-destabilizing mutation are protected against the development of ATTR.

In third-party clinical trials of tafamidis, another orally administered, small molecule TTR stabilizer, interventional approaches that increased TTR stabilization led to improved outcomes in this disease, as measured by all-cause mortality and cardiovascular-related hospitalizations, and were correlated with increases in serum TTR. Further, based on genetic data, there is a correlation between the level of TTR stabilization, serum TTR levels and disease severity. As a result, we believe that serum TTR is a predictive biomarker for disease prognosis and that observed data from the ATTRIBUTE-CM study showed increases in serum TTR from baseline levels were correlated with reductions in CVH and CVM over 30 months. Based on results from comparative nonclinical studies, we believe that acoramidis has the potential to stabilize TTR to a greater extent than other TTR stabilizers.

Summary of Key Clinical Outcomes and Development Milestones in 2025

Announcement Date	Study	Key Findings
March 31, 2025	ATTRIBUTE-CM Variant Subgroup Analysis	Acoramidis showed statistically significant reduction in the risk of ACM or first CVH in ATTR-CM Variant patients with a 59% risk reduction versus placebo through Month 30
May 13, 2025	ACT-EARLY	First participant dosed in ACT-EARLY, the first clinical study evaluating acoramidis for primary prevention in asymptomatic carriers of pathogenic TTR variants
May 19, 2025	ATTRIBUTE-CM Serum TTR Biomarker Analysis	Early and sustained increases in serum TTR levels were observed to be independently associated with improved survival
May 20, 2025	ATTRIBUTE-CM Post-Hoc Analysis	Acoramidis reduced cardiovascular hospitalizations due to atrial fibrillation/atrial flutter by 43% and reduced new-onset AF/AFL by 17% versus placebo in patients without prior AF history
August 30, 2025	ATTRIBUTE-CM Open-Label Extension (OLE)	Acoramidis demonstrated statistically significant reduction in cardiovascular mortality with a 44% hazard reduction through Month 42
September 28, 2025	ATTRIBUTE-CM Cumulative Cardiovascular Outcomes Analysis	Acoramidis was observed to begin reducing the risk of CVM and recurrent CVH within the first month of treatment with a 49% hazard reduction versus placebo at Month 30
November 8, 2025	ATTRIBUTE-CM Variant Subgroup Analysis	Acoramidis demonstrated statistically significant reduction in ACM or first CVH in the Variant V142I (V122I) population with a 69% risk reduction versus placebo through Month 30

NULIBRY

Fosdenopterin, an intravenous formulation of synthetic cyclic pyranopterin monophosphate, was developed as a treatment for molybdenum cofactor deficiency (“MoCD, Type A”). Fosdenopterin, under the brand name NULIBRY, was approved by the FDA in February 2021 for patients with MoCD Type A.

MoCD Type A is an ultra-rare condition, with estimated incidence ranging from approximately one in 341,000 to one in 411,000 live births. As a result, the addressable patient population is extremely small, and the commercial market is limited in absolute size. Prior to the approval of NULIBRY, there were no approved therapies for any form of MoCD, and treatment was limited to supportive and symptomatic care.

Upon FDA approval in February 2021, NULIBRY became the first and only approved therapy for this condition. The approval was supported by orphan drug designation and resulted in the issuance of a Priority Review Voucher.

In March 2022, Sentyln Therapeutics, Inc. acquired global rights to NULIBRY and assumed responsibility for its ongoing development, manufacturing, and commercialization worldwide. NULIBRY remains commercially available. BridgeBio did not generate significant royalty revenue from product sales of NULIBRY during 2025.

TRUSELTIQ

TRUSELTIQ (infigratinib) is a selective fibroblast growth factor receptor (“FGFR”) inhibitor. In May 2021, the FDA granted accelerated approval to TRUSELTIQ for the treatment of cholangiocarcinoma with an FGFR2 fusion or rearrangement, as detected by an FDA-approved test.

In May 2023, the FDA announced the withdrawal of the accelerated approval for TRUSELTIQ. Although TRUSELTIQ is no longer commercially available, we continue to utilize related intellectual property in ongoing clinical investigations involving other FGFR-related conditions.

Commercialization and Product Support

We have built our commercial organization in the U.S. to support the commercialization of Attruby in the U.S. Following FDA approval in November 2024, we launched Attruby in the U.S. with a sales force appropriately sized to call on all ATTR-CM treatment centers in the U.S. and other community cardiologists who treat ATTR-CM patients in the U.S.

Our sales force is focused on promoting Attruby to healthcare providers and effectively communicating product benefits. Attruby is the first and only approved product for adults with ATTR-CM in the U.S. with a label specifying near-complete stabilization of TTR. The full prescribing information (“PI”) for Attruby can be accessed at www.ATTRUBY.com.

We estimate that there are approximately 240,000 ATTR-CM patients in the U.S., part of a global patient population of around 500,000.

Attruby has already demonstrated category-leading results including:

- Demonstrated effects on clinical outcomes and quality of life, with effects observed as early as one month and three months, respectively
- 42% reduction in composite of all-cause mortality and recurrent cardiovascular-related hospitalization events at Month 30
- 50% reduction in the cumulative frequency of cardiovascular-related hospitalization events at Month 30

We believe these results support the strong value proposition of Attruby and underscore the opportunity to improve the lives of patients with ATTR-CM. To ensure patients can access and afford this treatment, we have established several industry-leading access programs. We also offer a Commercial Co-Pay program for eligible commercial patients, which can provide access to Attruby for free. We also offer Attruby for free to patients who are uninsured or underinsured through our Patient Assistance Program (“PAP”) and provide a free 28-day trial to patients new to Attruby. For Medicare patients, the Inflation Reduction Act (“IRA”) limited out-of-pocket costs (“OOP”) and capped OOP at \$2,000.00 annually, effective January 1, 2025. Additionally, patients participating in the Medicare Prescription Payment Program are eligible to spread their out-of-pocket costs into monthly payments, not to exceed \$167.00 per month, inclusive of all Part D medications. Dual-eligible and Low-Income Subsidy patients will pay no more than \$13.00 per month.

To ensure ease of access, Attruby is distributed in the U.S. through a limited network of specialty pharmacies, specialty distributors and third-party logistics providers. Medication can be dispensed directly to patients or directly from approved hospital pharmacies to patients.

We currently partner with Bayer for the commercialization of Beyontra in Europe and Alexion for commercialization of Beyontra in Japan. We plan to leverage a full-service distribution partnership to support commercialization of Beyontra in additional markets.

We continue to evaluate our commercialization strategy as we advance each product candidate through clinical development and to regulatory approval. In any core markets outside of the United States that we may identify, we may elect to utilize strategic partners, distributors or contract management and sales organizations to assist in the commercialization of any of our approved products in certain geographies.

Manufacturing

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We currently utilize third-party contract manufacturing organizations (“CMOs”) for all required raw materials, drug substance, drug product and packaging for our commercial products and for our preclinical research and our ongoing clinical trials of our product candidates. We have secured long-term manufacturing agreements with CMOs to produce and support our commercial sale of Attruby in the U.S., and of Beyontra in certain markets outside of the United States.

We intend to continue to rely on CMOs for later-stage development and commercialization of our product candidates, including any additional product candidates that we may identify. Although we rely on CMOs, we have employees and third-party consultants with extensive manufacturing experience to oversee the relationships with our contract manufacturers. Refer to Note 11 of Part II - Item 8. Financial and Supplementary Data - Notes to Consolidated Financial Statements of this Annual Report on Form 10-K for further details.

Development Portfolio – Phase 3 Registrational Candidates

Our Phase 3 portfolio comprises multiple programs with positive late-stage clinical data advancing toward potential regulatory submissions. Together, these programs represent the most mature assets in our portfolio and illustrate the breadth and commercial potential of our in-house development engine.

Infigratinib for Achondroplasia

Summary

We are developing low-dose infigratinib, an oral, selective FGFR1-3 tyrosine kinase inhibitor, for the treatment of children with achondroplasia and hypochondroplasia, two skeletal dysplasia programs caused by gain-of-function mutations in the fibroblast growth factor 3 (“FGFR3”) gene. Infigratinib acts directly at the pathophysiological cause of achondroplasia by inhibiting overactive FGFR3 signaling and addresses the underlying genetic driver of disease.

Our objective with low-dose infigratinib is to provide a differentiated treatment option that targets FGFR3 at its source while offering an oral route of administration that reduces treatment burden for children and their families.

Infigratinib has received Breakthrough Therapy Designation, and Rare Pediatric Disease Designation from the FDA for achondroplasia, as well as Fast Track Designation and Orphan Drug Designation for both achondroplasia and hypochondroplasia.

PROPEL 3 Top-Line Readout

On February 12, 2026, we reported positive Phase 3 Topline results from our PROPEL 3 study for oral infigratinib with the first statistically significant improvements in body proportionality in achondroplasia.

PROPEL 3 is a Phase 3, multicenter, randomized, double-blind, placebo-controlled pivotal study evaluating low-dose infigratinib at 0.25 mg/kg/day in children ages 3 to <18 years with open growth plates.

PROPEL 3 successfully met the primary endpoint of change from baseline in annualized height velocity (“AHV”) at Week 52 ($p < 0.0001$). Change from baseline in AHV was superior to placebo at Week 52 with a mean treatment difference against placebo of +2.10 cm/year; the least squares (“LS”) mean was +1.74 cm/year.

PROPEL 3 successfully met the key secondary endpoint of change from baseline in height Z-score (achondroplasia reference population) at Week 52 ($p < 0.0001$), with an LS mean increase on the treatment arm of +0.41 SD.

Oral infigratinib was well tolerated, with no discontinuations or serious adverse events related to the drug study, 3 cases (4%) of hyperphosphatemia considered mild and transient with not a single case requiring either dose reduction or discontinuation, and no adverse events associated with inhibition of FGFR1 or 2.

Market Opportunity

We believe that achondroplasia and other FGFR-driven skeletal dysplasias represent a potentially over \$5.0 billion total global market opportunity. We believe that low-dose infigratinib, if approved, would have meaningful commercial potential to demonstrate best-in-class efficacy as well as a differentiated oral route of administration preferred by many patients.

Infigratinib is administered orally as a sprinkle capsule that can be swallowed whole or the capsules can be opened with the granules administered on soft food. Despite the availability of approved injectable therapies, a substantial proportion of eligible children remain untreated, with injection burden frequently cited as the primary barrier to initiation or continuation of therapy.

If approved, we believe low-dose infigratinib could support broader uptake across both treatment-naïve patients and those currently receiving injectable therapies, particularly given its oral administration and mechanism designed to directly address FGFR3-driven disease biology.

Condition Overview and Design Criteria

Achondroplasia is the most common heritable cause of disproportionate short stature with a prevalence of greater than 55,000 in the United States and Europe. It is caused by gain-of-function variants in the gene encoding fibroblast growth factor 3 (“FGFR3”). This alteration impairs the process of endochondral skeletal ossification through inhibition of chondrocyte proliferation and differentiation. This inhibition occurs through the signal transducer and activator of transcription 1 (“STAT1”) and mitogen-activated protein kinase (“MAPK”) pathways in chondrocytes. Persons living with achondroplasia can have a variety of medical complications, functional limitations and psychosocial challenges.

We are developing low-dose infigratinib based upon two key design principles. First, we seek to target achondroplasia at its source (FGFR3 overactivity) in order to address all manifestations of the condition, not just height. Second, we also seek to provide a tolerable oral treatment option in order to provide a reduced burden of treatment versus injection for children and their families. As an FGFR1-3 inhibitor, we believe that low-dose infigratinib has the potential to decrease downstream signaling of FGFR3 and treat both conditions at the source. Unlike C-type natriuretic (“CNP”) analogs, which only inhibit MAPK signaling, our approach is aimed at also inhibiting STAT1 signaling. We believe low-dose infigratinib is the only investigational therapy with Phase 3 results that incorporates both these design principles.

Development Status and Next Steps

Based on the positive topline results of PROPEL 3, we intend to submit an NDA to the FDA and an MAA to the EMA in the second half of 2026 for achondroplasia.

In addition, we have dosed the first participant in the PROPEL infant and toddler study (“PROPEL I&T”). PROPEL I&T is a Phase 2b, randomized, double-blind, placebo-controlled clinical trial, preceded by a single ascending dose portion and a Phase 2 open-label portion, to evaluate the safety and efficacy of oral infigratinib in infants and young children living with achondroplasia.

In addition, the open-label, long-term extension study of infigratinib in children with achondroplasia is ongoing to evaluate the long-term safety, tolerability and efficacy of infigratinib in subjects with achondroplasia. This study will allow the confirmation that changes observed during the first or second year of treatment will continue during the growth period resulting in a clinically relevant improvement in final height and a trend toward improvement of other clinically relevant parameters, such as complications associated with ACH.

Infigratinib has received Breakthrough Therapy Designation, and Rare Pediatric Disease Designation from the FDA for achondroplasia, as well as Fast Track Designation and Orphan Drug Designation for both achondroplasia and hypochondroplasia.

Encaleret for the treatment of Autosomal Dominant Hypocalcemia Type 1

Summary

Encaleret is an investigational, oral small molecule, negative allosteric modulator of the calcium sensing receptor (“CaSR”) that we are developing for the treatment of Autosomal Dominant Hypocalcemia Type 1 (“ADH1”) and Chronic Hypoparathyroidism (“CHP”).

CALIBRATE Topline Readout

In October 2025, we reported positive data from our Phase 3 topline results for encaleret in patients with ADH1. The CALIBRATE study, our global Phase 3 registrational study of encaleret in adults with ADH1, met all prespecified primary and key secondary endpoints, demonstrating statistically significant superiority of encaleret compared to conventional therapy.

The CALIBRATE study was designed to study the efficacy and safety of encaleret in adult and adolescent ADH1 patients. The primary endpoint was defined as the proportion of participants randomized to receive encaleret achieving both serum calcium (8.3-10.7 mg/dL) and urine calcium (<300 mg/day for males and <250 mg/day for females) in the respective target ranges.

The primary endpoint—defined as the proportion of participants achieving both serum calcium and 24-hour urine calcium within their respective target ranges at Week 24—was achieved by 76% of participants administered encaleret, compared to 4% of the same participants while on conventional therapy (p<0.0001). In a key secondary analysis, 91% of participants receiving encaleret achieved intact parathyroid hormone (PTH) levels above the lower limit of the reference range at Week 24, compared to 7% on conventional therapy (p<0.0001).

Encaleret demonstrated rapid and sustained normalization of serum calcium and urine calcium, with improvements observed within days of treatment initiation and maintained through the 24-week maintenance period. Among participants who met the primary endpoint on encaleret, none required conventional therapy during the maintenance period. Encaleret was generally well tolerated, with no discontinuations related to the drug study. Among the randomized trial participants, 97% elected to join in the study’s long-term extension to further evaluate the durability of response to encaleret.

Following these results, we plan to submit an NDA to the FDA in the first half of 2026, followed by an MAA to the EMA.

Market Opportunity

We believe that ADH1 is a serious medical condition with unmet needs and represents a market with significant commercial potential. ADH1 is caused by gain-of-function variants of the CASR gene, and independent studies of general population genetic datasets estimate that there are 25,000 carriers of ADH1-causative variants in the EU and US. If approved, encaleret could be the first targeted therapy indicated for the treatment of ADH1. Additionally, if approved, we believe there are market expansion opportunities for encaleret in pediatric ADH1 and in chronic hypoparathyroidism given its profile as an orally administered therapy.

ADH1 Disease Overview and Design Criteria

ADH1 is a rare autosomal dominant genetic disease where gain of function variants in the CASR gene result in overactive CaSRs for patients. Overactive CaSRs cause dysregulation of calcium homeostasis including lower serum calcium and PTH levels as well as higher urine calcium levels. Symptoms of hypocalcemia can vary in severity, and include hypocalcemic seizures, paresthesia, tetany, and muscle cramps. Patients have a long-term risk of nephrolithiasis, nephrocalcinosis, and chronic kidney disease from elevated urine calcium levels.

ADH1 Development Status and Next Steps

We plan to dose the first participant in the registrational Phase 2/3 study of encaleret in pediatric ADH1 in the first quarter of 2026.

Our development activities are focused on expanding the potential populations that would benefit from encaleret. Some ADH1 patients start experiencing symptoms soon after birth and many end up being diagnosed with a hypocalcemia-related disorder earlier in life (median age of diagnosis is 4 years old). There is a median delay of approximately two decades before patients receive a genetically confirmed diagnosis. To expand treatment options for younger patients, we plan to dose the first participant in a registrational Phase 2/3 study investigating encaleret in pediatric ADH1 in the first quarter of 2026.

Encaleret has been granted orphan drug and fast track designations by the FDA for the treatment of autosomal dominant hypocalcemia. Encaleret has also been granted orphan designation by the European Commission and by the Japan Ministry of Health, Labor and Welfare as a treatment for hypoparathyroidism and ADH1.

BBP-418 for the treatment of Limb Girdle Muscular Dystrophy Type 2I/R9

Summary

BBP-418 is an investigational, orally administered, small molecule therapy that we are developing for the treatment of LGMD2I, also known as LGMDR9 FKRP-related.

FORTIFY Interim Topline Readout

In October 2025, we reported positive topline results from the planned interim analysis of FORTIFY, a global, randomized, double-blind, placebo-controlled Phase 3 study evaluating BBP-418 in individuals with LGMD2I/R9. The FORTIFY interim analysis met all primary and key secondary endpoints, demonstrating statistically significant and clinically meaningful improvements across biomarker and functional measures, with a favorable safety profile.

Based on the FORTIFY interim analysis results and prior regulatory interactions, we are engaging with the FDA as we plan for submission of an NDA in the first half of 2026. If approved, BBP-418 may be eligible for a Priority Review Voucher under the Rare Pediatric Disease program. The FORTIFY study remains ongoing, with additional data collection and longer-term follow-up continuing.

BBP-418 has received Orphan Drug Designation, Fast Track Designation, and Rare Pediatric Disease Designation from the FDA, as well as Orphan Drug Designation from the EMA.

Market Opportunity

LGMD2I/R9 affects an estimated approximately 7,000 individuals across the United States and Europe, including patients with LGMD2I/R9 and other potentially addressable dystroglycanopathies. The disease is underdiagnosed, and progression often leads to loss of ambulation, respiratory compromise, and cardiomyopathy.

If approved, BBP-418 has the potential to become the first disease-modifying therapy for LGMD2I/R9. We plan to commercialize BBP-418 globally and are leveraging BridgeBio's established rare disease commercial infrastructure, including launch experience, market access capabilities, and patient support services, to prepare for a potential launch.

Disease Overview and Design Criteria

LGMD2I/R9 is an inherited neuromuscular disorder characterized by lower-limb weakness and loss of ambulation, and possible pulmonary and cardiac dysfunction. BBP-418 has a potentially-addressable patient population of 7,000, including both LGMD2I/R9 and other potentially-addressable dystroglycanopathies, in the United States and Europe. Currently, there is no disease-modifying treatment available. Standard of care is supportive care to alleviate end organ dysfunction.

The rationale for developing BBP-418 as a potential treatment for LGMD2I/R9 is based on our understanding of the disease mechanism. In healthy tissue, a properly functioning Fukutin-Related Protein ("FKRP") glycosylates alpha-dystroglycan ("αDG"). This glycosylation helps to stabilize muscle cells by binding extracellular ligands. In LGMD2I/R9, mutated FKRP does not function properly and results in dysfunctional, hypo-glycosylated αDG in muscle cells, limiting αDG's ability to function as a "shock absorber" for muscle fibers and increasing cellular susceptibility to damage.

BBP-418 is designed to target the disease mechanism of LGMD2I/R9 by supplying supra-physiological levels of BBP-418 upstream to drive residual activity of the mutant FKRP enzyme and increase glycosylated αDG levels.

Development Status and Next Steps

BBP-418 is currently being evaluated in the ongoing FORTIFY Phase 3 study. Based on the positive interim analysis results and our interactions with the FDA to date, we intend to submit an NDA to the FDA in the first half of 2026.

The key findings from the planned interim analysis at 12 months included:

- A statistically significant near doubling (1.8-fold increase) in glycosylated αDG from baseline at 3 months compared to approximately no change in the placebo group ($p < 0.0001$), with improvements sustained through 12 months ($p < 0.0001$)
- An 82% mean reduction from baseline in serum creatine kinase (CK), a marker of muscle damage, which was statistically significant compared to placebo ($p < 0.0001$)
- Statistically significant improvements in ambulatory function, as measured by the 100-meter timed test ($p < 0.0001$), and pulmonary function, as measured by forced vital capacity (FVC) ($p = 0.0071$)

- Statistically significant and clinically meaningful 2.6 point benefit on North Star Assessment (NSAD) for limb-girdle type muscular dystrophies compared to placebo (nominal $p=0.0001$)
- Consistent treatment effects across planned subgroups, including genotype (individuals with the L276I homozygous genotype vs. those with other FKRP variants), age group (pediatric vs. adult), and pulmonary function (baseline FVC $\geq 80\%$ vs. baseline FVC 40-80%)
- Well-tolerated safety profile, with no new or unexpected safety findings and no treatment-related serious adverse events observed

The approval, timing, and scope of any potential regulatory submission will depend on further regulatory review, the completeness of the clinical data package, and discussions with regulatory authorities. If approved, we expect to leverage our commercial infrastructure to support the potential launch of BBP-418 globally, subject to all regulatory outcomes.

Development Portfolio – Phase 2 Pipeline Candidates

Our Phase 2 development portfolio includes expansion indications of our Phase 3 programs with commercial potential, as well as standalone programs that have demonstrated clinical proof-of-concept. These programs represent the next set of potential product candidates emerging from our portfolio-based development model.

Encaleret for the treatment of Chronic Hypoparathyroidism (“CHP”)

In September 2025, we completed a Phase 2 proof-of-concept study investigating the PTH-independent effects of encaleret on renal calcium handling in patients with post-surgical hypoparathyroidism. In collaboration with clinical researchers at the National Institutes of Health, the study enrolled 10 patients.

Encaleret treatment resulted in PTH-independent normalization of blood and urine calcium in 80% of participants to be within the normal reference range within 5 days of encaleret initiation compared to 0% of participants on conventional therapy at baseline. Encaleret was well tolerated with no serious adverse events reported over the study period.

Based on these positive results, we completed an End of Phase 2 interaction with the FDA, and we plan to initiate a registrational Phase 3 study in adults with CHP in the summer of 2026.

CHP represents a larger potential patient population with an estimated 200,000 patients in the US and Europe. Existing clinical data support the continued evaluation of encaleret as an orally administered treatment option for patients with CHP.

Infigratinib for Hypochondroplasia

We are developing low-dose infigratinib for hypochondroplasia, a related FGFR3-driven skeletal dysplasia characterized by disproportionate short stature and variable skeletal and neurologic manifestations. There are currently no FDA-approved pharmacologic therapies for hypochondroplasia.

We believe that the total global market opportunity for hypochondroplasia will approach that of the achondroplasia market, driven by growing awareness of the condition due to ongoing clinical trials in the condition. We believe that low-dose infigratinib, if approved, would have meaningful commercial potential as a differentiated oral route of administration preferred by many patients.

We are enrolling participants in ACCEL, a prospective natural history study in children with hypochondroplasia. This trial is designed to establish baseline growth parameters, including AHV, in children with hypochondroplasia. ACCEL is intended to support enrollment into ACCEL 2/3, a planned Phase 2/3 interventional program consisting of an initial open-label phase followed by a randomized, placebo-controlled study evaluating the safety and efficacy of infigratinib.

Enrollment in the Phase 2 portion of ACCEL 2/3 has been completed, with proof-of-concept results expected in the second half of 2026. Based on the positive PROPEL 3 study topline data for oral infigratinib for achondroplasia, we plan to accelerate the development of oral infigratinib in hypochondroplasia, and are enrolling the observational run-in for the Phase 3 trial.

BBP-812 for the treatment of Canavan disease

Canavan disease (“CD”) is an ultra-rare neurodegenerative disease with approximately 1,000 patients across the US and EU. CD is usually fatal within the first two decades of life, and more than 25% of patients die by the age of 10 years. Children with CD exhibit global and severe cognitive, motor, and language impairment, missing or regressing on most developmental milestones. There are currently no therapies approved for the treatment of CD.

If approved, BBP-812 has the potential to become the first disease-modifying therapy for CD. BBP-812 has previously received Orphan Drug, Fast Track, Regenerative Medicine Advanced Therapy, and Rare Pediatric Disease Designations from the FDA and Orphan Drug Designation from the EMA. Consistent with the Rare Pediatric Designation from the FDA, if BBP-812 is approved, we may qualify for a Priority Review Voucher.

We are conducting a Phase 1/2 study (CANaspire) for BBP-812 for Canavan disease. The program is designed to provide a first disease-modifying therapy by targeting the condition at its source and supporting accelerated approval through a single registrational study using a biomarker. It also leverages an established IV AAV9 safety profile while avoiding invasive neurosurgery through a less burdensome intravenous treatment approach.

Development Portfolio - Early-Stage and Clinical Development Interests

Our early-stage and clinical development activities and interests include a combination of internally developed programs and minority ownership interests in independent companies that were spun out of BridgeBio in 2024.

Evanesco (Depletter)

BridgeBio has initiated a next-generation depletter program for the potential treatment of ATTR-CM. While TTR stabilizers and gene-silencing therapies reduce the formation of new amyloid, many patients are diagnosed after meaningful amyloid deposition has already occurred. A therapeutic approach capable of removing existing amyloid deposits could be used in combination with current therapies and may expand the addressable patient population in ATTR-CM. If successfully developed, this program could complement BridgeBio's existing ATTR-CM portfolio and support a more comprehensive treatment regimen addressing both prevention of new deposits and clearance of existing amyloid burden.

The depletter is a monoclonal antibody designed to selectively bind misfolded, amyloidogenic TTR and promote clearance through macrophage-mediated phagocytosis. The program incorporates several design features intended to enhance differentiation, including preferential binding to amyloid fibrils over native TTR, Fcγ receptor enhancement to support immune-mediated clearance, pH-dependent antigen release to facilitate antibody recycling, and FcRn-mediated half-life extension to enable less frequent dosing.

The ATTR-CM depletter program is currently in preclinical development. BridgeBio plans to advance the program into the clinic in 2027–2028, subject to successful completion of IND-enabling studies and regulatory review.

GondolaBio

GondolaBio, LLC (“GondolaBio”) is an independent company focused on the discovery and development of therapies for rare genetic diseases. GondolaBio operates with its own management team and development strategy and maintains a diversified pipeline of early and mid-stage programs across multiple therapeutic areas and modalities, including hematologic, neurologic, renal, hepatic, and dermatologic genetic disorders. As of December 31, 2025, BridgeBio held a 27.5% ownership interest in GondolaBio, which is subject to dilution as additional capital is contributed to GondolaBio through equity investments by third-party investors.

A key program within the pipeline is PORT-77, a small-molecule ABCG2 inhibitor in Phase 2a development for erythropoietic protoporphyria (“EPP”), a rare genetic disease with significant unmet medical need, for which positive proof-of-concept clinical data have been reported. Based on clinical data to date, GondolaBio intends to initiate a Phase 2b/3 clinical trial in 2026, pending regulatory feedback.

BridgeBio Oncology Therapeutics, Inc.

BridgeBio Oncology Therapeutics (“BBOT”) is a clinical-stage biopharmaceutical company advancing a next-generation pipeline of novel small molecule therapeutics targeting RAS and Phosphoinositide 3-kinase malignancies. See Note 6 to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K for a description of transactions involving BBOT and TheRas, Inc., our former majority-owned subsidiary, which was deconsolidated in April 2024 and completed a business combination transaction with BBOT's predecessor, Helix Acquisition Corp. II, in August 2025.

On August 11, 2025, BridgeBio Oncology Therapeutics, Inc. became listed on Nasdaq under the ticker symbol “BBOT.” As of December 31, 2025, BridgeBio held an 18.2% ownership interest in BBOT.

BBOT's pipeline includes multiple clinical-stage and late preclinical programs, including direct KRAS inhibitors and other genetically targeted oncology assets. Several of BBOT's programs have advanced into clinical trials and have reported early clinical activity, supporting the continued progression of its pipeline. BBOT's programs span multiple tumor types and are designed to address resistance mechanisms and limitations of earlier-generation targeted therapies.

Competition

The biopharmaceutical industry is highly competitive, and we face competition from established pharmaceutical and biotechnology companies, as well as academic research institutions, developing therapies for similar indications. Some competitors may have greater financial, regulatory, manufacturing, and commercial resources.

Competition is based on factors including clinical performance, regulatory approval, intellectual property protection, pricing and reimbursement, and commercial execution. There can be no assurance that our products or product candidates, if approved, will achieve market acceptance relative to competing therapies.

Material Commercial Products

ATTRUBY

Attruby/Beyontra (acoramidis) for the treatment of adults with ATTR-CM competes with Vyndaqel / Vyndamax (tafamidis meglumine / tafamidis), which is a commercial product marketed by Pfizer, Inc. and approved in certain territories, including the United States, the European Union, and Japan as a treatment for ATTR-CM. In addition, Alnylam Pharmaceuticals, Inc.'s vutrisiran received regulatory approvals in 2025 for the treatment of ATTR-CM in multiple jurisdictions globally, and Attruby/Beyontra competes with vutrisiran in markets where it is approved. Additionally, there are a number of RNAi, antisense oligonucleotide, antibody, and gene editing product candidates that are currently in development as potential treatments for ATTR-CM.

Phase 3 Registrational programs

Infigratinib for Achondroplasia

Low-dose infigratinib is an orally administered selective FGFR1-3 inhibitor in late-stage clinical development for achondroplasia. Other companies are developing therapies for achondroplasia, including Ascendis Pharma A/S (TransCon CNP), Tyra Biosciences, Inc. (TYRA-300), and Ribomic (RBM-007), each of which targets pathways associated with FGFR3 signaling through different mechanisms.

If approved, infigratinib would compete with BioMarin Pharmaceutical Inc.'s Voxzogo® (vosoritide), which is approved in multiple territories, including the United States, the European Union, Japan, Brazil, and Australia, as well as with other investigational therapies that may receive regulatory approval in the future. We are aware of the following companies pursuing clinical development of product candidates for the treatment of achondroplasia: Ascendis Pharma A/S (TransCon CNP), Tyra Biosciences Inc. (TYRA-300), and Ribomic (RBM-007).

BBP-418 – Limb-Girdle Muscular Dystrophy Type 2I/R9 (LGMD2I/R9)

To our knowledge, there are currently no approved therapies indicated for LGMD2I/R9.

Encaleret – Autosomal Dominant Hypocalcemia Type 1 (ADH1)

There are currently no approved disease-modifying therapies specifically indicated for ADH1, and conventional therapy currently consists of oral calcium and/or activated vitamin D supplementation. Encaleret, if approved, may compete with conventional therapy and other investigational agents evaluated to normalize blood and urine calcium in ADH1.

Intellectual Property

Overview

We strive to protect the proprietary technology that we believe is important to our business through a variety of methods, including seeking and maintaining patents and patent applications intended to cover our product candidates and compositions, their methods of use and processes for their manufacture, our platform technologies and any other aspects of inventions that are commercially important to the development of our business. We seek to obtain domestic and international patent protection and, in addition to filing and prosecuting patent applications in the United States, we may file counterpart patent applications in additional countries where we believe such foreign filing is likely to be beneficial, including Australia, Canada, Europe, China, Japan, and Mexico. We have entered into various license agreements to obtain the rights to use certain patents for the development and commercialization of our product candidates, as discussed further in the section titled, “*Our Material Agreements*.” We also rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection.

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

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

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

As of February 6, 2026, our intellectual property portfolio is composed of over 200 issued patents and over 300 patent applications that we license from academic and research institutions and other third parties or that we own or co-own, including through our subsidiaries. These patents and patent applications generally provide us with the rights to develop our product candidates in the United States and worldwide. Our intellectual property portfolios for each of the programs that we consider to be our core value drivers are further described below.

For our subsidiary, QED Therapeutics, Inc. (“QED”), we license rights from Novartis under two issued U.S. patents, and related pending and issued foreign patents and patent applications in Australia, Canada, China, Europe, Japan and Mexico, as well as in other countries in Asia and in South America, that are directed to compositions of matter of infigratinib. The foreign patents and patent applications, if issued, are expected to expire between 2025 and 2030. The issued U.S. patents are expected to expire between 2028 and 2029, which takes into account patent term adjustments granted by the USPTO as well as a terminal disclaimer of one issued patent to another U.S. patent. Upon the initial approval of infigratinib, QED applied for 1,516 days of patent term extension (“PTE”), for the U.S. patent covering the infigratinib compound; assuming grant of the PTE application, the term of this patent may be extended from August 25, 2029, to October 19, 2033.

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

In addition, QED owns two pending U.S. patent applications, and related pending foreign patent applications in Australia, Canada, China, Europe, Japan and Mexico, as well as in other countries, that are directed to methods of treating skeletal disorders using infigratinib. If any patents issue from these patent applications, such patents would be expected to expire between 2041 and 2044.

For our subsidiary Eidos Therapeutics, Inc., we license rights from the Board of Trustees of the Leland Stanford Junior University, or Stanford, under ten issued U.S. patents, two pending U.S. patent applications, one issued European patent, and one issued Japanese patent with claims directed to composition of matter and methods of use relating to acoramidis. These patents are expected to expire in 2031 or 2033, not including any potential patent term extension. Upon approval of acoramidis, patent term extension applications were timely filed for multiple U.S. patents licensed from Stanford.

In addition, we own eight issued U.S. patents, five pending U.S. patent applications, one Patent Cooperation Treaty (“PCT”) patent application, and over 60 related foreign issued patents and patent applications in various jurisdictions, including Australia, Canada, Europe, China, Japan, and Mexico, with claims directed to salt and solid forms, methods of manufacturing, dosing methods, and/or formulations relating to acoramidis. The issued U.S. and foreign patents are expected to expire in 2038 or 2039. The pending U.S. and foreign patent applications, if issued, are also expected to expire between 2038 and 2044.

For our subsidiary, Calcilytix, Inc., we license rights from Japan Tobacco Company under one issued U.S. patent and two foreign patents in Europe and Japan that are directed to compositions of matter of encalaret. These patents expired in 2024 and 2025. In addition, Calcilytix owns or co-owns one issued U.S. patent, three pending U.S. patent applications, and over thirty related foreign patent applications pending in various jurisdictions, including Australia, Canada, Europe, China, Japan, and Mexico with claims to formulations, dosing methods, and patient selection methods relating to encalaret. The pending U.S. and foreign patent applications, if issued, are expected to expire between 2041 and 2044, not including any potential patent term extension.

For our subsidiary, ML Bio Solutions, Inc. (“ML Bio”), we license rights from the Charlotte-Mecklenburg Hospital Authority d/b/a Atrium Health under eight issued U.S. patents, two pending U.S. patent applications, and over thirty related foreign patent applications pending in various jurisdictions, including Australia, Canada, Europe, China, Japan, and Mexico with claims to methods of treatment, dosing methods, and compositions relating to BBP-418. The issued U.S. patents are expected to expire in 2037 or 2040, not including any potential patent term extension. The pending U.S. and foreign patent applications, if issued, are expected to expire between 2037 and 2041, not including any potential patent term extension. In addition, ML Bio owns one pending U.S. patent applications relating to assays. The pending U.S. patent application, if issued, is expected to expire in 2044.

Our Material Agreements

Acoramidis (Attruby/Beyontra)

License Agreement with Bayer

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, which was received in full in May 2024, and will be eligible to receive up to \$150.0 million in regulatory and sales milestone payments through 2026 (of which a regulatory milestone of \$75.0 million was achieved in February 2025 upon EC approval of acoramidis under the brand name Beyontra and received in April 2025), and additional payments up to \$450.0 million subject to the achievement of certain sales milestones. 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 Eidos may terminate the agreement in the event Bayer ceases exploitation of Beyontra under certain circumstances or challenges the validity or enforceability of Eidos’ patent rights.

In June 2024, BridgeBio Europe B.V. (“BridgeBio B.V.”) entered into a commercial supply agreement with Bayer (“Bayer Commercial Supply Agreement”) with an initial 30-month term ending in December 2026, for which BridgeBio B.V. will manufacture and supply to Bayer the commercial product ordered by Bayer solely for use in the commercialization in the Licensed Territory under the Bayer License Agreement. In March 2025, BridgeBio B.V. and Bayer entered into an agreement (“Bayer API Supply Agreement”) for the manufacture and supply by BridgeBio B.V. to Bayer of API solely for the use in the commercialization in the Licensed Territory. The Bayer API Supply Agreement has an initial term ending in December 2026, which is consistent with the Bayer Commercial Supply Agreement. The Bayer Commercial Supply Agreement and the Bayer API Supply Agreement are collectively referred to as the “Bayer Supply Agreements.” Under the Bayer Supply Agreements, Bayer shall pay to BridgeBio B.V. a per unit price equal to the applicable fully burdened manufacturing cost per unit of the product.

Refer to Footnote 11 of the “Notes to Consolidated Financial Statements” for further details.

License Agreement with Alexion

In September 2019, through our subsidiary Eidos, we entered into a license agreement (the “Eidos-Alexion License Agreement”), with Alexion Pharma International Operations Limited Company, a subsidiary of Alexion Pharmaceuticals, Inc. (together, “Alexion”), to develop and commercialize Beyontra in Japan. Under the terms of the Eidos-Alexion License Agreement, Eidos granted Alexion an exclusive license to certain of our intellectual property rights to develop, manufacture and commercialize Beyontra in Japan. In consideration for the license grant, Eidos received an upfront 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, and in June 2025, Eidos received the \$30.0 million regulatory milestone payment. Under the Eidos-Alexion License Agreement, Eidos is eligible to receive royalties in the low-teens based on net sales 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 Beyontra in Japan, or upon the introduction of generic competition into the market.

Furthermore, in October 2024, Alexion notified Eidos that it intends to initiate the ACT-EARLY clinical trial in Japan under the Eidos-Alexion License Agreement for an upfront payment received by Eidos of \$3.0 million.

Refer to Footnote 11 of the “Notes to Consolidated Financial Statements” for further details.

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

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

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

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

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

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

Refer to Footnote 12 of the “*Notes to Consolidated Financial Statements*” for further details.

Infigratinib

Kyowa Kirin Exclusive License

On February 7, 2024, the Company’s subsidiary, 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, which was received in full in June 2024, and will be eligible to receive development and sales milestone payments up to \$81.4 million. 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.

Refer to Footnote 11 of the “*Notes to Consolidated Financial Statements*” for further details.

License Agreement with Novartis International Pharmaceutical Ltd.

In January 2018, through our subsidiary QED, we entered into a license agreement with Novartis International Pharmaceutical Ltd. (“Novartis”), for certain intellectual property rights, including patents and know-how, related to infigratinib for the treatment of patients with FGFR-driven diseases, including achondroplasia and hypochondroplasia. We refer to this agreement as the Novartis License.

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

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

Under the terms of the Novartis License, we made a one-time payment of \$15.0 million to Novartis and agreed to issue shares of Series A preferred stock of QED valued at approximately \$1.7 million in the aggregate to Novartis. In addition, we are obligated to make contingent milestone payments totaling \$60.0 million upon achievement of certain regulatory milestones. We are also obligated to make contingent milestone payments totaling \$35.0 million upon achievement of certain sales milestones for therapeutic products incorporating infigratinib. QED also agreed to pay Novartis tiered low double-digit royalties on net sales of therapeutic products incorporating infigratinib. Following the FDA’s approval of TRUSELTIQTM in May 2021, we paid a one-time regulatory milestone payment to Novartis of \$20.0 million.

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

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

Corporate

Royalty Interest Purchase and Sale Agreement

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., a beneficial holder of our common equity and a related party, acquired a majority ownership interest in HCRx. Accordingly, HCRx became our related party following KKR & Co. Inc.'s acquisition of HCRx. 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"). 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 on the first \$500.0 million of annual net sales of Licensed Products in the Licensed Territory and (b) an initial hard cap equal to 145% of the Purchase Price. We recognized net cash proceeds of \$297.0 million in June 2025, after deducting debt issuance costs of \$3.0 million.

Refer to Footnote 10 of the "*Notes to Consolidated Financial Statements*" for further details.

2031 Notes

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 of 1933, as amended (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 further described in Footnote 9 of the "*Notes to Consolidated Financial Statements*" 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 in Footnote 9 of the "*Notes to Consolidated Financial Statements*", and pay any fees related thereto.

Subsequent Event - 2033 Notes, net

On January 21, 2026, we issued an aggregate of \$632.5 million principal amount of our 2033 Notes. Refer to Footnote 19 of the "*Notes to Consolidated Financial Statements*" for further details.

Financing Agreement

On January 17, 2024, we entered into a Financing Agreement (the “Financing Agreement”) with certain of our subsidiaries party thereto as guarantors, the lenders party thereto (the “Lenders”) and Blue Owl Capital Corporation, as administrative agent for the Lenders (the “Administrative Agent”), which was amended on February 12, 2024 and June 20, 2024 (the Financing Agreement, as amended by the second amendment, the “Amended Financing Agreement”). Pursuant to the terms and conditions of the Amended Financing Agreement, the Lenders have agreed to extend a senior secured credit facility to us in an aggregate principal amount of up to \$750.0 million comprised of (i) an initial term loan in an aggregate principal amount of \$450.0 million (the “Initial Term Loan”) and (ii) one or more incremental term loans in an aggregate amount not to exceed \$300.0 million (collectively, the “Incremental Term Loan,” and together with the Initial Term Loan, collectively, the “Term Loans”), subject to the satisfaction of certain terms and conditions set forth in the Amended Financing Agreement. The Initial Term Loan was funded on January 17, 2024. Incremental Term Loans are available at the Lenders’ and our mutual consent from time to time after January 17, 2024. On February 28, 2025, the Company 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 Footnote 9 of the “Notes to Consolidated Financial Statements” for further details.

Funding Agreement

On January 17, 2024, we and our subsidiaries entered into a Funding Agreement with LSI Financing 1 Designated Activity Company and CPPIB Credit Europe S.à r.l. together, the (“Purchasers”). Pursuant to the Funding Agreement, the Purchasers agreed to pay to the Company \$500.0 million (net of certain transaction expenses) upon the first FDA approval of acoramidis, subject to certain conditions relating to the FDA approval and other customary conditions (such date of payment, “Funding Date”). In return, we granted the Purchasers the right to receive payments (the “Royalty Interest Payments”) equal to 5% of the global net sales of acoramidis, and may adjust to a maximum rate of 10% (which would take effect in 2027, if certain conditions are met). Each Royalty Interest Payment will become payable to the Purchasers on a quarterly basis after the Funding Date. The Purchasers’ rights to the Royalty Interest Payments and ownership interest in Net Sales will terminate upon the earlier of the 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. In addition, we and our subsidiaries granted the collateral agent, for the benefit of the Purchasers, a security interest in specific assets related to acoramidis. The Funding Agreement will terminate upon customary events. Following the FDA approval of Attriby on November 22, 2024, and in accordance with the Funding Agreement, we received gross cash proceeds of \$500.0 million in December 2024, and recognized debt discount and issuance costs paid in cash of \$27.5 million.

Refer to Footnote 9 of the “Notes to Consolidated Financial Statements” for further details.

Government Regulation

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

U.S. Government Regulation of Drug and Biological Products

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

Our product candidates must be approved by the FDA through either an NDA or a Biologics License Application (“BLA”) process before they may be legally marketed in the United States. The process generally involves the following:

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

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

Preclinical Studies

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

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

Clinical Trials

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

In addition to the submission of an IND to the FDA before initiation of a clinical trial in the United States, certain human clinical trials involving recombinant or synthetic nucleic acid molecules are subject to oversight by institutional biosafety committees ("IBC") as set forth in the National Institute of Health ("NIH") Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules ("NIH Guidelines"). Under the NIH Guidelines, recombinant and synthetic nucleic acids are defined as (i) molecules that are constructed by joining nucleic acid molecules and that can replicate in a living cell (i.e., recombinant nucleic acids); (ii) nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules (i.e., synthetic nucleic acids); or (iii) molecules that result from the replication of those described in (i) or (ii). Specifically, under the NIH Guidelines, supervision of human gene transfer trials includes evaluation and assessment by an IBC, a local institutional committee that reviews and oversees research utilizing recombinant or synthetic nucleic acid molecules at that institution. The IBC assesses the safety of the research and identifies any potential risk to public health or the environment, and such review may result in some delay before initiation of a clinical trial. While the NIH Guidelines are not mandatory unless the research in question 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.

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

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

- Phase 1 clinical trials generally involve a small number of healthy volunteers or disease-affected patients who are initially exposed to a single dose and then multiple doses of the product candidate. The primary purpose of these clinical trials is to assess the metabolism, pharmacologic action, side effect tolerability and safety of the product candidate.

- Phase 2 clinical trials involve studies in disease-affected patients to evaluate proof of concept and/or determine the dose required to produce the desired benefits. At the same time, safety and further PK and PD information is collected, possible adverse effects and safety risks are identified, and a preliminary evaluation of efficacy is conducted.
- Phase 3 clinical trials generally involve a large number of patients at multiple sites and are designed to provide the data necessary to demonstrate the effectiveness of the product for its intended use, its safety in use and to establish the overall benefit/risk relationship of the product and provide an adequate basis for product labeling.

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

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

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

FDA Review Process

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

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

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

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

Orphan Drug Designation and Exclusivity

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

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

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication for seven years from the date of such approval, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity by means of greater effectiveness, greater safety or providing a major contribution to patient care or in instances of drug supply issues. Competitors, however, may receive approval of either a different product for the same indication or the same product for a different indication but that could be used off-label in the orphan indication. Orphan drug exclusivity also could block the approval of our products for seven years if a competitor obtains approval before we do for the same product, as defined by the FDA, for the same indication we are seeking approval, or if our product is determined to be contained within the scope of the competitor's product for the same indication or disease. In February 2026, Congress passed legislation codifying 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. If we pursue marketing approval for an indication broader than the orphan drug designation we have received, we may not be entitled to orphan drug exclusivity. Orphan drug status in the European Union has similar, but not identical, requirements and benefits.

Rare Pediatric Disease Designation and PRVs

Under the FDCA, as amended, the FDA incentivizes the development of drugs and biologics that meet the definition of a “rare pediatric disease,” defined to mean a serious or life-threatening disease in which the serious or life-threatening manifestations primarily affect individuals aged from birth to 18 years and the disease affects fewer than 200,000 individuals in the United States or affects more than 200,000 in the United States and for which there is no reasonable expectation that the cost of developing and making in the United States a drug for such disease or condition will be received from sales in the United States of such drug. The sponsor of a product candidate for a rare pediatric disease may be eligible for a voucher that can be used to obtain a priority review for a subsequent human drug or biologic application after the date of approval of the rare pediatric disease drug product, referred to as a PRV. A sponsor may request rare pediatric disease designation from the FDA prior to the submission of its NDA or BLA. A rare pediatric disease designation does not guarantee that a sponsor will receive a PRV upon approval of its NDA or BLA. If a PRV is received, it may be sold or transferred an unlimited number of times.

On February 3, 2026, Congress passed the Consolidated Appropriations Act of 2026, which reauthorized the rare pediatric disease priority review voucher program through September 30, 2029.

Expedited Development and Review Programs

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

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

Under the Food and Drug Omnibus Reform Act of 2022 (“FDORA”), a platform technology incorporated within or utilized by a drug or biologic is eligible for designation as a designated platform technology if (1) the platform technology is incorporated in, or utilized by, a drug approved under an NDA or BLA; (2) preliminary evidence submitted by the sponsor of the approved or licensed drug, or a sponsor that has been granted a right of reference to data submitted in the application for such drug, demonstrates that the platform technology has the potential to be incorporated in, or utilized by, more than one drug without an adverse effect on quality, manufacturing, or safety; and (3) data or information submitted by the applicable person indicates that incorporation or utilization of the platform technology has a reasonable likelihood to bring significant efficiencies to the drug development or manufacturing process and to the review process. A sponsor may request the FDA to designate a platform technology as a designated platform technology concurrently with, or at any time after, submission of an IND application for a drug that incorporates or utilizes the platform technology that is the subject of the request. If so designated, the FDA may expedite the development and review of any subsequent original NDA or BLA for a drug that uses or incorporates the platform technology. Designated platform technology status does not ensure that a drug will be developed more quickly or receive a faster FDA review process or ultimate FDA approval. In addition, the FDA may revoke a designation if the FDA determines that a designated platform technology no longer meets the criteria for such designation.

A product may also be eligible for accelerated approval if it is designed to treat a serious or life-threatening disease or condition and generally provides a meaningful advantage over available therapies upon a determination that the product has an effect on either a surrogate that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality (“IMM”), that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity, or prevalence of the disease or condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require that a sponsor of a drug or biologic receiving accelerated approval perform adequate and well-controlled post-marketing confirmatory clinical trials with due diligence and, under FDORA, the FDA is permitted to require, as appropriate, that such confirmatory studies be underway prior to approval or within a specified time period after accelerated approval is granted. In addition, the FDA currently requires, unless otherwise informed by the agency, pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. Under FDORA, the FDA has increased authority for expedited procedures to withdraw approval of a drug or indication approved under accelerated approval if, for example, the confirmatory trial fails to verify the predicted clinical benefit of the product.

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

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

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

Pediatric Information and Pediatric Exclusivity

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

A drug or biologic product can also obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods for all formulations, dosage forms, and indications of the active moiety and, for drugs, patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection and, for drugs, patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued “Written Request” for such a study provided that at the time pediatric exclusivity is granted there is not less than nine months of term remaining.

Post-Marketing Requirements

Following approval of a new product, the manufacturer and the approved product are subject to continuing regulation by the FDA, including, among other things, monitoring and record-keeping activities, reporting of adverse experiences to applicable regulatory authorities, complying with promotion and advertising requirements, which include, among other things, standards for direct-to-consumer advertising, requirements for promotional activities on the internet, restrictions on promoting products for unapproved uses or in patient populations that are not described in the product’s approved label (known as “off-label use”) and limitations on industry-sponsored scientific and educational activities. Although physicians may prescribe legally available products for off-label uses, manufacturers may not market or promote such off-label uses. The FDA does not regulate the behavior of physicians in their choice of treatment, but the FDA regulations do impose stringent restrictions on manufacturers’ communications regarding off-label uses. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including investigation by federal and state authorities. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use or first publication, and may be required to be reviewed in advance in certain circumstances such as for products that receive accelerated approval.

Further, if there are any modifications to the drug or biologic, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new NDA/BLA or NDA/BLA supplement, which may require the development of additional data or preclinical studies and clinical trials. Such regulatory reviews can result in denial or modification of the planned changes, or requirements to conduct additional tests or evaluations that can substantially delay or increase the cost of the planned changes.

The FDA may also place other conditions on approvals including the requirement for a Risk Evaluation and Mitigation Strategy, or REMS, to assure the safe use of the product. If the FDA concludes a REMS is needed, the sponsor of the NDA or BLA must submit a proposed REMS. The FDA will not approve the NDA or BLA without an approved REMS, if required. A REMS could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory requirements, if problems occur following initial marketing or if the FDA determines that the product is no longer safe or effective.

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

Any distribution of prescription drugs and biologics and pharmaceutical samples must comply with the U.S. Prescription Drug Marketing Act (“PDMA”) and the PHSA. In addition, the Drug Supply Chain Security Act, or DSCSA, was enacted in 2013 with the aim of building an electronic system to identify and trace certain prescription drugs and biologics distributed in the United States. The stabilization period has ended for trading partners to build and validate interoperable systems and processes to meet certain requirements of the DSCSA. Currently, trading partners without validated interoperable tracing systems must obtain an exemption from FDA. The DSCSA’s requirements also include the quarantine and prompt investigation of a suspect product, to determine if it is illegitimate, notifying trading partners and the FDA of any illegitimate product, and compliance with product tracking and tracing requirements.

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

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

From time to time, legislation is drafted, introduced, passed in Congress and signed into law that could significantly change the statutory provisions governing the approval, manufacturing, and marketing of products regulated by the FDA. In addition to new legislation, FDA regulations, guidance, and policies are often revised or reinterpreted by the agency in ways that may significantly affect the manner in which pharmaceutical products are regulated and marketed.

Regulation of Companion Diagnostics

We believe that the success of certain of our product candidates may depend, in part, on the development and commercialization of a companion diagnostic. Companion diagnostics identify patients who are most likely to benefit from a particular therapeutic product; identify patients likely to be at increased risk for serious side effects as a result of treatment with a particular therapeutic product; or monitor response to treatment with a particular therapeutic product for the purpose of adjusting treatment to achieve improved safety or effectiveness. Companion diagnostics are regulated as medical devices by the FDA. In the United States, the FDCA and its implementing regulations, and other federal and state statutes and regulations govern, among other things, medical device design and development, preclinical and clinical testing, premarket clearance or approval, registration and listing, manufacturing, labeling, storage, advertising and promotion, sales and distribution, export and import, and post-market surveillance. Unless an exemption or FDA exercise of enforcement discretion applies, diagnostic tests generally require marketing clearance or approval from the FDA prior to commercialization. The primary types of FDA marketing authorization applicable to a medical device are premarket notification, also called 510(k) clearance, approval of a premarket approval (“PMA”) application, or grant of a de novo request for classification.

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

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

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

To date, the FDA has required premarket approval for nearly all companion diagnostics for cancer therapies. In January 2024, the FDA announced its intention to initiate the reclassification process for most *in vitro* diagnostics, including companion diagnostics. Further, the FDA indicated that in addition to the reclassification process, the FDA will continue taking a risk-based approach in the initial classification of individual *in vitro* diagnostics to determine whether a new test may be classified into class II through the de novo classification process. In so doing, the FDA indicated that it may regulate most future companion diagnostics as class II devices.

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

Biosimilars and Exclusivity

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

A reference biological product is granted four and twelve year exclusivity periods from the time of first licensure of the product. The FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product, and the FDA will not approve an application for a biosimilar or interchangeable product based on the reference biological product until twelve years after the date of first licensure of the reference product. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity, and potency of the other company's product. "First licensure" typically means the initial date the particular product at issue was licensed in the United States. Date of first licensure does not include the date of licensure of (and a new period of exclusivity is not available for) a biological product if the licensure is for a supplement for the biological product or for a subsequent application by the same sponsor or manufacturer of the biological product (or licensor, predecessor in interest, or other related entity) for a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device or strength, or for a modification to the structure of the biological product that does not result in a change in safety, purity, or potency. Therefore, one must determine whether a new product includes a modification to the structure of a previously licensed product that results in a change in safety, purity, or potency to assess whether the licensure of the new product is a first licensure that triggers its own period of exclusivity. Whether a subsequent application, if approved, warrants exclusivity as the "first licensure" of a biological product is determined on a case-by-case basis with data submitted by the sponsor. The law is complex and is still being interpreted and implemented by the FDA.

Other Regulatory Matters

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

Healthcare providers, physicians, and third party payors will play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. Our current and future arrangements with healthcare providers and physicians and any future arrangements with third party payers, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any drugs for which we obtain marketing approval. In the United States, these laws include: the federal Anti-Kickback Statute, the False Claims Act, and the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

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

Additionally, the federal Physician Payments Sunshine Act (the “Sunshine Act”), within the ACA, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program (with certain exceptions) report annually to CMS information related to certain payments or other transfers of value made or distributed to physicians, certain other licensed health care practitioners and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, physicians, certain other healthcare professionals, and teaching hospitals and to report annually certain ownership and investment interests held by physicians, certain other healthcare professionals, and their immediate family members.

We may also be subject to federal price reporting laws, which require manufacturers to calculate and report complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement and/or discounts on approved products. Further, we may face obligations under federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

Similar federal, state and foreign fraud and abuse laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services. Such laws are generally broad and are enforced by various state agencies and private actions. Many U.S. states have adopted laws similar to the federal Anti-Kickback Statute and False Claims Act, and may apply to our business practices, including, but not limited to, research, distribution, sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental payors, including private insurers. In addition, some states have passed laws that require us to comply with the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and/or the Pharmaceutical Research and Manufacturers of America’s Code on Interactions with Healthcare Professionals. Additionally, we are subject to state and foreign equivalents of each of the healthcare laws and regulations described above, some of which may be broader in scope and may apply regardless of payor, in addition to items and services reimbursed under Medicaid and other state programs. Some state laws require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant federal government compliance guidance, and require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures. Several states also impose other marketing restrictions or require pharmaceutical companies to make marketing or price disclosures to the state and require the registration of pharmaceutical sales representatives. State and foreign laws, including, for example, the European Union General Data Protection Regulation, which became effective May 2018 also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. There are ambiguities as to what is required to comply with these state requirements and if we fail to comply with an applicable state law requirement we could be subject to penalties. Finally, there are state and foreign laws governing the privacy and security of health information, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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

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

In the United States, to help patients afford our approved product, we may utilize programs to assist them, including patient assistance programs and co-pay coupon programs for eligible patients. PAPs are regulated by and subject to guidance from CMS OIG. In addition, at least one insurer has directed its network pharmacies to no longer accept co-pay coupons for certain specialty drugs the insurer identified. Our co-pay coupon programs could become the target of similar insurer actions. In addition, in November 2013, the CMS issued guidance to the issuers of qualified health plans sold through the ACA's marketplaces encouraging such plans to reject patient cost-sharing support from third parties and indicating that the CMS intends to monitor the provision of such support and may take regulatory action to limit it in the future. The CMS subsequently issued a rule requiring individual market qualified health plans to accept third-party premium and cost-sharing payments from certain government-related entities. In September 2014, the OIG of the HHS issued a Special Advisory Bulletin warning manufacturers that they may be subject to sanctions under the federal anti-kickback statute and/or civil monetary penalty laws if they do not take appropriate steps to exclude Part D beneficiaries from using co-pay coupons. Accordingly, companies exclude these Part D beneficiaries from using co-pay coupons.

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

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

The civil monetary penalties statute imposes penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

U.S. Data Collection

We may be subject to data privacy and security regulations by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (“HITECH”) and their implementing regulations, including the Final Omnibus Rule published in January 2013, which imposes requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses, as well as their respective business associates, independent contractors, or agents of health covered entities, that perform services for them that involve the creation, maintenance, receipt, use, or disclosure of, individually identifiable health information relating to the privacy, security, and transmission of individual identifiable health information. Among other things, HITECH makes HIPAA’s security standards directly applicable to business associates, defined as independent contractors or agents of covered entities, which include certain health care providers, health plans, and healthcare clearinghouses, that create, receive or obtain protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys’ fees and costs associated with pursuing federal civil actions. In addition, there may be additional federal, state, and non-U.S. laws which govern the privacy and security of health and other personal information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and criminal penalties.

States are also active in creating specific rules relating to the processing of personal information. The California Consumer Privacy Act (“CCPA”) imposes requirements on businesses that process the personal information of California residents, including to provide notice to data subjects regarding the information collected about them, and offering data subjects the right to request access, correction, deletion and limit the sale and sharing of such personal information. The CCPA may result in significant penalties for companies that violate its requirements, and includes a private right of action for certain data breaches.

Similar laws have been passed and proposed in numerous other states. Like the CCPA, these laws create obligations related to the processing of personal information, as well as special obligations for the processing of “sensitive” data (which includes health data in some cases). The existence of comprehensive privacy laws in dozens of states around the country make our compliance obligations more complex and costly and may increase the likelihood that we may be subject to enforcement actions or otherwise incur liability for noncompliance.

Certain states have also specifically regulated consumer health information. For example, Washington’s My Health My Data Act, which went into effect on March 31, 2024, regulates the collection and sharing of consumer health information, and the law also has a private right of action, which further increases the relevant compliance risk. Connecticut and Nevada have also passed similar laws regulating consumer health data. In addition, other states have proposed and/or passed legislation that regulates the privacy and/or security of certain specific types of information. For example, a small number of states have passed laws that regulate biometric data specifically. These various privacy and security laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products.

All of these evolving compliance and operational requirements impose significant costs, such as costs related to organizational changes, implementing additional protection technologies, training employees and engaging consultants and legal advisors, which are likely to increase over time. Such requirements may require us to modify our data processing practices and policies, utilize management’s time and/or divert resources from other initiatives and projects. Any failure or perceived failure by us to comply with any applicable federal, state or foreign laws and regulations relating to data privacy and security could result in damage to our reputation, as well as proceedings or litigation by governmental agencies or other third parties, including class action privacy litigation in certain jurisdictions, which would subject us to significant fines, sanctions, awards, injunctions, penalties or judgments. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Regulators and legislators in the U.S. are increasingly scrutinizing and restricting certain personal data transfers and transactions involving foreign countries. For example, the Department of Justice's January 8, 2025, Rule on Preventing Access to U.S. Bulk Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons, prohibits transfers of data, including health data, genetic data, and biospecimens, to countries of concern, including China. The regulations also restrict certain investment agreements, employment agreements and vendor agreements involving such data and countries of concern, absent specified cybersecurity controls. Actual or alleged violations of these regulations may be punishable by criminal and/or civil sanctions, and may result in exclusion from participation in federal and state programs. and could restrict our ability to use certain vendors, sites, investigators, or service providers in global clinical trials.

Current and Future Legislation

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

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

- made several changes to the Medicaid Drug Rebate Program, including increasing pharmaceutical manufacturers' rebate liability by raising the minimum basic Medicaid rebate on most branded prescription drugs and adding a new rebate calculation for "line extensions" (i.e., new formulations, such as extended release formulations) of solid oral dosage forms of branded products.
- imposed a requirement on manufacturers of branded drugs to provide a 70% point-of-sale discount off the negotiated price of branded drugs dispensed to Medicare Part D beneficiaries in the coverage gap discount program as a condition for a manufacturer's outpatient drugs being covered under Medicare Part D.
- extended a manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations.
- expanded the entities eligible for discounts under the 340B Drug Discount Program.
- imposed an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs.
- established a Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research. The research conducted by the Patient-Centered Outcomes Research Institute may affect the market for certain pharmaceutical products. The ACA established the Center for Medicare and Medicaid Innovation within CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

In addition, other legislative and regulatory changes have also been proposed and adopted in the United States since the ACA was enacted:

- On August 2, 2011, the U.S. Budget Control Act of 2011, among other things, included aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2031.
- On January 2, 2013, the U.S. American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.
- On April 13, 2017, CMS published a final rule that gives states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces.
- On May 23, 2019, CMS published a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020.

- On March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug’s average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. Due to the Statutory Pay-As-You-Go Act of 2010, estimated budget deficit increases resulting from the American Rescue Plan Act of 2021, and subsequent legislation, Medicare payments to providers will be further reduced starting in 2025 absent further legislation. These laws and regulations may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.
- In August 2022, the Inflation Reduction Act of 2022 (“IRA”) was signed into law. The IRA includes several provisions that will impact our business to varying degrees, including provisions that reduce the out-of-pocket cap for Medicare Part D beneficiaries to \$2,000 starting in 2025; impose new manufacturer financial liability on certain drugs in Medicare Part D, allow the U.S. government to negotiate Medicare Part B and Part D price caps for certain high-cost drugs and biologics without generic or biosimilar competition, require companies to pay rebates to Medicare for certain drug prices that increase faster than inflation, and delay the rebate rule that would limit the fees that pharmacy benefit managers can charge. Further under the IRA, and subsequent revisions under the One Big Beautiful Bill Act of 2025, orphan drugs are exempted from the Medicare drug price negotiation program. Effective for the 2028 initial price applicability year, all orphan drugs, regardless of the number of orphan drug designations or indications, are exempt from the Medicare drug price negotiation program. The implementation of the IRA is currently subject to ongoing litigation challenging the constitutionality of the IRA’s Medicare drug price negotiation program. Although the effects of the IRA on our business and the healthcare industry in general are not yet known, we are taking into consideration the potential impact of the IRA on our development and commercialization activities.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to drug pricing practices. Specifically, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, and review the relationship between pricing and manufacturer patient programs. On April 15, 2025, the current administration published Executive Order 14273, “Lowering Drug Prices by Once Again Putting Americans First,” which generally directs the federal government to take measures to reduce drug prices, including eliminating the so-called “pill penalty” under the IRA that creates a distinction between small molecule and large molecule products for purposes of determining when a drug may be eligible for drug price negotiation. On May 12, 2025, the current administration published Executive Order 14297, “Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients” which generally, among other things, directs the federal government to establish and communicate most-favored-nation (“MFN”) price targets to pharmaceutical manufacturers to bring prices for American patients in line with comparably developed nations. Further, the Executive Order directs the federal government to support regulatory paths to allow direct-to-patient sales for companies that meet these targets. It also states that the Administration will take additional aggressive action (for example, examining whether marketing approvals should be modified or rescinded or opening the door for individual drug importation waivers) should manufacturers fail to offer American consumers the MFN lowest price. It also directs the Secretary of Commerce and the U.S. Trade Representative to “take all necessary and appropriate action to ensure foreign countries are not engaged in any act, policy, or practice that may be unreasonable or discriminatory or that may impair United States national security . . . including by suppressing the price of pharmaceutical products below fair market value in foreign countries.” Notably, a similar “Most-Favored-Nation” pricing rule enacted under the first Trump administration was subject to an injunction resulting from judicial challenges to the rule, which was formally rescinded by the former Biden Administration in August 2021.

On November 6, 2025, the Centers for Medicare & Medicaid Services (“CMS”) announced a new drug payment model designed to make MFN-level prices available to state Medicaid programs via manufacturer rebates. Referred to as the “GENErating cost Reductions fOr U.S. Medicaid Model” (“GENEROUS”), the initiative is designed to run from 2026 through 2030 and is voluntary for both manufacturers and state Medicaid programs. Under the model, participating states will be able to access MFN-level prices for participating manufacturers’ drugs through CMS-negotiated supplemental rebates tied to an MFN net price benchmark.

On December 19, 2025, the Centers for Medicare & Medicaid Services (“CMS”) proposed a mandatory Center for Medicare and Medicaid Innovation (“CMMI”) drug payment model to test whether alternative methods for calculating Medicare rebates, based on international pricing metrics rather than inflation-based metrics, reduce costs for Medicare fee-for-service (“FFS”) beneficiaries and the Medicare program while preserving quality of care. The Guarding U.S. Medicare Against Rising Drug Costs (“GUARD”) Model, would test an alternative approach to calculating rebates for certain Medicare Part D products using international pricing benchmarks. The GUARD Model would begin on January 1, 2027, and run through December 31, 2033. Further, on December 19, 2025, CMS proposed the Global Benchmark for Efficient Drug Pricing Model (“GLOBE”) for Medicare Part B, would require manufacturers of specified single source drugs and sole source biologics to pay incremental rebates based on international benchmark prices, with participation triggered for products meeting CMS’s spending and eligibility criteria. As proposed, GLOBE would begin a five-year performance period on October 1, 2026.

A number of these and other proposed measures may change or be repealed by the current administration and it is possible that new legislation may be introduced. We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. Federal Government will pay for healthcare drugs and services, which could result in reduced demand for our drug candidates or additional pricing pressures.

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Individual states in the United States have also become 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 drug access and marketing cost disclosure and transparency measures, and designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, financial condition, results of operations and prospects. Certain states are also pursuing cost containment efforts through Prescription Drug Affordability Boards (“PDABs”) and similar entities. While many PDABs have been granted authority to promote drug price transparency and reporting, some states have granted PDABs more expansive authority, including to set Upper Payment Limits (UPLs) on select, high price drugs. The adoption and implementation of UPLs may put downward pressure on drug prices and impact our company’s future net product revenues. In addition, regional healthcare 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 healthcare programs. This could reduce the ultimate demand for our drugs or put pressure on our drug pricing, which could negatively affect our business, financial condition, results of operations and prospects.

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

Packaging and Distribution in the United States

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

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

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

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

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

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

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

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

U.S. Patent Term Extension and Marketing Exclusivity

Depending upon the timing, duration and specifics of FDA approval of a drug or biologic, some U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Act. The Hatch-Waxman Act permits extension of a patent term of up to five years beyond the normal expiration date of the patent as compensation for patent term lost during the FDA regulatory review process. Patent term extension, however, cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension. An NDA or BLA applicant may apply for extension of patent term for its currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant NDA or BLA.

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

European Union Drug Development

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

Similar to the United States, the various phases of preclinical and clinical research in the European Union are subject to significant regulatory controls.

In April 2014, the EU adopted the new Clinical Trials Regulation (EU) No 536/2014 (“EU Clinical Trials Regulation”), which replaced the Clinical Trials Directive 2001/20/EC on January 31, 2022. The transitory provisions of the new EU Clinical Trials Regulation provided that, by January 31, 2025, all ongoing clinical trials must have transitioned to the new EU Clinical Trials Regulation.

The EU Clinical Trials Regulation overhauled the previous system of approvals for clinical trials in the EU. Specifically, the EU Clinical Trials Regulation, which is directly applicable in all Member States (meaning no national implementing legislation in each EU Member State is required), aims at simplifying and streamlining the approval of clinical trials in the EU. For instance, it provides for a streamlined application procedure via a single entry point (through the Clinical Trials Information Systems) and strictly defined deadlines for the assessment of clinical trial applications. Compliance with the more complex procedural requirements of the EU Clinical Trials Regulation could result in some delay in the initiation of clinical trials.

European Union Drug Review and Approval

In the EU, medicinal products can only be commercialized after obtaining a marketing authorization (“MA”). There are different routes to obtain an MA in the EU.

- The centralized MA is issued by the European Commission through the centralized procedure, based on the opinion of the Committee for Medicinal Products for Human Use (“CHMP”) of the EMA, and is valid throughout the entire territory of the EU, and in the additional countries of the European Economic Area (Iceland, Liechtenstein and Norway). The centralized procedure is mandatory for certain types of products, including medicines produced by biotechnological processes, products designated as orphan medicinal products, advanced-therapy medicinal products (gene-therapy, somatic cell-therapy or tissue-engineered medicines) and medicinal products containing a new active substance indicated for the treatment of HIV, AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and other immune dysfunctions and viral diseases. The centralized procedure is optional for products containing a new active substance not yet authorized in the EU, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU.
- Under the centralized procedure, the CHMP is responsible for conducting the initial assessment of a product and for several post-authorization and maintenance activities, such as the assessment of modifications or extensions to an existing MA. Under the centralized procedure in the EU, the maximum timeframe for the evaluation of a marketing authorization application (“MAA”) by the EMA is 210 days, excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP. Clock stops may extend the timeframe of evaluation of an MAA considerably beyond 210 days. Where the CHMP gives a positive opinion, it provides the opinion together with supporting documentation to the European Commission, which makes the final decision to grant an MA, which is issued within 67 days of receipt of the EMA’s recommendation. Accelerated assessment may be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of major public health interest, particularly from the point of view of therapeutic innovation. If the CHMP accepts such request, the time limit of 210 days will be reduced to 150 days, excluding clock stops, but it is possible that the CHMP may revert to the standard time limit for the centralized procedure if it determines that the application is no longer appropriate to conduct an accelerated assessment.

- National MAs, which are issued by the competent authorities of the Member States of the EU and only cover their respective territory, are available for products not falling within the mandatory scope of the centralized procedure. Where a product has already been authorized for marketing in a Member State of the EU, this national MA can be recognized in another Member State through the mutual recognition procedure. If the product has not received a national MA in any Member State at the time of application, it can be approved simultaneously in various Member States through the decentralized procedure. Under the decentralized procedure an identical dossier is submitted to the competent authorities of each of the Member States in which the MA is sought, one of which is selected by the applicant as the Reference Member State (“RMS”). The competent authority of the RMS prepares a draft assessment report, a draft summary of the product characteristics (“SmPC”), and a draft of the labeling and package leaflet, which are sent to the other Member States (referred to as the Concerned Member States) for their approval. If the Concerned Member States raise no objections, based on a potential serious risk to public health, to the assessment, SmPC, labeling, or packaging proposed by the RMS, the product is subsequently granted a national MA in all the Member States (i.e., in the RMS and the Concerned Member States).

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

European Union New Chemical Entity Exclusivity

In the EU, innovative medicinal products approved on the basis of a complete and independent data package qualify for eight years of data exclusivity upon marketing authorization and an additional two years of market exclusivity. The data exclusivity, if granted, prevents generic or biosimilar applicants from referencing the innovator’s preclinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar MA in the EU, during a period of eight years from the date on which the reference product was first authorized in the EU. During the additional two-year period of market exclusivity, a generic or biosimilar MAA can be submitted, and the innovator’s data may be referenced, but no generic or biosimilar product can be placed on the EU market until the expiration of the market exclusivity. The overall 10-year period will be extended to a maximum of 11 years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are determined to bring a significant clinical benefit in comparison with currently approved therapies. There is no guarantee that a product will be considered by the EMA to be an innovative medicinal product, and products may not qualify for data exclusivity. Even if a product is considered to be an innovative medicinal product so that the innovator gains the prescribed period of data exclusivity, however, another company could nevertheless also market another version of the product if such company obtained an MA based on an MAA with a complete and independent data package of pharmaceutical tests, preclinical tests and clinical trials.

European Union Orphan Designation and Exclusivity

In the EU, the European Commission (upon recommendation of the EMA’s Committee for Orphan Medicinal Products) may grant an orphan designation in respect of a product if its sponsor can establish that: (1) the product is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; (2) either (i) such condition affects no more than five in 10,000 persons in the EU when the application is made, or (ii) it is unlikely that the product, without the benefits derived from orphan status, would generate sufficient return in the EU to justify the necessary investment in its development; and (3) there must be no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the EU, or, if such a method exists, the product would be of significant benefit to those affected by that condition.

In the EU, orphan designation entitles a party to financial incentives such as reduction of fees or fee waivers and ten years of market exclusivity is granted following grant of a marketing authorization. During this market exclusivity period, neither the EMA nor the European Commission nor any of the competent authorities in the EU Members States can accept an application or grant a marketing authorization for a “similar medicinal product” for the same therapeutic indication. A “similar medicinal product” is defined as a medicinal product containing a similar active substance or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication. This period may be reduced to six years if the orphan designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity. Market exclusivity may also be revoked in very select cases, such as if (i) it is established that a similar medicinal product is safer, more effective or otherwise clinically superior to the authorized product; (ii) the marketing authorization holder for the authorized orphan product consents to such revocation; or (iii) the marketing authorization holder for the authorized orphan product cannot supply enough orphan medicinal product. Orphan designation must be requested before submitting an application for marketing authorization. Orphan designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. Furthermore, when applying for a marketing authorization for an orphan medicinal product, the applicant is required to submit a report justifying the maintenance of the orphan designation, which the EMA will assess in parallel with assessing the application for marketing authorization. There is a risk that any orphan designation granted for our products will not be maintained upon granting of a marketing authorization and that our products will therefore not receive the market exclusivity granted to orphan medicinal products.

European Pediatric Investigation Plan

In the EU, MAAs for new medicinal products have to include the results of studies conducted in the pediatric population, in compliance with a pediatric investigation plan (“PIP”) agreed with the EMA’s Pediatric Committee (“PDCO”) unless the EMA has granted a product-specific waiver, a class waiver, or a deferral for one or more of the measures included in the PIP. This requirement also applies when a company wants to add a new indication, pharmaceutical form or route of administration for a medicine that is already authorized. The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the drug for which marketing authorization is being sought. The PDCO can grant a deferral of the obligation to implement some or all of the measures of the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults. Further, the obligation to provide pediatric clinical trial data can be waived by the PDCO when this data is not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. If an MA is obtained and trial results are included in the product information, even when negative, the product may be eligible for a six month-extension of any existing supplementary protection certificate extension. In the case of orphan medicinal products, a two year extension of the orphan market exclusivity may be available. This pediatric reward is subject to specific conditions and is not automatically available when data in compliance with the PIP are developed and submitted.

Regulatory Requirements After a Marketing Authorization has been Obtained

If authorization for a medicinal product in the EU is obtained, the holder of the MA is required to comply with a range of requirements applicable to the manufacturing, marketing, promotion, and sale of medicinal products. These include:

- Compliance with the EU’s stringent pharmacovigilance or safety reporting rules must be ensured. These rules can impose post-authorization studies and additional monitoring obligations.
- The manufacturing of authorized medicinal products, for which a separate manufacturer’s license is mandatory, must also be conducted in strict compliance with the applicable EU laws, regulations and guidance, including Directive 2001/83/EC, Directive 2017/1572, Regulation (EC) No 726/2004 and the European Commission Guidelines for Good Manufacturing Practice. These requirements include compliance with EU cGMP standards when manufacturing medicinal products and active pharmaceutical ingredients, including the manufacture of active pharmaceutical ingredients outside of the EU with the intention to import the active pharmaceutical ingredients into the EU.

- We are a party to and may from time to time enter into additional agreements with commercial partners to supply our partner with API and bulk or finished drug product for their commercial sales of our product in a licensed territory. In connection with this supply of product, we must comply with any applicable regulations for the purchase, distribution, storage, exporting and sale of API and medicinal products in the licensed territory. For example in June 2024, our wholly-owned subsidiary BridgeBio Europe B.V. (“BridgeBio BV”), which is domiciled in the Netherlands, entered into the Bayer Supply Agreement for which BridgeBio BV has agreed to manufacture and supply to Bayer our commercial product Beyontra to sell in the EU. To support our obligations under the Bayer Supply Agreement, we have also entered into a commercial manufacturing agreement with a third-party CMO in Germany to manufacture and package the final drug product Beyontra. We are required to obtain the necessary registration or authorization from the relevant EU authority in order to import the API into the EU, deliver it to our German CMO, and have the final drug product for Beyontra supplied to Bayer, as well as to export drug product or finished product. Under applicable EU and Dutch regulations, this requires BridgeBio BV to obtain a registration for activities related to API (“API Registration”) and an authorization for wholesale distribution of medicinal products (“WDA”). In order to receive the API Registration and the WDA, we must pass an inspection.
- Much like the Anti-Kickback Statute prohibition in the United States, the provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the European Union. The provision of benefits or advantages to induce or reward improper performance generally is governed by the national anti-bribery laws of the European Union Member States, and the Bribery Act 2010 in the UK. Infringement of these laws could result in substantial fines and imprisonment. EU Directive 2001/83/EC, which is the EU Directive governing medicinal products for human use, further provides that, where medicinal products are being promoted to persons qualified to prescribe or supply them, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons unless they are inexpensive and relevant to the practice of medicine or pharmacy. This provision has been transposed into the Human Medicines Regulations 2012 and so remains applicable in the UK despite its departure from the EU. Payments made to physicians in certain EU Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician’s employer, his or her competent professional organization and/or the regulatory authorities of the individual EU Member States. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the EU Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

The aforementioned EU rules are generally applicable in the European Economic Area (“EEA”) which consists of the EU Member States, plus Norway, Liechtenstein, and Iceland.

Reform of the Regulatory Framework in the EU

The European Commission introduced legislative proposals in April 2023 that, if implemented, will replace the current regulatory framework in the EU for all medicines (including those for rare diseases and for children). In April 2024, the European Parliament adopted its position on the legislative proposals and, in June 2025, the Council of the European Union adopted its position. A common position on the text has been agreed upon on December 11, 2025, in the context of subsequent inter-institutional trilogue negotiations. The proposed revisions remain to be adopted, and are not expected to become applicable before 2028.

Brexit and the Regulatory Framework in the United Kingdom (UK)

Following the end of the Brexit transition period on January 1, 2021 and the implementation of the Windsor Framework on January 1, 2025, the UK is not generally subject to EU laws in respect of medicines. The EU and the UK have concluded a trade and cooperation agreement (a “TCA”), which was provisionally applicable since January 1, 2021 and has been formally applicable since May 1, 2021. The TCA includes specific provisions concerning pharmaceuticals, which include the mutual recognition of GMP, inspections of manufacturing facilities for medicinal products and GMP documents issued, but does not provide for wholesale mutual recognition of UK and EU pharmaceutical regulations.

The EU laws that have been transposed into UK law through secondary legislation remain applicable in the UK as “retained EU law.” However, new EU legislation, such as the EU Clinical Trials Regulation, is not applicable in the UK. Under the Medicines and Medical Devices Act 2021, the Secretary of State or an ‘appropriate authority’ have delegated powers to amend or supplement existing regulations in the area of medicinal products and medical devices. This allows new rules to be introduced in the future by way of secondary legislation, which aims to allow flexibility in addressing regulatory gaps and future changes in the fields of human medicines, clinical trials and medical devices. The UK regulatory framework in relation to clinical trials is governed by the Medicines for Human Use (Clinical Trials) Regulations 2004, as amended, which is derived from the Clinical Trials Directive, as implemented into UK national law through secondary legislation. In April 2025, the UK introduced the Medicines for Human Use (Clinical Trials) (Amendment) Regulations. These changes, which will take full effect from April 2026, aim to create a streamlined, risk-proportionate system that accelerates approvals while maintaining robust safety standards.

As of January 1, 2021, the Medicines and Healthcare products Regulatory Agency, or MHRA, is the UK’s standalone medicines and medical devices regulator. As a result of the Ireland/Northern Ireland protocol, different rules applied in Northern Ireland than in England, Wales, and Scotland (together, “Great Britain”), which continued to follow the EU regulatory regime. However, on January 1, 2025 a new arrangement called the “Windsor Framework” came into effect and reintegrated Northern Ireland under the regulatory authority of the MHRA with respect to medicinal products. The Windsor Framework removes EU licensing processes and EU labeling and serialization requirements in relation to Northern Ireland and introduces a UK-wide licensing process for medicines. A single UK-wide marketing authorization may be granted by the MHRA for novel medicinal products to be sold in the UK, enabling products to be sold in a single pack and under a single authorization throughout the UK. In addition, the new arrangements require certain medicines supplied to Northern Ireland under a UK authorization to be labelled “UK only”, indicating they are not for sale in the EU.

The MHRA has also introduced changes to national licensing procedures, including procedures to prioritize access to new medicines that will benefit patients, including a 150-day assessment and a rolling review procedure. On January 1, 2024, a new international recognition framework was put in place, under which the MHRA may have regard to decisions on the approval of marketing authorizations made by the European Medicines Agency and certain other regulators (including the FDA) when determining an application for a UK authorization. The MHRA also has the power to have regard to marketing authorizations approved in EU Member States (or Iceland, Liechtenstein, Norway) through decentralized or mutual recognition procedures when determining an application for a UK authorization.

EU and UK Data Collection

The collection and processing of personal data (including health data) in the European Economic Area (EEA) is governed by the General Data Protection Regulation (“EU GDPR”). Similarly, the collection and use of personal data (including health data) in the UK is governed by the UK General Data Protection Regulation and the UK Data Protection Act 2018, collectively the UK GDPR, and together with the EU GDPR, “GDPR.” Currently, the EU GDPR and UK GDPR remain largely aligned. The GDPR applies to any company established in the EEA/UK and to companies established outside the EEA that process personal data in connection with the offering of goods or services to data subjects in the EEA or the monitoring of the behavior of data subjects in the EEA. The GDPR imposes numerous stringent requirements on companies that process personal data, including requirements relating to processing of special categories of personal data (such as health and data), relying on a legal basis or condition for processing personal data, if required obtaining consent of data subjects, providing detailed information to data subjects about how personal data is used, conducting privacy impact assessments for “high risk” processing, implementing safeguards to protect the security and confidentiality of personal data, implementing limitations on the retention of personal data, providing mandatory data breach notification, implementing “privacy by design” requirements, and taking certain measures when engaging service providers acting as data processors. The GDPR also imposes strict rules on the transfer of personal data outside of the EEA/UK to countries that do not ensure an adequate level of protection, like the United States in certain circumstances unless derogation exists or a valid GDPR transfer mechanism (for example, the European Commission approved Standard Contractual Clauses (“SCCs”), and the UK International Data Transfer Agreement/Addendum, or UK IDTA) have been put in place. Where relying on the SCCs /UK IDTA for data transfers, we may also be required to carry out transfer impact assessments to assess whether the recipient is subject to local laws which allow public authority access to personal data. Failure to comply with the requirements of the GDPR and the related national data protection laws of the EEA Member States may result in fines up to €20 million (or £17.5 million in the UK) or 4% of a company’s global annual revenues for the preceding financial year, whichever is higher. Moreover, the GDPR grants data subjects and consumer associations the right to claim material and non-material damages resulting from infringement of the GDPR. Although the UK is regarded as a third country under the European Union’s GDPR, the European Commission has now issued a decision recognizing the UK as providing adequate protection under the EU GDPR and, therefore, transfers of personal data originating in the EU to the UK remain unrestricted.

The UK Government has introduced a Data Protection and Digital Information Bill to reform the UK data protection legal framework which failed in the UK legislative process. A new Data (Use and Access) Bill (“UK Bill”) has been introduced into parliament. If passed, the final version of the UK Bill may have the effect of further altering the similarities between the UK and EEA data protection regime and threaten the UK Adequacy Decision from the European Commission. Further, this may lead to additional compliance costs and could increase our overall risk.

Rest of the World Regulation

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

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

Additional Laws and Regulations Governing International Operations

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

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

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

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

Coverage and Reimbursement

Successful commercialization of new drug products depends in part on the extent to which reimbursement for those drug products will be available from government health administration authorities, private health insurers, and other organizations. In the United States and markets in other countries, patients generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Our ability to successfully commercialize our product candidates 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. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drug products they will pay for and establish reimbursement levels. The availability and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford a drug product. Sales of drug products depend substantially, both domestically and abroad, on the extent to which the costs of drugs products are paid for by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors.

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

There is also significant uncertainty related to the insurance coverage and reimbursement of newly approved products and coverage may be more limited than the purposes for which the medicine is approved by the FDA or comparable foreign regulatory authorities. In the United States, the principal decisions about reimbursement for new drug products are typically made by CMS, an agency within the HHS. CMS decides whether and to what extent a new drug product will be covered and reimbursed under Medicare, and private payors tend to follow CMS to a substantial degree. However, no uniform policy of coverage and reimbursement for drug products exists among third-party payors and coverage and reimbursement levels for drug products can differ significantly from payor to payor. Factors payors consider in determining reimbursement are based on whether the product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Third-party payors may limit coverage to specific products on an approved list or formulary, which might not include all of the FDA-approved products for a particular indication. Also, third-party payors may refuse to include a particular branded drug on their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or another alternative is available. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Third-party payors are increasingly challenging the prices charged for medical products and services, examining the medical necessity, and reviewing the cost-effectiveness of medical products and services and imposing controls to manage costs. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, the level of reimbursement. In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price (“ASP”) and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs.

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

For a drug product to receive federal reimbursement under the Medicaid or Medicare Part B programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the 340B drug pricing program. The required 340B discount on a given product is calculated based on the average manufacturer price (“AMP”) and Medicaid rebate amounts reported by the manufacturer. As of 2010, the ACA expanded the types of entities eligible to receive discounted 340B pricing, although under the current state of the law these newly eligible entities (with the exception of children’s hospitals) will not be eligible to receive discounted 340B pricing on orphan drugs. As 340B drug pricing is determined based on AMP and Medicaid rebate data, the revisions to the Medicaid rebate formula and AMP definition described above could cause the required 340B discount to increase.

These laws, and future state and federal healthcare reform measures may be adopted in the future, and may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used. If third-party payors do not consider our drugs to be cost-effective compared to other available therapies, they may not cover our drugs after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our drugs on a profitable basis.

Outside of the United States, the pricing of pharmaceutical products and medical devices is subject to governmental control in many countries. For example, in the European Union, pricing and reimbursement schemes vary widely from country to country. Some Member States provide that products may be marketed only after the proposed pricing has been approved. Some Member States may require the completion of additional studies that compare the cost effectiveness of a particular therapy to currently available therapies or so-called health technology assessments, in order to obtain reimbursement or pricing approval. A Member State may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Member States may allow companies to fix their own prices for products, but monitor and control product volumes and issue guidance to physicians to limit prescriptions. Efforts to control prices and utilization of pharmaceutical products and medical devices will likely continue as countries attempt to manage healthcare expenditures. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our product candidates. Historically, products launched in the European Union do not follow price structures of the U.S. and generally prices tend to be significantly lower.

Human Capital Management

Our human capital philosophy relies on attracting and retaining team members who consistently demonstrate top performance. Our culture and our approach to talent reinforces this philosophy, including recruiting, professional development, performance management and total rewards. We have provided below additional details on some of our core human resources processes.

As of December 31, 2025, we had 834 full-time employees and 5 part-time employees. Of these, 405 focus on driving forward research and development programs, 281 focus on our commercialization efforts, either directly or through our affiliates, and 153 work across our affiliates to provide strategic business development, finance and executive leadership expertise, as well as general and administrative services generally across our affiliates. We have never had a work stoppage, and none of our employees is represented by a labor organization or under any collective-bargaining arrangements. We consider our employee relations to be good.

Recruiting

We have a dedicated talent acquisition capability to support our affiliates in hiring the right talent at the right time. Our team of experienced talent acquisition professionals works closely with hiring managers to understand the required skills and capabilities for an open role, and then supports the interview process and evaluation of candidates. We strive to hire top talent, and therefore need a high-quality recruiting process and candidate experience. We endeavor to fill every role with the most qualified candidate possible, which sometimes requires partnership with an external recruitment agency. We are consistently looking at new opportunities and avenues to recruit talented individuals to work at BridgeBio.

The talent acquisition team's focus is to meet the hiring needs across BridgeBio and our affiliates. We recognize that our current and potential future team members have options for employment opportunities, including with other biotech and pharma companies, research and academic institutions, government entities, and consulting and investment firms. To attract and retain top performing team members, we focus on creating an environment that allows for autonomy, professional growth, and impact while also offering a competitive total rewards package.

Professional Development and Performance Management

We invest in the professional development of our team members through regular feedback and guidance, as well as targeted learning and development opportunities to meet demonstrated needs. We established a set of five core attributes that we expect every BridgeBio team member to demonstrate while performing in their roles: Patient Champion, Entrepreneurial Operator, Truth Seeker, Inspires Excellence and High-Quality Executor.

BridgeBio conducts semi-annual performance review processes for all team members to evaluate performance and provide feedback against these attributes. The feedback focuses on strengths and opportunities for improvement to enable the professional development of all team members. At the end of the year, the performance review includes self, peer, and manager feedback and also includes a formal rating and informs compensation decisions, including performance bonus, salary adjustments, and promotions.

Core Values and Ethics

Millions worldwide are afflicted with genetic diseases, but small patient populations and industry reluctance to conduct early-stage development means that for many, treatments have not been forthcoming. We are committed to bridging this gap: between business case and scientific possibility, between patient and hope. This starts with our first core value: to put patients first. We also strive to think independently. Our goal is to not simply accept the ideas and opinions of others as fact, but instead to ask "why?" and "why not?" We endeavor to bring a rigorous, first-principles mindset to each problem that we take on. We encourage all our team members to speak up when they have an idea or feedback to share, taking pride in a culture that is radically transparent when it comes to debating ideas. A commitment to independent thinking requires us to consider the ideas of others and to adopt them if they prove best. We strive to maintain a culture where any idea is worthy of both consideration and testing. We know that every minute counts. Our decentralized model strives to deliver treatments from discovery to patients as fast as humanly possible by utilizing focused teams of experts for each asset. Big decisions can be taken by people best-equipped to understand them, without wasting time on unnecessary cycles. And we let Science speak. Our model was designed to promote the rational assessment of our programs. Decisions about a program's fate are driven by its performance against a set of objective criteria, giving each potential medicine's scientific merits the last word. All employees are responsible for upholding these values and the BridgeBio Code of Business Conduct and Ethics, which forms the foundation of our policies and practices.

Total Rewards

To attract and retain top talent, we offer a competitive total rewards package. We target total direct compensation at the upper end of market. We link a portion of every employee's compensation to performance through a performance bonus program. To create a sense of ownership and align employee incentives with our long-term success, we offer eligible employees equity ownership in the company through stock option or restricted stock unit grants and our employee stock purchase plan. We also designed a program to incentivize affiliate-level employees to achieve specific milestones at core value-inflection points, such as IND or NDA approval.

We focus our benefits offering on areas critical to keeping our employees and their immediate families healthy and productive. We offer physical and mental health benefits to all employees who work at least 30 hours per week, on average. We have a flexible paid time off policy to empower team members to take the time they need, when they need it.

Community

We believe that building a strong sense of community at BridgeBio is critical to our success. Team members can only live up to our values of thinking independently, letting science speak, and being radically transparent when they feel a sense of belonging. This is also important to our ability to bring together team members from diverse backgrounds and experiences. We are proud to promote unique voices within and outside our organization, and are eager to learn from others' experiences.

To build community, we make targeted investments at the BridgeBio level. We offer a robust onboarding program for each new hire to ensure they understand the BridgeBio history and culture and are set up for success in their roles. We work closely with people managers to ensure they understand the expectations for the critical role of leading teams. Understanding that communications is essential for a community to thrive, we have regular Town Halls to update the organization on important progress across our scientific and clinical programs. In addition to these large gatherings, we have implemented a number of communications tools to help employees stay informed and connected. Finally, our community is anchored by our commitment to patients, underscored by our commitment to bring the entire company together multiple times a year for Patient Days. On these impactful days, we hear stories from the people who are living with rare genetic diseases, their caregivers and advocates.

Corporate and Other Information

We were incorporated as a Delaware corporation in 2019 under the name BridgeBio Pharma, Inc. Our principal executive offices are located at 3160 Porter Drive, Suite 250, Palo Alto, CA 94304. Our telephone number is (650) 391-9740.

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

ITEM 1A. RISK FACTORS

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

Risks Related to Commercialization

Our business is substantially dependent on the commercial success of Attruby and Beyontra. 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 Beyontra. The commercial success of Attruby and Beyontra 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 Beyontra 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 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 Beyontra, 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 Beyontra 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 Beyontra 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 United States, as we have done with Bayer and Alexion in the case of Beyontra, 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 Beyontra 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 United States, recently enacted legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenue we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates even if those product candidates may obtain marketing approval. See the section titled, “*Business - Government Regulation - Coverage and Reimbursement.*”

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 United States 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 United States. 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 Beyontra 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 Beyontra in Europe and Japan, respectively, and we plan to commercialize Attruby and Beyontra 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 Beyontra and any future drugs we may develop or for which we obtain commercial rights outside the United States, 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 United States and elsewhere play a primary role in the recommendation and prescription of pharmaceutical products. Arrangements with third-party payors and customers can expose pharmaceutical manufacturers to broadly applicable fraud and abuse and other healthcare laws and regulations, 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.*”

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 United States 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 United States, numerous federal and state laws and regulations, including federal health information privacy laws, state data breach notification laws, state health information privacy laws, 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, as discussed further in the section titled, "*Business - Government Regulation – U.S. Data Collection*," 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 United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of our product candidates or any future product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product for which we obtain marketing approval. Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of 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 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 Beyontra 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 two-fold strategy to reduce drug costs in the United States. While it is unclear whether and how the current administration’s proposals will be implemented, these policies are likely to have a negative impact on the pharmaceutical industry and on our ability to receive adequate revenues for our products. The current administration has threatened to impose significant tariffs on pharmaceutical manufacturers that do not adopt pricing policies such as most-favored-nation pricing, which would tie the price for drugs in the United States to the lowest price in a group of other countries. While the United States has not implemented these tariffs, the United States could impose them with minimal notice to the public. In response, multiple manufacturers have entered into confidential pricing agreements with the federal government. On the other hand, the current administration is pursuing traditional regulatory pathways to impose drug pricing policies and published two proposed regulations in December 2025, referred to as GLOBE and GUARD. If finalized, these regulations would implement mandatory payment models under which manufacturers of eligible drugs would be required to pay rebates to the federal government on a portion of the units of their drugs that are reimbursed by Medicare, with the rebate amount based on most-favored-nation pricing. Imposing a rebate in the United States that is based on drug prices outside the United States would mark a drastic and unprecedented shift in the U.S. pharmaceutical market, and while the impact of the GLOBE and GUARD proposed regulations, if finalized, cannot yet be determined, it is likely to be significant depending on the final language. 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 Beyontra 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.

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 United States 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.

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 suggesting that the administration may impose significant tariffs on pharmaceuticals if such manufacturers do not reach agreements to implement MFN pricing. Further, in November 2025, the Centers for Medicare & Medicaid Services ("CMS") introduced the GENEROUS (GENERating cost Reductions fOr U.S. Medicaid) 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. 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 Global Benchmark for Efficient Drug Pricing ("GLOBE") for Medicare Part B and Guarding U.S. Medicare Against Rising Drug Costs ("GUARD") for Medicare Part D. If finalized, these models would impose additional mandatory rebates on manufacturers of certain Medicare Part B and Medicare Part D drugs, for select Medicare populations intended to represent 25% of Medicare patients, if the Medicare prices for such products exceed those paid in economically comparable countries. Both the GLOBE and GUARD models have proposed seven-year testing periods, with the GLOBE model proposed to begin on October 1, 2026 and the GUARD model proposed to begin on January 1, 2027.

If the GLOBE and GUARD models are finalized as proposed under CMMI authority, 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 products 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. These reforms remain subject to change, potential legal challenges, 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 United States, including foreign countries where the drugs are sold at lower prices than in the United States, which could materially adversely affect our operating results.

We face competition in the United States 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 United States, the Medicare Modernization Act contains provisions that may change U.S. importation laws and expand pharmacists' and wholesalers' ability to import cheaper versions of an approved drug and competing products from Canada, where there are government price controls. 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*" 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 Beyontra 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, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products than we do.

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive than any products that we may develop. Furthermore, currently approved products could be discovered to have application for treatment of our targeted disease indications or similar indications, which could give such products significant regulatory and market timing advantages over our product candidates. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours and may obtain orphan product exclusivity from the FDA for indications that we are targeting, which could result in our competitors establishing a strong market position before we are able to enter the market. Additionally, products or technologies developed by our competitors may render our 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 preclinical, toxicology or other *in vivo* or *in vitro* data to support the initiation or continuation of clinical trials;
- delays in confirming target engagement, patient selection or other relevant biomarkers to be utilized in preclinical and clinical product candidate development;
- delays in reaching a consensus with regulatory agencies as to the design or implementation of our clinical trials;

- delays in reaching agreement on acceptable terms with prospective 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, such as the COVID-19 pandemic;
- 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 preclinical 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 and preclinical studies and clinical trials may not be predictive of the results of later-stage clinical trials, and interim results of a clinical trial do not necessarily predict final results. In addition, for certain of our product candidates that we acquired, we did not undertake the preclinical studies and clinical trials ourselves. The results of preclinical studies and clinical trials in one set of patients or disease indications, or from preclinical studies or clinical trials that we did not lead, may not be predictive of those obtained in another. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the dosing regimen and other clinical trial protocols and the rate of dropout among clinical trial participants. In addition, preclinical and clinical data are often susceptible to various interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through nonclinical studies and initial clinical trials. A number of companies in the pharmaceutical and biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, 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 United States 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 preclinical studies or clinical trials or have characteristics that are unexpected, we may elect to abandon their development or limit their development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective, which may limit the commercial expectations for the product candidate if approved. We may also be required to modify or terminate our study plans based on findings in our preclinical studies or clinical trials. AEs that we may observe in our ongoing and future preclinical 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 health care practitioners. Furthermore, if we or others later identify undesirable side effects caused by our product candidates once approved, several potentially significant negative consequences could result, including:

- regulatory authorities may suspend or withdraw approvals of such product 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 for our Phase 3 study of encaleret in autosomal dominant hypocalcemia type 1. 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 preclinical 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 preclinical or clinical development, which is a lengthy and expensive process with uncertain outcomes and the potential for substantial delays. We cannot give any assurance that any of our 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 preclinical and clinical development could result in additional costs to us and negatively impact our ability to generate revenue. Our future success is dependent on our ability to successfully develop, obtain regulatory approval for, and then successfully commercialize product candidates.

Our product candidates require additional development; management of preclinical, clinical and manufacturing activities; and regulatory approval. In addition, we will need to obtain adequate manufacturing supply; 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 Beyontra received regulatory approval for commercial sale in the United States, EU, UK 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 preclinical studies or clinical trials beyond those that we currently anticipate;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from nonclinical studies or clinical trials;
- the data collected from clinical trials of product candidates that we may identify and pursue may not be sufficient to support the submission of a new drug application ("NDA") biologics license application ("BLA"), or other submission for regulatory approval in the United States or elsewhere;

- we may be unable to demonstrate to the FDA or comparable foreign regulatory authorities that a product candidate's risk-benefit ratio for its proposed indication is acceptable;
- the FDA or comparable foreign regulatory authorities may identify deficiencies in the manufacturing processes, test procedures and specifications, or facilities of third party manufacturers with which we contract for clinical and commercial supplies; and the approval policies or regulations of the FDA or comparable foreign regulatory authorities may change in a manner that renders the clinical trial design or data insufficient for approval.

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 United States 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, preclinical studies and clinical trials that the applicable product candidate is both safe and effective for use in each target indication, and in the case of our product candidates regulated as biological products, that the product candidate is safe, pure, and potent for use in its targeted indication. Each product candidate must demonstrate an adequate risk versus benefit profile in its intended patient population and for its intended use.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical development process. Most product candidates that begin clinical trials are never approved by regulatory authorities for commercialization. We have limited experience in designing clinical trials and may be unable to design and execute a clinical trial to support 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 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 United States, 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 United States, including in Europe. The acceptance by the FDA or comparable foreign regulatory authority of study data from clinical trials conducted outside the United States or another jurisdiction may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; (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 an 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 United States or the applicable jurisdiction, and the FDA has discussed proposals to increase user fees for marketing applications containing certain foreign clinical data. 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 United States, we may never obtain approval to commercialize any of these product candidates outside of the United States, which would limit our ability to realize their full market potential.

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

Seeking foreign regulatory approval could result in difficulties and costs and require additional nonclinical studies or clinical trials which could be costly and time-consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our product candidates in those countries. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. While we previously had two products approved for sale in the United States, we do not have any product candidates 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 United States 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. See the section titled, "*Business — Government Regulation — Orphan Drug Designation and Exclusivity.*"

We have obtained from the FDA orphan drug designations, including for: Attriby 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 United States may be limited if we seek approval for an indication broader than the orphan designated indication and may be lost if the FDA later determines that the request for designation was materially defective, 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. 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.

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, 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 I; 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. See the section titled, “*Business — Government Regulation — Expedited Development and Review Programs*” for additional information regarding RMAT designation.

Although some of our product candidates, including the following, 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:

- BBP-418 for the treatment of LGMD2I,
- encalcret for the treatment of ADH1, and
- BBP-812 for the treatment of Canavan Disease.

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 preclinical studies and early clinical trials appear to support development of a companion diagnostic for a product candidate, data generated in later clinical trials may fail to support the analytical and clinical validation of the companion diagnostic. We and our future collaborators may encounter difficulties in developing, obtaining regulatory approval for, manufacturing and commercializing companion diagnostics similar to those we face with respect to our therapeutic candidates 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 preclinical 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 Beyontra 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 Beyontra 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 United States and requirements of comparable foreign regulatory authorities.

Manufacturers and manufacturers’ facilities are required to comply with extensive requirements imposed by the FDA and comparable foreign regulatory authorities, including ensuring that quality control and manufacturing procedures conform to current good manufacturing practices (“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 United States. 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 Beyontra 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 Beyontra 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 Beyontra 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 United States 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 preclinical 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 Beyontra is currently supplied by one primary supplier. Although we have entered into a master agreement with an alternative supplier of drug product for this commercial product and expect the initial commercial batch of this material to be released to us later this year from this secondary supplier, we may encounter unexpected delays in the manufacture and supply of commercial drug product.

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 Beyontra 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 United States. These regulations govern manufacturing processes and procedures, including recordkeeping, and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of contaminants or to inadvertent changes in the properties or stability of our product candidates. Our failure, or the failure of third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, suspension of production, seizures or recalls of product candidates or marketed drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect clinical or commercial supplies of our product candidates.

We or our CMOs must supply all necessary documentation in support of an NDA, BLA or MAA on a timely basis, and must adhere to regulations enforced by the FDA and other regulatory agencies through their facilities inspection program. Some of our CMOs have never produced a commercially approved pharmaceutical product and therefore have not obtained the requisite regulatory authority approvals to do so. The facilities and quality systems of some or all of our third-party contractors must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our product candidates or any of our other potential products. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our product candidates or our other potential products or the associated quality systems for compliance with the regulations applicable to the activities being conducted. Although we oversee the CMOs, we cannot control the manufacturing process of, and are completely dependent on, our CMO partners for compliance with the regulatory requirements. If these facilities do not pass a pre-approval plant inspection, regulatory approval of the 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 Beyontra 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 Beyontra 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 preclinical or clinical development programs related to the collaboration could be delayed or terminated. Also, collaborators may pursue existing or other development-stage products or alternative technologies in preference to those being developed in collaboration with us. Finally, if we fail to make required milestone or royalty payments to collaborators or to observe other obligations in agreements with them, the collaborators may have the right to terminate or stop performance of those agreements.

Establishing strategic collaborations is difficult and time-consuming. Our discussions with potential collaborators may not lead to the establishment of collaborations on favorable terms, if at all. Potential collaborators may reject collaborations based upon their assessment of our financial, regulatory or intellectual property position. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. Even if we successfully establish 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 Beyontra in certain territories outside the United States 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 preclinical testing, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research or testing.

We currently rely and expect to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to conduct some aspects of research and preclinical testing and clinical trials. Any of these third parties may terminate their engagements with us or be unable to fulfill their contractual obligations. If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative third parties on commercially reasonable terms, or at all. If we need to enter into alternative arrangements, it 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 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 Beyontra 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 United States, the European Union or other jurisdictions. Further, approvals by one regulatory agency may not be indicative of what other regulatory agencies may require for approval.

Regulatory requirements governing 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 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 Beyontra 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 United States and other countries with respect to our product candidates and technology. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to 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 United States, or vice versa. Further, we may not be aware of all third-party intellectual property rights potentially relating to our product candidates. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or, in some cases, not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. Furthermore, the scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history and can involve other factors such as expert opinion. Our analysis of these issues, including interpreting the relevance or the scope of claims in a patent or a pending application, determining applicability of such claims to our proprietary technologies, product candidates, predicting whether a third party's pending patent application will issue with claims of relevant scope, and determining the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our product candidates. We do not always conduct independent reviews of pending patent applications of and patents issued to third parties. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued that protect our product candidates, in whole or in part, or which effectively prevent others from commercializing competitive 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 United States Patent and Trademark Office ("USPTO") or become involved in opposition, derivation, reexamination, *inter partes* review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize drugs without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

In addition, the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical product candidates to ours, or limit the duration of the patent protection of our product candidates. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such 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 United States. Any exercise by the government of such rights or by any third party of its reserved rights could harm our competitive position, business, financial condition, results of operations, and prospects.

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

We currently are reliant upon licenses of certain intellectual property rights and proprietary technology from third parties that are important or necessary to the development of our proprietary technology, including technology related to 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 United States and the European Union.

In spite of our efforts, our licensors might conclude that we have materially breached our obligations under such license agreements and might therefore terminate the license agreements, thereby removing or limiting our ability to develop and commercialize products and technology covered by these license agreements. For example, if our license agreement with Stanford is terminated, competitors or other third parties would have the freedom to seek regulatory approval of, and to market, products identical to 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 United States, 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 Beyontra, low-dose infigratinib, BBP-418, encalerec 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 ability to raise additional funds or otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

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

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional or international patent application filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including generics or biosimilars. Given the amount of time required for the development, testing and regulatory review of 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 United States under the Hatch-Waxman Act and in foreign countries under similar legislation, thereby potentially extending the marketing exclusivity term of our product candidates, our business may be materially harmed.

Depending upon the timing, duration and specifics of FDA marketing approval of our product candidates, one of the U.S. patents covering each of such 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 United States or in any foreign country because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the term of extension, as well as the scope of patent protection during any such extension, afforded by the governmental authority could be less than we request.

If we are unable to obtain patent term extension, or 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 United States are less willing or unwilling to protect trade secrets. Trade secrets will also over time be disseminated within the industry through independent development, the publication of journal articles and the movement of personnel skilled in the art from company to company or academic to industry scientific positions. Though our agreements with third parties typically restrict the ability of our advisors, employees, collaborators, licensors, suppliers, third-party contractors and consultants to publish data potentially relating to our trade secrets, our agreements may contain certain limited publication rights. In addition, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position. Despite employing the contractual and other security precautions described above, the need to share trade secrets increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. If any of these events occurs or if we otherwise lose protection for our trade secrets, the value of this information may be greatly reduced and our competitive position, business, financial condition, results of operations, and prospects would be harmed.

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

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

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

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

If we or one of our licensing partners initiated legal proceedings against a third party to enforce a patent covering one or more of our product candidates, the defendant could counterclaim that the patent covering the relevant product candidate is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including novelty, nonobviousness, written description or enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover our 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 were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Such a loss of patent protection would have a material adverse impact on our business.

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

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

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

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and/or applications. We have systems in place to remind us to pay these fees, and we employ an outside 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 United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may also export infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

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

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

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

The America Invents Act also includes a number of significant changes that affect the way patent applications are prosecuted and also may affect patent litigation. These include allowing third party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a 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 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, 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 December 31, 2025, we had 834 full-time employees and 5 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 December 31, 2025, we had 834 full-time employees and 5 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 United States and similar foreign fraudulent misconduct laws; or report financial information or data accurately or to disclose unauthorized activities. If we obtain FDA approval of our product candidates and begin commercializing those products in the United States, 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 United States.

We currently market Attruby and Beyontra outside of the United States 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 United States. If we receive regulatory approval for and commercialize any of our product candidates in patient populations outside the United States, we may hire sales representatives and conduct physician and patient association outreach activities outside of the United States. Doing business internationally involves a number of risks, including, but not limited to:

- multiple, conflicting, and changing laws and regulations such as privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements, and other governmental approvals, permits, and licenses;
- failure by us to obtain and maintain regulatory approvals for the use of our products in various countries;
- additional potentially relevant third-party patent rights;
- complexities and difficulties in obtaining protection and enforcing our intellectual property;
- difficulties in staffing and managing foreign operations;
- complexities associated with managing multiple payor reimbursement regimes, government payors, or patient self-pay systems;
- limits in our ability to penetrate international markets;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of 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 eventually 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 U.S. Food and Drug Administration, for example, issued guidance on the use of artificial intelligence in medical devices, requiring detailed risk management and review processes to obtain approvals. If we develop or use AI systems that are governed by these laws or regulations, 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 - European Data Collection*”). 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 United States; any inability to transfer personal data from the EEA and UK to the United States 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 the macroeconomic economy or 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 United States. In February 2025, Beyontra 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 in each year since our inception in April 2015. Our net losses for the years ended December 31, 2025, 2024 and 2023 were \$732.9 million, \$543.3 million and \$653.3 million, respectively. As of December 31, 2025, we had an accumulated deficit of \$3.8 billion. In November 2024, Attruby was approved for commercial sale in the United States and in February 2025, Beyontra 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 Beyontra, 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 contract research organizations (“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 or preclinical 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, preclinical testing and human studies, may establish pilot scale and commercial scale manufacturing processes and facilities, and establish and develop quality control, regulatory, marketing, sales and administrative capabilities to support our existing programs and pursue potential additional programs. We are also responsible for the payments to third parties of expenses that may include milestone payments, license maintenance fees and royalties, including in the case of certain of our agreements with academic institutions or other companies from whom intellectual property rights underlying their respective programs have been in-licensed or acquired. Because the outcome of any preclinical or clinical development and regulatory approval process is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development, regulatory approval process and commercialization of any future product candidates we may identify.

As of December 31, 2025, we had working capital of \$509.8 million, of which cash, cash equivalents and marketable securities amounted to \$587.5 million. 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 infgratinib, 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, preclinical studies, clinical trials and other related activities, including the ability to enroll patients in a timely manner, for the ongoing and planned clinical trials set forth above, and potential future clinical trials;
- the costs of obtaining adequate clinical and commercial supplies of raw materials and drug products for our product candidates, including 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 December 31, 2025, we and our subsidiaries had total consolidated indebtedness of \$1.9 billion related to the Notes and deferred royalty obligations of \$866.3 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”) and \$575.0 million of indebtedness outstanding under our 1.75% Convertible Senior Notes due 2031 (the “2031 Notes”). 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”). 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 and 2031 Notes became convertible for a limited period starting on January 1, 2026 under the conversion condition met and will remain convertible until March 31, 2026.

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 BEYONTTTRA 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 the sale or issuance of common stock to, or through, Goldman Sachs & Co. LLC ("Goldman Sachs"), and SVB Securities LLC ("SVB") pursuant to our Equity Distribution Agreement, dated May 4, 2023 (the "ATM Agreement") 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 2023, we entered into the ATM Agreement with Goldman Sachs and SVB, pursuant to which we may offer and sell our common stock, having aggregate sales proceeds of up to \$450.0 million, to or through Goldman Sachs and SVB, from time to time, in an "at-the-market" offering program. In connection with the ATM Agreement, we filed a registration statement on Form S-3/ASR (File No. 333-271650) pursuant to which we may issue the shares of common stock subject to the ATM Agreement, and, so long as we qualify as a "well-known seasoned issuer" as defined in Rule 405 of the Securities Act of 1933, as amended, or the Securities Act, an unlimited amount of shares of our common stock, preferred stock, debt securities, warrants and/or units. Sales to, or through, Goldman Sachs and SVB by us under the ATM Agreement or otherwise pursuant to the registration statement 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 stockholders' deficit 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.

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, 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 Beyontra, 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 preclinical 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 future products;
- inability to obtain adequate clinical or commercial supply for our product candidates or the inability to do so at acceptable prices;
- adverse regulatory decisions, including failure to reach agreement with applicable regulatory authorities on the design or scope of our planned clinical trials;
- failure to obtain and maintain regulatory exclusivity for our product candidates;
- regulatory approval or commercialization of new products or other methods of treating our target disease indications by our competitors;
- failure to meet or exceed financial projections we may provide to the public or to the investment community;
- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us, our strategic collaboration 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 Israel and the Gaza Strip;
- 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 any potential new indebtedness.

In addition, companies trading in the stock market in general, and The Nasdaq Global 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 Israel and the Gaza Strip, 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 2021 Amended and Restated 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 July 26, 2023 and November 2, 2023 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 December 31, 2025, our beneficial stockholders, directors, and executive officers beneficially own 36.7% 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 United States 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 Beyontra 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 Beyontra 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 Beyontra 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 Beyontra 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 Beyontra 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 Israel and the Gaza Strip.

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 “OBBA”) was enacted in the United States. 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 and do not currently intend to pay dividends on our common stock, and, consequently, our stockholders’ ability to achieve a return on their investment will depend on appreciation in the price of our common stock.

We have never paid cash dividends on any of our capital stock and do not currently intend to pay any cash dividends on our common stock for the foreseeable future. We currently intend to invest our future earnings, if any, to fund our growth. Therefore, you are not likely to receive any dividends on your common stock for the foreseeable future. Since we do not intend to pay dividends, your ability to receive a return on your investment will depend on any future appreciation in the market value of our common stock. There is no guarantee that our common stock will appreciate or even maintain the price at which our holders have purchased it.

We 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 ongoing tariff announcements, 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 the change in the U.S. federal administration, 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 United States 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, President Trump has stated that he intends to use other authorities to maintain historically elevated tariffs. 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 United States and the various countries, in light of the U.S. Supreme Court's February 20, 2026 decision, is not yet clear. Moreover, the United States has threatened to impose special tariffs on certain imported pharmaceutical products, which could take effect with minimal public notice. 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 United States, political influences and inflationary pressures. For example, an overall decrease in or loss of insurance coverage among individuals in the United States 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 conflict in Israel and the Gaza Strip) 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 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 1C. CYBERSECURITY

Cybersecurity Risk Management

We have implemented an information security program that is informed by, and incorporates elements of, industry standards and frameworks, including those issued by NIST (National Institute of Standards and Technology), ISO (International Organization for Standardization), and CIS (Center for Internet Security). Our security program is designed to identify, assess, manage, mitigate, and respond to cybersecurity threats.

Our cybersecurity risk management program includes a number of components, such as information security program assessments and ongoing monitoring of critical risks from cybersecurity threats using automated tools. We periodically engage third parties to conduct risk assessments and testing of our systems, including penetration testing and other vulnerability analyses. Additionally, we have implemented an employee education program that is designed to raise awareness of cybersecurity threats, including risks posed by phishing attempts. We have implemented a process for this training to be included during the employee onboarding process and periodically thereafter.

As part of our cybersecurity risk management program, we maintain processes to assess and review the cybersecurity practices of third-party vendors and service providers. Our process includes a security assessment informed by vendor questionnaires and contractual security requirements related to data privacy for certain vendors.

We, like other companies in our industry, face a number of cybersecurity risks in connection with our business. Although our business strategy, results of operations, and financial condition have not, to date, been materially affected by risks from cybersecurity threats, including as a result of previously identified cybersecurity incidents, 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. For more information on our cybersecurity related risks, see "*Our internal computer systems, or those used by our third-party collaborators, contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our development programs and business operations*" in Item 1A- Risk Factors.

Governance

Our internal information security team is responsible for day-to-day operations related to our cybersecurity risk management strategy, including identifying, assessing, and managing cybersecurity threats and risks. We established a process that intends for our Incident Response Team to respond to and address incidents as they arise. The Incident Response Team is multidisciplinary and comprised of members of our information technology and security function, accounting and finance department, and legal department. This team is led by our Director of Security and Network Infrastructure. The Director of Security and Network Infrastructure role is currently held by an individual who has approximately twenty (20) years of information technology and ten (10) years of information security related experience.

The Incident Response Team provides periodic reports to our Data Privacy and Security Committee, as well as our Chief Executive Officer and other members of our senior management, as appropriate. These reports include updates on the Company's cybersecurity risk management program, assessments of current cybersecurity risks, and status updates for projects designed to enhance our information security systems. Our Data Privacy and Security Committee meets to further discuss such items periodically on a quarterly basis and reports periodically to the Audit Committee of the Board of Directors.

Our Board of Directors, as a whole and through its committees, has oversight responsibility over the Company's strategy and risk management, including our response to critical risks related to cybersecurity threats. The Audit Committee of the Board of Directors specifically oversees the management of enterprise risks, including risks associated with privacy and data security (including cybersecurity), in accordance with its charter. The Audit Committee engages in periodic discussions, on at least a bi-annual basis, with a member of the Data Privacy and Security Committee as well as members of legal and executive leadership as appropriate regarding the Company's significant financial risk exposures and the measures implemented to monitor and control these risks, including those that may result from critical cybersecurity threats. Executive leadership periodically reports on critical cybersecurity risks and risk management to the full Board of Directors.

ITEM 2. PROPERTIES

As of December 31, 2025, we occupied the following principal physical properties:

Property Description	Location	Square Footage	Owned or Leased	Initial Lease Term End Date	Lease Extension Options
Office space and laboratory facility	Raleigh, NC	21,263	Leased	2026	Five-year option to extend
Office space and laboratory facility	Palo Alto, CA	24,428	Leased	2026	One-year option to extend
Office space	San Francisco, CA	52,604	Leased	2027	Two-year option to extend
Laboratory facility	Montreal, Québec	20,039	Leased	2032	Five-year option to extend

ITEM 3. LEGAL PROCEEDINGS

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

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

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

Holders

As of February 12, 2026, there were 34 stockholders of record of our common stock. As many of our shares of common stock are held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of stockholders represented by these record holders.

Dividend Policy

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

Securities Authorized for Issuance Under Equity Compensation Plans

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

Stock Performance Graph

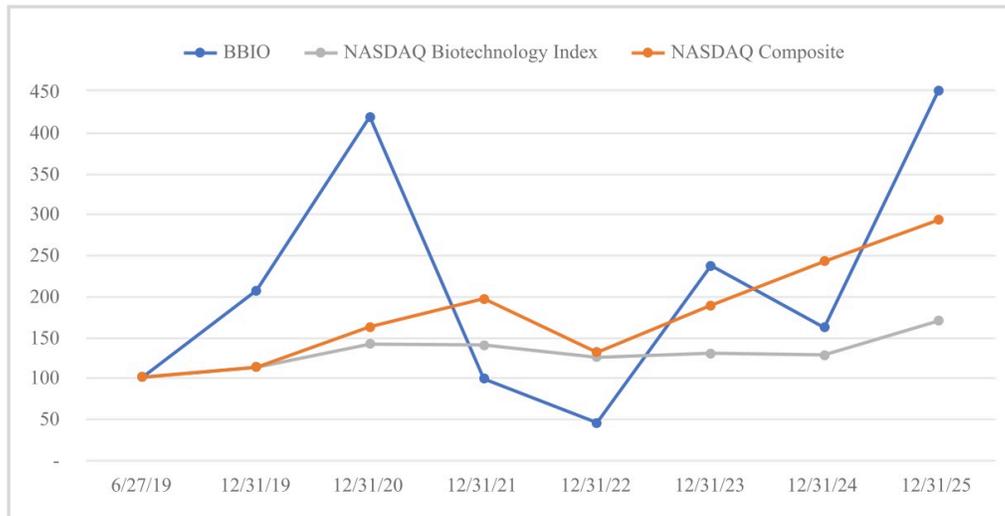
The graph set forth below compares the cumulative total stockholder return on our common stock for the period commencing on June 27, 2019, the date our common stock began trading on the Nasdaq, and ending on December 31, 2025, with the cumulative total return of the Nasdaq Composite Index and the Nasdaq Biotechnology Index over the same period. This graph assumes the investment of \$100.00 as of the close of market on June 27, 2019 in each share of our common stock at the initial public offering price of \$17.00, the Nasdaq Composite Index, and the Nasdaq Biotechnology Index, and assumes the reinvestment of dividends.

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

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

COMPARISON OF CUMULATIVE TOTAL RETURN*

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



* \$100.00 invested on June 27, 2019 in shares of our common stock or index, including reinvestment of dividends. The stock price performance shown in the graph represents past performance and should not be considered an indication of future stock price performance.

Sales of Unregistered Securities

During the year ended December 31, 2025, we did not issue or sell any unregistered securities other than as disclosed in Note 9 of Part II - Item 8. Financial and Supplementary Data - Notes to Consolidated Financial Statements of this Annual Form 10-K.

Issuer Purchases of Equity Securities

During the year ended December 31, 2025, we did not repurchase any Company equity securities other than as disclosed in Note 9 of Part II - Item 8. Financial and Supplementary Data - Notes to Consolidated Financial Statements of this Annual Form 10-K.

ITEM 6. [Reserved]

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

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

This Annual Report on Form 10-K contains "forward-looking statements" within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). In some cases, you can identify these statements by forward-looking words such as "may," "will," "expect," "believe," "anticipate," "intend," "could," "should," "estimate," or "continue," and similar expressions or variations. Such forward-looking statements are subject to risks, uncertainties and other factors that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified below, and those discussed in Part I, Item 1A, "Risk Factors" in this Annual Report on Form 10-K. The forward-looking statements in this Annual Report on Form 10-K represent our views as of the date of this Annual Report on Form 10-K. Except as may be required by law, we assume no obligation to update these forward-looking statements or the reasons that results could differ from these forward-looking statements. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Annual Report on Form 10-K.

Overview

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.

As described in Part I, Item 1. "Business" of this Annual Report on Form 10-K, we currently generate material revenues from one commercial product and have multiple product candidates in late-stage development. Acoramidis received FDA approval on November 22, 2024 as Attruby, and it received approval as Beyontra 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), and (iii) the United Kingdom Medicines and Healthcare Products Regulatory Agency in the UK in April 2025. In Part I, Item 1. "Business" you can also find a summary of key events in 2024 and 2025 to date related to our commercial product and our late-stage development programs.

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 years ended December 31, 2025 and 2024, we incurred net losses of \$732.9 million and \$543.3 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 Beyontra, 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 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., a beneficial holder of our common equity and a related party, acquired a majority ownership interest in HCRx. Accordingly, HCRx became our related party following KKR & Co. Inc.’s acquisition of HCRx.

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, which was received in full in May 2024, and will be eligible to receive up to \$150.0 million in regulatory and sales milestone payments through 2026 (of which a regulatory milestone of \$75.0 million was achieved in February 2025 upon EC approval of acoramidis under the brand name Beyontra and received in April 2025), and additional payments up to \$450.0 million subject to the achievement of certain sales milestones. 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 9 of our notes to the 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 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, and in June 2025, Eidos received the \$30.0 million regulatory milestone payment. Under the Eidos-Alexion License Agreement, Eidos is eligible to receive royalties in the low-teens based on net sales of acoramidis in Japan.

Due to the inherently unpredictable nature of preclinical 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 preclinical 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. During the years ended December 31, 2025 and 2024, our restructuring, impairment, and related charges amounted to \$21.3 million and \$15.6 million, respectively, which consisted primarily of winding down costs, exit and other related costs, and severance and employee-related costs.

Results of Operations

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

	Years Ended December 31,	
	2025	2024
	(in thousands)	
Total revenues, net	\$ 502,076	\$ 221,902
Total cost of revenues	\$ 20,962	\$ 3,878
Research and development	\$ 451,953	\$ 506,461
Selling, general and administrative	\$ 531,225	\$ 288,931
Restructuring, impairment, and related charges	\$ 21,347	\$ 15,605
Loss from operations	\$ (523,411)	\$ (592,973)
Interest income	\$ 19,854	\$ 17,249
Interest expense	\$ (53,103)	\$ (90,991)
Noncash interest expense on deferred royalty obligations (1)	\$ (125,138)	\$ (8,299)
Gain on deconsolidation of subsidiaries	\$ —	\$ 178,321
Loss on extinguishments of debt	\$ (21,155)	\$ (26,590)
Net loss from equity method investments	\$ (72,608)	\$ (31,183)
Other income, net	\$ 43,058	\$ 12,272
Provision for income taxes	\$ 435	\$ 1,153
Net loss	\$ (732,938)	\$ (543,347)
Net loss attributable to redeemable convertible noncontrolling interests and noncontrolling interests	\$ 8,007	\$ 7,585
Net loss attributable to common stockholders of BridgeBio	\$ (724,931)	\$ (535,762)

(1) Including a related party amount of \$(10,944) for the year ended December 31, 2025 (as described in Note 10 to our consolidated financial statements).

Cash, Cash Equivalents and Marketable Securities

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

	December 31, 2025	December 31, 2024
	(in thousands)	
Cash and cash equivalents	\$ 570,119	\$ 681,101
Marketable securities	17,363	—
Total cash, cash equivalents and marketable securities	\$ 587,482	\$ 681,101

As of December 31, 2025, we had cash, cash equivalents and marketable securities of \$587.5 million, compared to cash and cash equivalents of \$681.1 million as of December 31, 2024.

Revenues, Net

The following table summarizes our revenues for the following periods:

	Years Ended December 31,		
	2025	2024	Change
	(in thousands)		
Net product revenue	\$ 362,368	\$ 2,884	\$ 359,484
License and services revenue	128,322	218,849	(90,527)
Royalty revenue	11,386	169	11,217
Total revenues, net	\$ 502,076	\$ 221,902	\$ 280,174

Total revenues, net increased by \$280.2 million for the year ended December 31, 2025, compared to 2024, which consisted of an increase of \$359.5 million in net product revenue, a decrease of \$90.5 million in license and services revenue, and an increase of \$11.2 million in royalty revenue.

Net product revenue for the year ended December 31, 2025 was \$362.4 million. This revenue was generated from the commercial sale of Attruby in the U.S. following FDA approval in November 2024.

License and services revenue decreased for the year ended December 31, 2025, compared to 2024, primarily due to recognition of \$207.7 million of upfront license fees and services revenue recognized in 2024 under the Bayer License Agreement and KKC License Agreement. License and services revenue in 2025 primarily consisted of \$105.0 million recognized for milestone achievements following approval of Beyontra in the EU and pricing approval of Beyontra in Japan. The remaining change in license and services revenue is primarily driven by service revenue recognized on the non-refundable upfront payments received in 2024 and from the sale of clinical and commercial product supply to our collaboration partners.

Royalty revenue for the year ended December 31, 2025 was \$11.4 million. This revenue primarily relates to royalties earned from net product sales of Beyontra in the EU, following EC approval in February 2025, and in Japan, following pricing approval in May 2025.

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. In addition, following the FDA approval of Attruby on November 22, 2024, we commercialized Attruby in the U.S. and anticipate our future revenue to primarily be generated from recurring net product revenue. Furthermore, following the regulatory approvals of Beyontra in the EU in February 2025, in Japan in March 2025 and in the UK in April 2025, we anticipate significant future royalty revenue to be generated from the commercial sales of Beyontra by Bayer and Alexion.

Operating Costs and Expenses

Cost of Revenues

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

	Years Ended December 31,		
	2025	2024	Change
		(in thousands)	
Cost of goods sold	\$ 15,687	\$ 1,442	\$ 14,245
Cost of license, services, and royalty revenue	5,275	2,436	2,839
Total cost of revenues	\$ 20,962	\$ 3,878	\$ 17,084

Total cost of revenues increased by \$17.1 million for the year ended December 31, 2025, compared to 2024, primarily due to an increase of \$14.3 million in cost of goods sold and an increase of \$2.8 million in cost of license, services, and royalty revenue.

Cost of goods sold for the years ended December 31, 2025 and 2024 consists of 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. We began incurring cost of goods sold following FDA approval and commercial launch of Attruby in November 2024.

Cost of license, services, and royalty revenue for the years ended December 31, 2025 and 2024, consists mainly of third-party royalties associated with commercial sales of Beyontra, manufacturing costs relating to product supply of Beyontra 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 Beyontra 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:

	Years Ended December 31,		
	2025	2024	Change
	(in thousands)		
Research and development	\$ 451,953	\$ 506,461	\$ (54,508)

Research and development expenses decreased by \$54.5 million for the year ended December 31, 2025, compared to 2024. The decrease consisted of a \$32.4 million decrease in external costs, a \$9.4 million decrease in personnel-related expenses, and a \$0.6 million decrease in stock-based compensation expenses, which are collectively primarily driven by decreased R&D activities related to the Attruby and Beyontra program following regulatory approval and the reprioritization of our R&D programs. In addition, there was a \$12.1 million decrease in license fees due to timing of milestones achieved.

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 preclinical, 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:

	Years Ended December 31,	
	2025	2024
	(in thousands)	
Acoramidis for the treatment of ATTR-CM and primary prevention in asymptomatic carriers of a pathogenic TTR variant	\$ 116,844	\$ 164,782
Infigratinib for achondroplasia and hypochondroplasia	122,685	91,869
BBP-418 for LGMD2I/R9	56,008	40,220
Encaleret for ADH1	59,955	49,091
Other development programs	22,703	71,732
Other research programs	73,758	88,767
Total	\$ 451,953	\$ 506,461

Selling, General and Administrative Expenses

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

	Years Ended December 31,		
	2025	2024	Change
	(in thousands)		
Selling, general and administrative	\$ 531,225	\$ 288,931	\$ 242,294

Selling, general and administrative expenses increased by \$242.3 million for the year ended December 31, 2025, compared to 2024. The increase was primarily driven by a \$132.9 million increase in external costs and a \$88.6 million increase in personnel-related expenses, largely due to activities supporting our commercial launch and ongoing activities of Attruby, as well as a \$20.8 million increase in stock-based compensation expenses.

Restructuring, Impairment, and Related Charges

The following table summarizes our restructuring, impairment, and related charges during the periods indicated:

	Years Ended December 31,		
	2025	2024	Change
	(in thousands)		
Restructuring, impairment, and related charges	\$ 21,347	\$ 15,605	\$ 5,742

As discussed in Note 16 to our consolidated financial statements, 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.

Other Income (Expense), Net

Interest Income

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

	Years Ended December 31,		
	2025	2024	Change
	(in thousands)		
Interest income	\$ 19,854	\$ 17,249	\$ 2,605

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 years ended December 31, 2025 and 2024 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:

	Years Ended December 31,		
	2025	2024	Change
	(in thousands)		
Interest expense	\$ (53,103)	\$ (90,991)	\$ 37,888

Interest expense consists primarily of interest expense incurred under our 2031 Notes issued in February 2025, our 2029 Notes issued in January 2021, and our 2027 Notes issued in March 2020. Refer to Note 9 to our consolidated financial statements.

Our outstanding term loan principal balance under our Amended Financing Agreement was fully repaid on February 28, 2025 upon receipt of proceeds from the 2031 Notes. Refer to the *Liquidity and Capital Resources* section below and Note 9 to our 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:

	Years Ended December 31,		
	2025	2024	Change
	(in thousands)		
Noncash interest expense on deferred royalty obligations	\$ (125,138)	\$ (8,299)	\$ (116,839)

Noncash interest expense consists primarily of interest expense accreted on our deferred royalty obligations, net under the Funding Agreement and Royalty Purchase Agreement. Refer to Note 10 to our consolidated financial statements.

Gain on Deconsolidation of Subsidiaries

The following table summarizes our gain on deconsolidation of subsidiaries during the periods indicated:

	Years Ended December 31,		
	2025	2024	Change
	(in thousands)		
Gain on deconsolidation of subsidiaries	\$ —	\$ 178,321	\$ (178,321)

As more fully discussed in Note 6 to our consolidated financial statements, TheRas, Inc. (“Legacy BBOT”), completed a \$200.0 million private equity financing with external investors on April 30, 2024. As a result of the private equity financing transaction, we deconsolidated Legacy BBOT on April 30, 2024 and recognized a gain from deconsolidation of \$126.3 million for the year ended December 31, 2024.

As more fully discussed in Note 6 to our consolidated financial statements, we deconsolidated GondolaBio, LLC (“GondolaBio”), inclusive of Portal Therapeutics, Inc. and Sub21, Inc., on August 16, 2024, and recognized a gain from deconsolidation of \$52.0 million for the year ended December 31, 2024.

Loss on Extinguishments of Debt

The following table summarizes our loss on extinguishments of debt during the periods indicated:

	Years Ended December 31,		
	2025	2024	Change
	(in thousands)		
Loss on extinguishments of debt	\$ (21,155)	\$ (26,590)	\$ 5,435

On February 28, 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 consolidated statements of operations. On January 17, 2024, upon receipt of proceeds from the Financing Agreement, we fully repaid the term loan under the Amended Loan Agreement and recognized a loss on extinguishment of debt of \$26.6 million on our consolidated statements of operations. Refer to Note 9 to our consolidated financial statements.

Net Loss from Equity Method Investments

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

	Years Ended December 31,		
	2025	2024	Change
	(in thousands)		
Net loss from equity method investments	\$ (72,608)	\$ (31,183)	\$ (41,425)

Subsequent to the deconsolidation of GondolaBio on August 16, 2024 and Legacy BBOT on April 30, 2024, 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 6 to our consolidated financial statements) using the equity method of accounting. For the year ended December 31, 2025 we recorded net loss from the equity method investments in GondolaBio and BBOT of \$35.1 million and \$37.5 million, respectively. For the year ended December 31, 2024 we recorded net loss from equity method investments in GondolaBio and Legacy BBOT of \$8.5 million and \$22.7 million, respectively.

Other Income, Net

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

	Years Ended December 31,		
	2025	2024	Change
	(in thousands)		
Other income, net	\$ 43,058	\$ 12,272	\$ 30,786

The increase of \$30.8 million for the year ended December 31, 2025, compared to 2024, was primarily driven by \$19.7 million of other income recorded for the change in fair value of the embedded derivative liability component of our deferred royalty obligation under the Funding Agreement, \$8.8 million of noncash income from our equity method investments, and a \$7.4 million increase in income recognized under the Transition Service Agreements with GondolaBio and BBOT, partially offset by a \$5.8 million decrease in net realized gains from our investment in equity securities.

Provision for Income Taxes

The following table summarizes our provision for income taxes during the periods indicated:

	Years Ended December 31,		
	2025	2024	Change
	(in thousands)		
Provision for income taxes	\$ 435	\$ 1,153	\$ (718)

We are subject to U.S. federal, state and foreign income taxes as a corporation. For U.S. federal income tax purposes, we are required to file a consolidated U.S. federal income tax return for the consolidated entities that meet the requirements as prescribed by the consolidated regulations. Those entities that do not meet the threshold to be included in the consolidated filing continue to file separate U.S. federal income tax returns. To the extent we incur operating losses in the periods in which we are treated as a corporation for tax purposes, net operating loss carryforwards may generally be used by us to offset cash taxes on future taxable income, subject to applicable tax laws.

Current tax law in the U.S. imposes tax on U.S. stockholders for global intangible low-taxed income (“GILTI”) earned by certain foreign subsidiaries. The Company is required to make an accounting policy election of either: (1) treating taxes due on future amounts included in the U.S. taxable income related to GILTI as a current period tax expense when incurred (“the period cost method”); or (2) factoring such amounts into the Company’s measurement of its deferred tax expense (the “deferred method”). The Company has elected the period cost method for its accounting for GILTI.

Beginning in 2022, the 2017 Tax Cuts and Jobs Act amended Section 174 of the Internal Revenue Code of 1986, as amended, to eliminate current-year deductibility of research and experimentation (“R&E”) expenditures and software development costs (collectively, “R&E expenditures”) and instead require taxpayers to charge their R&E expenditures to a capital account amortized over five years (15 years for expenditures attributable to R&E activity performed outside the U.S.). The Company generated a deferred tax asset for capitalized R&E expenditures for the year ended December 31, 2024 which was fully offset by a valuation allowance. 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 as of December 31, 2025. Due to our valuation allowance on deferred tax assets, this tax law change did not result in a material impact to our consolidated financial statements.

As of December 31, 2025, we have net operating loss carryforwards available to reduce future taxable income, if any, for federal and state income tax purposes of approximately \$1.7 billion and \$462.2 million, respectively.

The federal net operating losses generated prior to 2018 amounting to \$10.8 million will begin to expire in 2036, losses generated after 2018 amounting to \$1.6 billion will carry over indefinitely and will be subject to an 80% taxable income limitation in the year utilized. State net operating losses will generally begin to expire in 2036. We also have foreign net operating loss carryforwards of \$543.0 million available to reduce future taxable income, if any, which will begin to expire in 2030.

As of December 31, 2025, we have federal research and development and orphan drug credit carryforwards of approximately \$141.3 million, which will expire beginning in 2038 if not utilized.

As of December 31, 2025, we have California and other state research and development tax credit carryforwards of \$37.4 million. The state research and development tax credits will expire at various dates while the California research and development tax credits will carry over indefinitely.

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

The valuation allowance increased by \$240.7 million, \$55.2 million and \$138.2 million for the years ended December 31, 2025, 2024 and 2023, respectively.

Utilization of the net operating loss and credit carryforwards may be subject to a substantial annual limitation due to an ownership change limitation as provided by Section 382 of the Internal Revenue Code of 1986, as amended, and similar state provisions. The annual limitation may result in the expiration of net operating losses and credits before utilization. In the event that we have a change of ownership, utilization of the net operating loss and tax credit carryforwards may be restricted.

Net Loss Attributable to Redeemable Convertible Noncontrolling Interests and Noncontrolling Interests

The following table summarizes our net loss attributable to redeemable convertible noncontrolling interests and noncontrolling interests during the periods indicated:

	Years Ended December 31,		
	2025	2024	Change
		(in thousands)	
Net loss attributable to redeemable convertible noncontrolling interests and noncontrolling interests	\$ 8,007	\$ 7,585	\$ 422

Net loss attributable to redeemable convertible noncontrolling interests and noncontrolling interests on our consolidated statements of operations consists of the portion of the net loss of those consolidated entities that is not allocated to us. Changes in the amount of net loss attributable to noncontrolling interests are directly impacted by changes in the net loss of our consolidated entities and are the result of ownership percentage changes. Refer to Note 5 to our consolidated financial statements.

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 licensing arrangements. As of December 31, 2025, we have cash, cash equivalents, and marketable securities of \$587.5 million, including funds held by our wholly-owned subsidiaries and controlled entities. As of December 31, 2025, we have outstanding debt of \$1.9 billion and deferred royalty obligations of \$866.3 million, both of which are net of amortization of debt discount and issuance costs.

Since inception, we have incurred significant operating losses. For the years December 31, 2025 and 2024, we incurred net losses of \$732.9 million and \$543.3 million, respectively. We incurred net cash outflow from operations of \$445.9 million and \$520.7 million for the same periods, respectively. We had an accumulated deficit as of December 31, 2025 and 2024 of \$3.8 billion and \$3.1 billion, respectively. While we have 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 2033 Notes (refer to Note 19 to our consolidated financial statements), 2031 Notes, 2029 Notes, and 2027 Notes (refer to Note 9 to our consolidated financial statements), our deferred royalty obligations, net under the Funding Agreement and Royalty Purchase Agreement (refer to Note 10 to our consolidated financial statements), obligations under our real estate leases (refer to Note 13 to our consolidated financial statements), accounts payable, accrued liabilities and the remaining liabilities under our restructuring initiative (refer to Note 16 to our consolidated financial statements).

We also have performance-based milestone compensation arrangements with certain employees and consultants, whose vesting is contingent upon meeting various regulatory and development milestones, with fixed monetary amounts known at inception that can be settled in the form of cash or equity at our sole election, upon achievement of each contingent milestone (refer to Note 8 to our 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 preclinical 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 will fund our operations for at least the next 12 months from the date of filing of this Annual Report on Form 10-K 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/Beyontra, 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/Beyontra, 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 on November 22, 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 and 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 received an upfront payment of \$135.0 million in May 2024 and will be eligible to receive up to \$150.0 million in regulatory and sales milestone payments through 2026 (of which a regulatory milestone of \$75.0 million was achieved and recognized as license and services revenue in February 2025 upon EC approval of acoramidis under the brand name Beyontra and received in April 2025), and additional payments up to \$450.0 million subject to the achievement of certain sales milestones. 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, 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, which was received in full in June 2024, and will be eligible to receive development and sales milestone payments up to \$81.4 million. 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 based on net sales 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., a beneficial holder of our common equity and a related party, acquired a majority ownership interest in HCRx. Accordingly, HCRx became our related party following KKR & Co. Inc.’s acquisition of HCRx.

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 11), 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 10 to our 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 Attriby on November 22, 2024, and in accordance with the Funding Agreement (as described below), 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 10 to our consolidated financial statements for other details.

Debt

As of December 31, 2025, we have borrowings under the 2031 Notes, the 2029 Notes, and the 2027 Notes, which are discussed below.

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 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 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 2029 Notes and 2027 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 9 to our consolidated financial statements for other details, including our future minimum payments under the 2031 Notes.

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 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; 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 9 to our consolidated financial statements for other details, including our future minimum payments under the 2029 Notes.

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 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 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 Indenture contains customary terms and covenants, including that upon certain events of default occurring and continuing, either the 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 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.

Refer to Note 9 to our consolidated financial statements for other details, including our future minimum payments under the 2027 Notes.

As of December 31, 2025, the 2029 Notes were not convertible. The holders of the 2027 Notes and 2031 Notes, however, have the right to convert their notes during the period from January 1, 2026 through March 31, 2026 because an early conversion condition relating to the price of BridgeBio's common stock, as discussed above, was met, which resulted in the 2027 Notes and 2031 Notes becoming convertible for a limited period beginning January 1, 2026. Notwithstanding the satisfaction of this conversion condition, the 2027 Notes and 2031 Notes were classified as noncurrent liabilities as of December 31, 2025 because the Company has the ability to settle any conversions in shares of BridgeBio's common stock, as permitted under the terms of the 2027 Notes Indenture and 2031 Notes Indenture, respectively.

Subsequent Event - 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. The 2033 Notes issued in the 2026 Note Offering include \$82.5 million aggregate principal amount of 2033 Notes sold to the initial purchasers (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 our common stock and intend to use the remaining 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.

Refer to Note 19 to our consolidated financial statements for further details.

Public offerings

In March 2024, we entered into an Underwriting Agreement (the "2024 Follow-on Agreement") with J.P. Morgan Securities LLC, Cantor Fitzgerald & Co. and Mizuho Securities USA LLC, as representatives of several underwriters (collectively, the "2024 Underwriters"), relating to an underwritten public offering (the "2024 Follow-on offering") of 8,620,690 shares of our common stock, \$0.001 par value per share, at a public offering price of \$29.00 per share. We also granted the 2024 Underwriters a 30-day option to purchase, at the public offering price less underwriting discounts and commissions, up to an additional 1,293,103 shares of Common Stock, which the 2024 Underwriters exercised in full on the closing of the 2024 Follow-on offering. We paid the Underwriters a commission of 3.6% of the aggregate gross proceeds received from all sales of the common stock under the Follow-on Agreement. In March 2024, 9,913,793 shares (including the 1,293,103 shares issued upon exercise of the 2024 Underwriters' option to purchase additional shares) were issued under the 2024 Follow-on Agreement, for net proceeds of \$276.6 million, after deducting underwriting fees and commissions of \$10.3 million and offering costs of \$0.6 million.

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 will pay 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. During the year ended December 31, 2023, 2,171,217 shares were issued under the ATM Agreement, for net proceeds of \$65.0 million, after deducting sales agent fees and commissions of \$1.0 million. During the year ended December 31, 2024, 1,061,991 shares were issued under the ATM Agreement, for net proceeds of \$38.1 million, after deducting sales agent fees and commissions of \$0.6 million. During the year ended December 31, 2025, there were no shares issued under the ATM Agreement. As of December 31, 2025, we are still eligible to sell up to \$345.3 million of our common stock pursuant to the ATM Agreement under the 2023 Shelf.

Cash Flows

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

	Years Ended December 31,		
	2025	2024	Change
	(in thousands)		
Net cash used in operating activities	\$ (445,910)	\$ (520,726)	\$ 74,816
Net cash provided by (used in) investing activities	(24,487)	60,781	(85,268)
Net cash provided by financing activities	359,293	748,457	(389,164)
Net increase (decrease) in cash, cash equivalents and restricted cash	\$ (111,104)	\$ 288,512	\$ (399,616)

Net Cash Flows Used in Operating Activities

Net cash used in operating activities was \$445.9 million for the year ended December 31, 2025 and consisted of our net loss of \$732.9 million, adjustments for noncash items totaling \$338.1 million, and net cash outflow of \$51.1 million related to changes in operating assets and liabilities. The adjustments for noncash items totaling \$338.1 million primarily included \$133.0 million in stock-based compensation expense, \$125.1 million in noncash interest expense on deferred royalty obligations, \$72.6 million in net loss from equity method investments, \$21.2 million in loss on extinguishments of debt from the repayment of the term loan under the Amended Financing Agreement, \$6.0 million in amortization of debt discount and issuance costs, and \$5.4 million in depreciation and amortization; partially offset by \$19.7 million in change in fair value of the embedded derivative associated with the deferred royalty obligation under the Funding Agreement (as described in Note 10 of our consolidated financial statements) and \$8.8 million in noncash income from our equity method investments. The net cash outflow of \$51.1 million related to changes in operating assets and liabilities was attributed mainly to an increase of \$134.7 million in accounts receivable, net primarily related to receivables for net product revenues, an increase of \$25.3 million in inventories due to a continuing build-up of Attruby inventory following its commercialization in November 2024, an increase of \$8.8 million in prepaid expenses and other current assets primarily due to timing of payments and fluctuations in our operations, and a decrease of \$11.4 million in deferred revenue primarily related to the Bayer License Agreement and KKC License Agreement; partially offset by an increase of \$26.6 million in accounts payable, an increase of \$23.0 million in accrued compensation and benefits, and an increase of \$77.8 million in other liabilities, which are collectively primarily due to timing of payments.

Net cash used in operating activities was \$520.7 million for the year ended December 31, 2024 and consisted primarily of our net loss of \$543.3 million, adjustments for noncash items totaling \$9.4 million, and net cash inflow of \$32.0 million related to changes in operating assets and liabilities. The adjustments for noncash items totaling \$9.4 million primarily included a gain of \$178.3 million from the deconsolidation of subsidiaries, and a net gain of \$8.1 million from investment in equity securities; partially offset by \$95.8 million in stock-based compensation expense, \$31.2 million net loss from equity method investments, \$26.6 million in loss on extinguishment of debt from the repayment of the term loan under the Amended Loan Agreement, \$8.3 million in noncash interest expense on deferred royalty obligations, \$7.5 million in accretion of debt, and \$6.1 million in depreciation and amortization. The \$32.0 million net cash inflow related to changes in operating assets and liabilities was attributed mainly to an increase in deferred revenue of \$21.9 million primarily related to the Bayer License Agreement and KKC License Agreement, an increase of \$17.0 million in accrued compensation and benefits, and an increase of \$8.7 million in accrued research and development liabilities; partially offset by an increase in prepaid expenses and other current assets of \$13.9 million, which were collectively primarily due to timing of payments.

Net Cash Flows Provided by (Used in) Investing Activities

Net cash used in investing activities was \$24.5 million for the year ended December 31, 2025, attributable primarily to purchases of marketable securities of \$28.2 million and the aggregate payments made for intangible assets of \$8.5 million; partially offset by maturities of marketable securities of \$11.0 million and a special cash dividend from an investment in equity securities of \$2.3 million.

Net cash provided by investing activities was \$60.8 million for the year ended December 31, 2024, attributable primarily to \$95.0 million in proceeds from the maturities of marketable securities, \$63.2 million in proceeds from the sale of investments in equity securities, and \$25.7 million in special cash dividends received from an investment in equity securities; partially offset by purchases of marketable securities of \$93.8 million, purchases of investments in equity securities of \$20.3 million and \$8.0 million in payments made for intangible assets.

Net Cash Flows Provided by Financing Activities

Net cash provided by financing activities was \$359.3 million for the year ended December 31, 2025 and consisted primarily of \$575.0 million in proceeds from the issuance of the 2031 Notes, \$300.0 million in gross cash proceeds from the royalty obligation under the Royalty Purchase Agreement, and \$19.9 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, \$15.5 million repayments of deferred royalty obligations, and \$3.0 million payment of issuance costs associated with the royalty obligation under the Royalty Purchase Agreement.

Net cash provided by financing activities was \$748.5 million for the year ended December 31, 2024 and consisted primarily of \$500.0 million in proceeds from the royalty obligation under the Funding Agreement, \$450.0 million in proceeds from the term loan under the Amended Financing Agreement, and \$314.7 million in net proceeds from the issuance of common stock through public offerings, which includes \$276.6 million in net proceeds through the 2024 Follow-on offering and \$38.1 million in net proceeds through the ATM offering. These increases were partially offset by the \$473.4 million repayment of the term loan under the Amended Loan Agreement, \$27.5 million in issuance costs and discount associated with the Funding Agreement, and \$16.0 million in issuance costs and discounts associated with the Amended Financing Agreement.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States ("U.S. GAAP"). The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, as well as revenues and expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our consolidated financial statements for the periods in this report.

Collaborative Agreements

We enter into collaboration arrangements with partners, under which we may grant licenses to further develop, manufacture and commercialize our drug compounds and/or product candidates. We may also perform research, development, manufacturing, commercialization, and supply activities under our collaboration agreements. Consideration under these arrangements may include, upfront payments, development and regulatory milestones, expense reimbursements, royalties based on net sales of commercial products, and commercial sales milestone payments.

When we enter into collaboration agreements, we assess whether the arrangements fall within the scope of Accounting Standards Codification ("ASC") 808, *Collaborative Arrangements*, based on whether the arrangements involve joint operating activities and whether both parties have active participation in the arrangement and are exposed to significant risks and rewards. To the extent that the arrangement falls within the scope of ASC 808, we assess whether the payments between us and our partner fall within the scope of other accounting literature. If we conclude that payments from the partner to us represent consideration from a customer, such as license fees, contract manufacturing, and research and development activities, we account for those payments within the scope of ASC 606. However, if we conclude that our partner is not a customer for certain activities and associated payments, such as for certain collaborative research, development, manufacturing, and commercial activities, we record such payments as a reduction of research and development expense or selling, general and administrative expense, based on where we present the underlying expense. Additionally, if we reimburse our collaboration partners for these activities, we record such reimbursements as research and development expense or selling, general and administrative expense, depending upon the nature of the underlying expense.

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, returns, chargebacks, rebates, co-pay assistance and other allowances that are offered within contracts between us and our customers, health care 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 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 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 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.
- *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 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 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 consolidated balance sheets in the period the related product revenue is recognized.

Accrued Research and Development Liabilities

We record accruals for estimated costs of research and development activities conducted by third-party service providers, which include the conduct of preclinical studies, clinical trials, and contract manufacturing activities. We record the estimated costs of research and development activities based upon the estimated amount of services provided but not yet invoiced, and include these costs in “Accrued research and development liabilities” on the consolidated balance sheets and within “Research and development expenses” on the consolidated statements of operations. These costs are a significant component of our research and development expenses.

Examples of estimated research and development expenses that we accrue include:

- fees paid to CROs in connection with preclinical and toxicology studies and clinical trials;
- fees paid to investigative sites in connection with clinical trials;
- fees paid to CMOs in connection with the production of product and clinical trial materials; and
- professional service fees for consulting and related services.

We base our expense accruals related to clinical trials on our estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and CROs that conduct and manage clinical trials on our behalf. The financial terms of these agreements vary from contract to contract and may result in uneven payment flows. Payments under some of these contracts depend on factors, such as the successful enrollment of patients and the completion of clinical trial milestones. Our service providers generally invoice us monthly in arrears for services performed. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If we do not identify costs that we have begun to incur or if we underestimate or overestimate the level of services performed or the costs of these services, our actual expenses could differ from our estimates. We record advance payments to service providers as prepaid expenses.

We record accruals for the estimated costs of our contract manufacturing activities performed by third parties. The financial terms of these agreements are subject to negotiation, vary from contract to contract, and may result in uneven payment flows to our vendors. Payments under the contracts include upfront payments and milestone payments, which depend on factors such as the achievement of the completion of certain stages of the manufacturing process. For purposes of recognizing expense, we assess whether we consider the production process sufficiently defined to be considered the delivery of a good or the delivery of a service, where processes and yields are developing and less certain. If we consider the process to be the delivery of a good, we recognize expense when the drug product is delivered, or we otherwise bear risk of loss. If we consider the process to be the delivery of a service, we recognize expense based on our best estimates of the contract manufacturer’s progress towards completion of the stages in the contract. We base our estimates on the best information available at the time. However, additional information may become available to us which may allow us to make a more accurate estimate in future periods. In this event, we may be required to record adjustments to research and development expenses in future periods when the actual level of activity becomes more certain. Any increases or decreases in cost are generally considered to be changes in estimates and will be reflected in research and development expenses in the period identified.

To date, we have not experienced significant changes in our estimates of accrued research and development liabilities after a reporting period. However, due to the nature of estimates, there is no assurance that we will not make changes to our estimates in the future as we become aware of additional information about the status or conduct of our clinical studies and other research activities.

Accrued Milestone Compensation Arrangements

We have performance-based milestone compensation arrangements with certain employees and consultants, whose vesting is contingent upon meeting various regulatory and development milestones, with fixed monetary amounts known at inception that can be settled in the form of (1) cash, (2) equity of BridgeBio, or (3) cash or equity of BridgeBio at our sole election, upon achievement of each contingent milestone. For arrangements that involve settlement by cash or equity of BridgeBio at our sole election, we will classify the milestone compensation arrangements as liability-classified awards when it is probable of achievement because of the possible fixed monetary amounts settlement outcomes. The arrangements would also result in settlement with a variable number of shares based on the then-current stock price at achievement date of each contingent milestone should we elect to settle in equity.

We record accruals for the compensation expense arising from each development milestone when the specific contingent development milestone is probable of achievement and such accruals are measured at each reporting period. We estimate the probability of achieving such milestones based on the progression and expected outcome of the related clinical programs. We base our estimates on the best available information at that time. However, additional information may become available to us which may allow us to make a more accurate estimate in future periods. In this event, we may be required to record adjustments to milestone compensation expenses in future periods. Any increases or decreases in such expenses are generally considered to be changes in estimates and will be reflected in the period identified.

To date, we have not experienced significant changes in our estimates of accrued milestone compensation expenses after a reporting period. However, due to the nature of estimates, there is no assurance that we will not make changes to our estimates in the future as we become aware of additional information about the progression and expected outcome of our clinical programs.

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 10 as deferred royalty obligations, amortized using the effective interest rate method over the estimated life of the 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 periodically assess our expected net sales using internal projections, impute interest on the carrying value of the deferred royalty obligations, and record interest expense using the imputed effective interest rate. To the extent our estimates of future net sales are greater or less than previous estimates or the estimated timing of such payments is materially different than previous estimates, we will account for any such changes by adjusting the effective interest rate on a prospective basis, with a corresponding impact to the reclassification of our deferred royalty obligations. The assumptions used in determining the expected repayment terms of the deferred royalty obligations and amortization period of the debt discount and issuance costs requires that we make estimates that could impact the classification of such costs, as well as the period over which such costs will be amortized.

Recent Accounting Pronouncements

See Note 2, “*Summary of Significant Accounting Policies - Recently Adopted Accounting Pronouncement*” to our consolidated financial statements appearing under Part II, Item 8 for more information.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As of December 31, 2025, we held cash, cash equivalents and marketable securities of \$587.5 million. Our cash equivalents consist of amounts invested in money market funds, agency discount notes, and high investment grade fixed income securities that are primarily invested in commercial paper, 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 December 31, 2025, our 2031 Notes, 2029 Notes, and 2027 Notes had principal balances of \$575.0 million, \$747.5 million and \$550.0 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 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the stockholders and the Board of Directors of BridgeBio Pharma, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of BridgeBio Pharma, Inc. and its subsidiaries and controlled entities (the “Company”) as of December 31, 2025 and 2024, the related consolidated statements of operations, comprehensive loss, redeemable convertible noncontrolling interests and stockholders’ deficit, and cash flows, for each of the three years in the period ended December 31, 2025, and the related notes (collectively referred to as the “financial statements”). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2025 and 2024, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2025, in conformity with accounting principles generally accepted in the United States of America.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company’s internal control over financial reporting as of December 31, 2025, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 24, 2026, expressed an unqualified opinion on the Company’s internal control over financial reporting.

Basis for Opinion

These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current-period audit of the financial statements that was communicated or required to be communicated to the audit committee and that (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Accrued research and development liabilities, Prepaid expenses and other current assets, Other assets, and Research and development expenses from Contract Research Organizations (CROs) and Contract Manufacturing Organizations (CMOs) — Refer to Note 2 to the financial statements

Critical Audit Matter Description

The Company incurs research and development expenses related to the costs of research and development activities, including third-party service agreements with CROs and CMOs to provide research and development services related to preclinical studies and clinical trials, which are estimated at each reporting period. The Company records these expenses based on estimates of the services and activities completed to date pursuant to the provisions of the signed contracts relative to the amounts invoiced and paid to date, resulting in an accrued liability or prepaid expense balance at period end.

We identified the recording of these third-party research and development costs as a critical audit matter because of the judgments necessary for management to estimate both the cost of services provided but not yet invoiced and the amounts paid ahead of services being incurred, the significant volume of transactions and the varied nature of audit evidence obtained from vendor to vendor. The amount of expense recognized and the corresponding accrual and prepaid balances recorded are based on the unique terms and conditions in each arrangement and are often dependent on limited information available from the vendors regarding the progress of the services through the reporting date. This required extensive audit effort due to the volume and variability in the arrangements and available information from the vendors and required a high degree of auditor judgment when performing audit procedures to audit management's estimates of total expenses, accrued and prepaid balances and evaluating the results of those procedures.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to the estimate of research and development expenses and the related accrued and prepaid balances included the following, among others:

- We evaluated the design and tested the operating effectiveness of controls over the Company's research and development expense accrual process, including controls over the estimation of activities completed to date.
- We evaluated publicly available information (e.g., the Company's website, news articles, press releases, and investor presentations) and board of directors' materials, and corroborated this information gathered with Company personnel responsible for overseeing the clinical trial activities regarding the status of such activities. We then compared this information to the judgments applied in management's estimate of the recorded expenses and corresponding accrual and prepaid balances.
- We evaluated management's ability to accurately estimate accrual of these third-party research and development costs by performing a lookback analysis over a sample of prior year accrual and prepaid balances, comparing invoices received subsequent to the prior year end to management's historical estimates recorded in the financial statements.
- For a sample of contracts, we evaluated the third-party research and development expenses and the corresponding accrued and prepaid expense balances by:
 - Inspecting related agreements, including (but not limited to) master service agreements, change orders, statements of work, and amendments, and agreeing key provisions of the agreements including timeline, budget, and relevant rates, to the Company's analysis of estimated expenses incurred to date.
 - Selecting specific amounts recognized as research and development expense and testing accuracy and completeness by obtaining invoices, contracts and other underlying support.
 - Sending written confirmations directly to CROs or CMOs to confirm completeness of agreements as well as payments received, invoices billed and yet to be billed, and costs incurred to date and inspecting correspondence received directly from them, including status reports, and comparing such information to the amounts used in the Company's estimates.
 - Agreeing other third-party information to the inputs used in the Company's analysis and recalculating the Company's estimated expense, accrual, and prepaid balances.
 - Performing a lookback analysis by comparing the estimated accrual balance as of December 31, 2025, to the vendor confirmations received by management after year-end to evaluate the Company's ability to estimate the accrual.

/s/ Deloitte & Touche LLP

San Francisco, California

February 24, 2026

We have served as the Company's auditor since 2018.

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

	December 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	\$ 570,119	\$ 681,101
Marketable securities	17,363	—
Accounts receivable, net	139,444	4,722
Inventories	26,753	—
Prepaid expenses and other current assets	44,070	34,869
Total current assets	797,749	720,692
Equity method investments	79,972	143,747
Property and equipment, net	5,366	7,011
Operating lease right-of-use assets	8,149	5,767
Intangible assets, net	28,077	23,926
Other assets	16,712	18,195
Total assets	\$ 936,025	\$ 919,338
Liabilities, Redeemable Convertible Noncontrolling Interests and Stockholders' Deficit		
Current liabilities:		
Accounts payable	\$ 36,228	\$ 9,618
Accrued compensation and benefits	76,703	58,329
Accrued research and development liabilities	41,436	34,272
Operating lease liabilities, current portion	6,192	4,506
Deferred revenue, current portion	7,190	14,604
Other current liabilities (1)	120,222	33,071
Total current liabilities	287,971	154,400
2031 Notes, net	564,565	—
2029 Notes, net	740,890	738,872
2027 Notes, net	547,015	545,173
Term loan, net	—	437,337
Deferred royalty obligations, net (2)	855,030	479,091
Operating lease liabilities, net of current portion	3,811	4,696
Deferred revenue, net of current portion	13,080	17,095
Other long-term liabilities	244	286
Total liabilities	3,012,606	2,376,950
Commitments and contingencies (Note 8)		
Redeemable convertible noncontrolling interests	(570)	142
Stockholders' deficit:		
Undesignated preferred stock, \$0.001 par value; 25,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock, \$0.001 par value; 500,000,000 shares authorized; 202,369,129 shares issued and 194,771,957 shares outstanding as of December 31, 2025, 196,236,234 shares issued and 190,044,473 shares outstanding as of December 31, 2024	202	196
Treasury stock, at cost; 7,597,172 shares as of December 31, 2025; 6,191,761 shares as of December 31, 2024	(323,276)	(275,000)
Additional paid-in capital	2,057,646	1,903,155
Accumulated other comprehensive income	12	8
Accumulated deficit	(3,821,194)	(3,096,263)
Total BridgeBio stockholders' deficit	(2,086,610)	(1,467,904)
Noncontrolling interests	10,599	10,150
Total stockholders' deficit	(2,076,011)	(1,457,754)
Total liabilities, redeemable convertible noncontrolling interests and stockholders' deficit	\$ 936,025	\$ 919,338

(1) Including a related party amount of \$2,003 as of December 31, 2025 (as described in Note 10).

(2) Including a related party amount of \$204,650 as of December 31, 2025 (as described in Note 10).

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

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

	Years Ended December 31,		
	2025	2024	2023
Revenues:			
Net product revenue	\$ 362,368	\$ 2,884	\$ —
License and services revenue	128,322	218,849	9,303
Royalty revenue	11,386	169	—
Total revenues, net	<u>502,076</u>	<u>221,902</u>	<u>9,303</u>
Operating costs and expenses:			
Cost of revenues:			
Cost of goods sold	15,687	1,442	—
Cost of license, services, and royalty revenue	5,275	2,436	2,446
Total cost of revenues	<u>20,962</u>	<u>3,878</u>	<u>2,446</u>
Research and development	451,953	506,461	455,711
Selling, general and administrative	531,225	288,931	150,590
Restructuring, impairment, and related charges	21,347	15,605	7,926
Total operating costs and expenses	<u>1,025,487</u>	<u>814,875</u>	<u>616,673</u>
Loss from operations	(523,411)	(592,973)	(607,370)
Other income (expense), net:			
Interest income	19,854	17,249	18,038
Interest expense	(53,103)	(90,991)	(81,289)
Noncash interest expense on deferred royalty obligations (1)	(125,138)	(8,299)	—
Gain on deconsolidation of subsidiaries	—	178,321	—
Loss on extinguishments of debt	(21,155)	(26,590)	—
Net loss from equity method investments	(72,608)	(31,183)	—
Other income, net	43,058	12,272	17,370
Total other income (expense), net	<u>(209,092)</u>	<u>50,779</u>	<u>(45,881)</u>
Loss before income taxes	<u>(732,503)</u>	<u>(542,194)</u>	<u>(653,251)</u>
Provision for income taxes	435	1,153	—
Net loss	<u>(732,938)</u>	<u>(543,347)</u>	<u>(653,251)</u>
Net loss attributable to redeemable convertible noncontrolling interests and noncontrolling interests	8,007	7,585	10,049
Net loss attributable to common stockholders of BridgeBio	<u>\$ (724,931)</u>	<u>\$ (535,762)</u>	<u>\$ (643,202)</u>
Net loss per share attributable to common stockholders of BridgeBio, basic and diluted	<u>\$ (3.78)</u>	<u>\$ (2.88)</u>	<u>\$ (3.95)</u>
Weighted-average shares used in computing net loss per share attributable to common stockholders of BridgeBio, basic and diluted	<u>191,527,482</u>	<u>186,075,873</u>	<u>162,791,511</u>

(1) Including a related party amount of \$(10,944) for the year ended December 31, 2025 (as described in Note 10).

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

BRIDGEBIO PHARMA, INC.
Consolidated Statements of Comprehensive Loss
(in thousands)

	Years Ended December 31,		
	2025	2024	2023
Net loss	\$ (732,938)	\$ (543,347)	\$ (653,251)
Other comprehensive loss:			
Unrealized gains (losses) on available-for-sale securities	4	(23)	359
Comprehensive loss	(732,934)	(543,370)	(652,892)
Comprehensive loss attributable to redeemable convertible noncontrolling interests and noncontrolling interests	8,007	7,585	10,049
Comprehensive loss attributable to common stockholders of BridgeBio	\$ (724,927)	\$ (535,785)	\$ (642,843)

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

BRIDGEBIO PHARMA, INC.
Consolidated Statements of Redeemable Noncontrolling Interests and Stockholders' Deficit
(in thousands, except share amounts)

	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, 2022	\$ (1,589)	150,625,572	\$ 157	6,191,761	\$ (275,000)	\$ 938,703	\$ (328)	\$ (1,918,149)	\$ (1,254,617)	\$ 11,282	\$ (1,243,335)
Issuance of shares under equity compensation plans	—	4,193,444	4	—	—	6,004	—	—	6,008	—	6,008
Issuance of common stock under employee stock purchase plan (ESPP)	—	339,979	—	—	—	3,398	—	—	3,398	—	3,398
Repurchase of restricted stock unit (RSU) shares to satisfy tax withholding	—	(301,984)	—	—	—	(6,880)	—	—	(6,880)	—	(6,880)
Stock-based compensation	—	—	—	—	—	98,601	—	—	98,601	—	98,601
Issuance of common stock under public offerings, net	—	20,225,940	20	—	—	449,790	—	—	449,810	—	449,810
Issuance (repurchase) of noncontrolling interests	1,500	—	—	—	—	—	—	—	—	(2,006)	(2,006)
Transfers from (to) noncontrolling interests	4,851	—	—	—	—	(10,534)	—	(238)	(10,772)	5,921	(4,851)
Deconsolidation of a subsidiary	899	—	—	—	—	1,950	—	850	2,800	1,151	3,951
Unrealized loss on available-for-sale securities	—	—	—	—	—	—	359	—	359	—	359
Net loss	(5,183)	—	—	—	—	—	—	(642,964)	(642,964)	(5,104)	(648,068)
Balances as of December 31, 2023	478	175,082,951	181	6,191,761	(275,000)	1,481,032	31	(2,560,501)	(1,354,257)	11,244	(1,343,013)
Issuance of shares under equity compensation plans	—	4,044,996	4	—	—	3,652	—	—	3,656	—	3,656
Issuance of common stock under ESPP	—	194,138	—	—	—	4,502	—	—	4,502	—	4,502
Repurchase of RSU shares to satisfy tax withholding	—	(253,396)	—	—	—	(7,526)	—	—	(7,526)	—	(7,526)
Stock-based compensation	—	—	—	—	—	111,997	—	—	111,997	—	111,997
Issuance of common stock under public offerings, net	—	10,975,784	11	—	—	314,730	—	—	314,741	—	314,741
Issuance of noncontrolling interests	—	—	—	—	—	—	—	—	—	200	200
Transfers from (to) noncontrolling interests	4,012	—	—	—	—	(5,819)	—	—	(5,819)	1,807	(4,012)
Deconsolidation of subsidiaries	—	—	—	—	—	587	—	178,321	178,908	136	179,044
Unrealized gain on available-for-sale securities	—	—	—	—	—	—	(23)	—	(23)	—	(23)
Net loss	(4,348)	—	—	—	—	—	—	(714,083)	(714,083)	(3,237)	(717,320)
Balances as of December 31, 2024	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	—	6,146,003	6	—	—	27,729	—	—	27,735	—	27,735
Issuance of common stock under ESPP	—	261,422	—	—	—	6,414	—	—	6,414	—	6,414
Repurchase of RSU shares to satisfy tax withholding	—	(274,530)	—	—	—	(14,226)	—	—	(14,226)	—	(14,226)
Stock-based compensation	—	—	—	—	—	140,168	—	—	140,168	—	140,168
Issuance of noncontrolling interests	2,150	—	—	—	—	—	—	—	—	—	—
Transfers from (to) noncontrolling interests	3,380	—	—	—	—	(5,594)	—	—	(5,594)	2,214	(3,380)
Unrealized gain on available-for-sale securities	—	—	—	—	—	—	4	—	4	—	4
Net loss	(6,242)	—	—	—	—	—	—	(724,931)	(724,931)	(1,765)	(726,696)
Balances as of December 31, 2025	\$ (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)

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

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

	Years Ended December 31,		
	2025	2024	2023
Operating activities:			
Net loss	\$ (732,938)	\$ (543,347)	\$ (653,251)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation	133,024	95,800	108,710
Loss on extinguishments of debt	21,155	26,590	—
Noncash interest expense on deferred royalty obligations (1)	125,138	8,299	—
Amortization of debt discount and issuance costs	5,967	7,464	8,907
Depreciation and amortization	5,434	6,075	6,494
Noncash lease expense	4,902	4,110	4,032
Net loss from equity method investments	72,608	31,183	—
Change in fair value of the embedded derivative associated with the deferred royalty obligation	(19,652)	(1,550)	—
Noncash income from equity method investments	(8,833)	—	—
(Gain) loss on deconsolidation of subsidiaries	—	(178,321)	1,241
Gain from investment in equity securities, net	—	(8,136)	(18,314)
Accrual of payment-in-kind interest on term loan	—	—	10,207
Other noncash adjustments, net	(1,651)	(935)	(803)
Changes in operating assets and liabilities:			
Accounts receivable, net	(134,722)	(2,971)	15,328
Inventories	(25,307)	—	—
Prepaid expenses and other current assets	(8,777)	(13,918)	(2,702)
Other assets	1,113	1,542	(1,546)
Accounts payable	26,609	1,512	2,780
Accrued compensation and benefits	23,022	16,986	7,802
Accrued research and development liabilities	7,163	8,729	(9,855)
Operating lease liabilities	(6,547)	(5,902)	(4,829)
Deferred revenue	(11,428)	21,875	(5,438)
Other liabilities (2)	77,810	4,189	3,517
Net cash used in operating activities	(445,910)	(520,726)	(527,720)
Investing activities:			
Purchases of marketable securities	(28,197)	(93,811)	(29,726)
Maturities of marketable securities	11,000	95,000	82,550
Purchases of investments in equity securities	—	(20,271)	(107,538)
Proceeds from sales of investments in equity securities	—	63,229	110,556
Proceeds from special cash dividends received from an investment in equity securities	2,302	25,682	—
Payment for intangible assets	(8,495)	(7,975)	—
Purchases of property and equipment	(1,097)	(933)	(1,306)
Decrease in cash and cash equivalents resulting from deconsolidation of subsidiaries	—	(140)	(503)
Net cash provided by (used in) investing activities	(24,487)	60,781	54,033
Financing activities:			
Proceeds from issuance of 2031 Notes	575,000	—	—
Issuance costs and discounts associated with 2031 Notes	(12,034)	—	—
Repurchase of common stock	(48,276)	—	—
Proceeds from a royalty obligation under the Royalty Purchase Agreement	300,000	—	—
Issuance costs associated with a royalty obligation under the Royalty Purchase Agreement	(3,010)	—	—
Proceeds from royalty obligation under Funding Agreement	—	500,000	—
Issuance costs and discounts associated with royalty obligation under Funding Agreement	—	(27,513)	—
Proceeds from term loan under the Amended Financing Agreement	—	450,000	—
Issuance costs and discounts associated with term loan under the Amended Financing Agreement	—	(15,986)	—
Repayment of term loans	(459,000)	(473,417)	—
Repayments of deferred royalty obligations (3)	(15,460)	—	—
Proceeds from issuance of common stock through public offerings, net	—	314,741	449,810
Proceeds from common stock issuances under ESPP	6,414	4,502	3,398
Proceeds from stock option exercises, net of repurchases	27,735	3,656	6,008
Transactions with noncontrolling interests	2,150	—	(801)
Repurchase of RSU shares to satisfy tax withholding	(14,226)	(7,526)	(6,880)
Net cash provided by financing activities	359,293	748,457	451,535
Net increase (decrease) in cash, cash equivalents, and restricted cash	(111,104)	288,512	(22,152)
Cash, cash equivalents, and restricted cash at beginning of year	683,244	394,732	416,884
Cash, cash equivalents, and restricted cash at end of year	\$ 572,140	\$ 683,244	\$ 394,732

(1) Including a related party amount of \$10,944 for the year ended December 31, 2025 (as described in Note 10).

(2) Including a related party amount of \$2,003 for the year ended December 31, 2025 (as described in Note 10).

(3) Including a related party amount of \$(2,295) for the year ended December 31, 2025 (as described in Note 10).

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

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

	Years Ended December 31,		
	2025	2024	2023
Supplemental Disclosure of Cash Flow Information:			
Cash paid for interest	\$ 43,670	\$ 91,342	\$ 61,108
Cash paid for income taxes	\$ 1,198	\$ —	\$ —
Supplemental Disclosures of Noncash Investing and Financing Information:			
Unpaid property and equipment	\$ 43	\$ 279	\$ 100
Transfers to noncontrolling interests	\$ (5,594)	\$ (5,819)	\$ (10,534)
Reconciliation of Cash, Cash Equivalents and Restricted Cash:			
Cash and cash equivalents	\$ 570,119	\$ 681,101	\$ 375,935
Restricted cash — Included in "Prepaid expenses and other current assets"	550	126	16,653
Restricted cash — Included in "Other assets"	1,471	2,017	2,144
Total cash, cash equivalents and restricted cash at end of years shown on the consolidated statements of cash flows	\$ 572,140	\$ 683,244	\$ 394,732

BRIDGEBIO PHARMA, INC.
Notes to Consolidated Financial Statements

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 United States 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 Beyontra™ (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 Beyontra for the treatment of ATTR-CM in Japan, and on May 21, 2025, the National Health Insurance in Japan approved the pricing of Beyontra. In April 2025, the United Kingdom Medicines and Healthcare Products Regulatory Agency approved Beyontra for the treatment of ATTR-CM in the UK in April 2025. In addition, we have three product candidates (low-dose infigratinib for achondroplasia, encaleret for ADH1, and BBP-418 for limb-girdle muscular dystrophy type 2I/R9, or LGMD2I/R9) in our late-stage development pipeline.

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 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 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.

The consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States (“U.S. GAAP”) 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. Certain reclassifications have been made to prior period amounts to conform to current period presentations. The results of operations for the years ended December 31, 2025, 2024 and 2023 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 period.

Variable Interest Entities and Voting Interest Entities

BridgeBio consolidates those entities in which it has a direct or indirect controlling financial interest based on either the VIE model or the VOE model.

BRIDGEBIO PHARMA, INC.
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VIEs are entities that, by design, either (i) lack sufficient equity to permit the entity to finance its activities without additional subordinated financial support from other parties; or (ii) have equity investors that do not have the ability to make significant decisions relating to the entity's operations through voting rights, or do not have the obligation to absorb the expected losses, or do not have the right to receive the residual returns of the entity.

The primary beneficiary of a VIE is required to consolidate the assets and liabilities of the VIE. The primary beneficiary is the party that has both (i) the power to direct the activities of the VIE that most significantly impact the VIE's economic performance, and (ii) the obligation to absorb losses or the right to receive benefits from the VIE that could potentially be significant to the VIE through its interest in the VIE.

To assess whether BridgeBio has the power to direct the activities of a VIE that most significantly impact the VIE's economic performance, BridgeBio considers all the facts and circumstances, including its role in establishing the VIE and its ongoing rights and responsibilities. This assessment includes identifying the activities that most significantly impact the VIE's economic performance and identifying which party, if any, has power over those activities. In general, the parties that make the most significant decisions affecting the VIE (management and representation on the Board of Directors) and have the right to unilaterally remove those decision-makers are deemed to have the power to direct the activities of a VIE.

To assess whether BridgeBio has the obligation to absorb losses of the VIE or the right to receive benefits from the VIE that could potentially be significant to the VIE, BridgeBio considers all of its economic interests, which primarily include equity investments in preferred and common stock and issuance of notes that are convertible into preferred stock, that are deemed to be variable interests in the VIE. This assessment requires BridgeBio to apply judgment in determining whether these interests, in the aggregate, are considered potentially significant to the VIE. Factors considered in assessing the significance include: the design of the VIE, including its capitalization structure, subordination of interests, payment priority, relative share of interests held across various classes within the VIE's capital structure, and the reasons why the interests are held by BridgeBio.

At the VIE's inception, BridgeBio determines whether it is the primary beneficiary and if the VIE should be consolidated based on the facts and circumstances. We have determined that the consolidated VIEs, in which BridgeBio is the primary beneficiary, individually meet the definition of a business. There are no significant restrictions on the assets and liabilities of BridgeBio's consolidated VIEs. BridgeBio then performs ongoing reassessments of the VIE based on reconsideration events and reevaluates whether a change to the consolidation and disclosure conclusions are required each reporting period.

Entities that do not qualify as a VIE are assessed for consolidation under the VOE model. Under the VOE model, BridgeBio consolidates the entity if it determines that it, directly or indirectly, has greater than 50% of the voting shares and that other equity holders do not have substantive voting, participating, or liquidation rights. Refer to Note 5.

Equity Method and Other Equity Investments

We use the equity method to account for any of our investments under the scope of Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 323 *Investments - Equity Method and Joint Ventures* ("ASC 323"), where we may not be the primary beneficiary, but may still exercise significant influence over the financial and operating policies of the investee. Our consolidated net loss includes our Company's proportionate share of the net income or loss from equity method investment and amortization of any in-process research and development asset ("IPR&D asset"). Our judgment regarding the level of influence over each equity method investee includes considering key factors such as our ownership interest, representation on the board of directors, participation in policy-making decisions, and other material transactions.

We measure the fair value of our investment in equity securities at each reporting period in accordance with ASC 321, *Investments - Equity Securities* ("ASC 321"). Changes in fair value resulting from observable price changes are included in "Other income (expense), net" on our consolidated statements of operations. Upon sale of an equity security, any realized gain or loss is recognized in our consolidated statements of operations. We generally classify our investment in equity securities as a noncurrent asset, unless we intend to liquidate these investments to fund current operations, in which case we would classify these investments as a current asset.

Refer to Note 6 for further discussions on our equity method investments and other equity security investment.

BRIDGEBIO PHARMA, INC.
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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 December 31, 2025 and 2024.

During the year ended December 31, 2025, our revenues were generated primarily from product sales to customers and from license and collaboration agreements with strategic partners. During the years ended December 31, 2024 and 2023, our revenues were generated primarily from license and collaboration agreements with strategic partners.

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

	Years Ended December 31,		
	2025	2024	2023
Bayer (as described in Note 11)	14.4%	59.3%	*
Kyowa Kirin Co., Ltd (as described in Note 11)	*	34.3%	*
Bristol-Myers Squibb Company (as described in Note 11)	*	*	80.6%
LianBio (as described in Note 6)	*	*	14.5%
Customer A	18.5%	*	*
Customer B	19.8%	*	*
Customer C	14.5%	*	*
Customer D	14.5%	*	*
Customer E	11.1%	*	*

* 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 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%. As of December 31, 2024, five customers each accounted for more than 10% of our consolidated gross accounts receivable balance, at 17.3%, 17.3%, 16.9%, 12.0% and 11.9%.

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 Beyontra 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 source manufacturer. The sale of our commercial product and 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.

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Notes to Consolidated Financial Statements

Use of Estimates

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

- revenue recognition for transactions accounted for under 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 recoverability and estimated useful lives of our long-lived assets,
- 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, 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.

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, U.S. treasury bills, agency discount notes, and 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 agency discount notes. We classify our marketable securities as available-for-sale securities and report them at fair value in cash equivalents or marketable securities on the consolidated balance sheets with related unrealized gains and losses included as a component of 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 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 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 third parties 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.

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

Fair Value Measurements

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

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

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

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

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

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

Property and Equipment, net

Property and equipment are stated at cost, net of accumulated depreciation. Depreciation of property and equipment is calculated using the straight-line method over the estimated useful lives of the respective assets. Maintenance and repairs that do not improve or extend the life of the assets are expensed when incurred. Upon sale or retirement of assets, the cost and accumulated depreciation is removed from the consolidated balance sheets and any resulting gain or loss is reflected in the consolidated statements of operations in the period realized.

The estimated useful lives of our property and equipment are as follows:

Furniture and office equipment	3 - 5 years
Laboratory and machinery equipment	5 - 15 years
Leasehold improvements	Shorter of remaining lease term or estimated useful life of the related asset

Depreciation expense of property and equipment was \$2.5 million, \$3.7 million and \$4.1 million for the years ended December 31, 2025, 2024 and 2023, respectively.

Leases

Our lease portfolio includes leases for our corporate headquarters, office spaces, and laboratory facilities. We determine if an arrangement is a lease at the inception of the contract. The asset component of our operating leases is recorded as "Operating lease right-of-use assets", and the liability component is recorded as "Operating lease liabilities, current portion" and "Operating lease liabilities, net of current portion" on our consolidated balance sheets. The asset component of our finance leases is included in "Property and equipment, net", and current and noncurrent finance lease liabilities are presented as part of "Other current liabilities" and "Other long-term liabilities", respectively, on our consolidated balance sheets. Assets under finance leases are depreciated in a manner similar to other property and equipment.

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Right-of-use assets and lease liabilities are recognized based on the present value of lease payments over the lease term at the lease commencement date. The present value of lease payments is determined by using the interest rate implicit in the lease, if that rate is readily determinable; otherwise, we use an incremental borrowing rate based on the information available at lease commencement date in determining the present value of lease payments. Right-of-use assets are adjusted for lease incentive amounts expected to be received. On the lease commencement date, we estimate and include in our lease payments any lease incentive amounts based on future events when (1) the events are within our control and (2) the event triggering the right to receive the incentive is deemed reasonably certain to occur. If the lease incentive received is greater or less than the amount recognized at lease commencement, we recognize the difference as an adjustment to right-of-use asset and/or lease liability, as applicable.

Right-of-use assets and lease liabilities are remeasured upon certain modifications to leases using the present value of remaining lease payments and estimated incremental borrowing rate upon lease modification. Operating lease cost is recognized on a straight-line basis over the lease term, and includes amounts related to short-term leases. For finance leases, we record interest expense on the lease liability in addition to amortizing the right-of-use asset, which is generally straight-line, over the shorter of the lease term or the useful life of the right-of-use asset. We recognize variable lease payments as operating expenses in the period in which the obligation for those payments is incurred. Variable lease payments primarily include common area maintenance, utilities, real estate taxes, insurance, and other operating costs that are passed on from the lessor in proportion to the space we lease.

Other Current Liabilities

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

	December 31, 2025	December 31, 2024
	(in thousands)	
Accrued rebates and other related costs	\$ 45,909	\$ 210
Accrued commercial	35,773	11,267
Accrued interest	14,411	11,056
Deferred royalty obligations, current portion (1)	11,221	144
Accrued professional services	3,665	3,673
Milestone-based liabilities	—	1,595
Other accrued liabilities	9,243	5,126
Total other current liabilities	\$ 120,222	\$ 33,071

(1) Including a related party amount of \$2,003 as of December 31, 2025 (as described in Note 10).

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”), which 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 preclinical, 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.

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

	Years Ended December 31,		
	2025	2024	2023
	(in thousands)		
Revenues:			
Net product revenue	\$ 362,368	\$ 2,884	\$ —
License and services revenue	128,322	218,849	9,303
Royalty revenue	11,386	169	—
Total revenues, net	<u>502,076</u>	<u>221,902</u>	<u>9,303</u>
Operating costs and expenses:			
Cost of revenues:			
Cost of goods sold	15,687	1,442	—
Cost of license, services, and royalty revenue	5,275	2,436	2,446
Total cost of revenues	<u>20,962</u>	<u>3,878</u>	<u>2,446</u>
Research and development by significant program:			
Acoramidis for the treatment of ATTR-CM and primary prevention in asymptomatic carriers of a pathogenic TTR variant	116,844	164,782	101,041
Infigratinib for achondroplasia and hypochondroplasia	122,685	91,869	63,239
BBP-418 for LGMD21/R9	56,008	40,220	33,903
Encaleret for ADHI	59,955	49,091	44,773
Other development programs	22,703	71,732	82,165
Other research programs	73,758	88,767	130,590
Total segment research and development	<u>451,953</u>	<u>506,461</u>	<u>455,711</u>
Selling, general and administrative	531,225	288,931	150,590
Restructuring, impairment, and related charges	21,347	15,605	7,926
Total operating costs and expenses	<u>1,025,487</u>	<u>814,875</u>	<u>616,673</u>
Loss from operations	(523,411)	(592,973)	(607,370)
Other income (expense), net:			
Interest income	19,854	17,249	18,038
Interest expense	(53,103)	(90,991)	(81,289)
Noncash interest expense on deferred royalty obligations (1)	(125,138)	(8,299)	—
Gain on deconsolidation of subsidiaries	—	178,321	—
Loss on extinguishments of debt	(21,155)	(26,590)	—
Net loss from equity method investments	(72,608)	(31,183)	—
Other income, net	43,058	12,272	17,370
Total other income (expense), net	<u>(209,092)</u>	<u>50,779</u>	<u>(45,881)</u>
Loss before income taxes	(732,503)	(542,194)	(653,251)
Provision for income taxes	435	1,153	—
Net loss	(732,938)	(543,347)	(653,251)
Net loss attributable to redeemable convertible noncontrolling interests and noncontrolling interests	8,007	7,585	10,049
Segment net loss attributable to common stockholders of BridgeBio	<u>\$ (724,931)</u>	<u>\$ (535,762)</u>	<u>\$ (643,202)</u>

(1) Including a related party amount of \$(10,944) for the year ended December 31, 2025 (as described in Note 10).

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.”

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

	Years Ended December 31,		
	2025	2024	2023
U.S.	72.2 %	6.0 %	84.9 %
Europe, Middle East, and Africa (EMEA)	25.3 %	59.5 %	0.6 %
Asia-Pacific (APAC)	2.5 %	34.5 %	14.5 %
Total	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 consolidated balance sheets. 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. As of December 31, 2024, our capitalized property and equipment located in the U.S., Canada and the rest of the world are approximately 51.6%, 44.7% and 3.7%, respectively.

Capped Call Transactions

In connection with the issuance of the 2029 Notes and the 2027 Notes (see Note 9), BridgeBio entered into certain capped call transactions (the “Capped Call Transactions”). The Capped Call Transactions are generally expected to reduce the potential dilution to the holders of BridgeBio’s common stock upon any conversion of the 2029 Notes and the 2027 Notes and/or offset any cash payments BridgeBio is required to make in excess of the principal amount of converted 2029 Notes and 2027 Notes, with such reduction and/or offset subject to a cap based on the cap price (see Note 9). The capped calls meet the conditions outlined in ASC 815-40, *Derivatives and Hedging*, to be classified in stockholders’ equity as a reduction to additional paid-in capital and are not subsequently remeasured as long as the conditions for equity classification continue to be met.

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 10 as deferred royalty obligations, amortized using the effective interest rate method over the estimated life of the 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 periodically assess our expected net sales using internal projections, impute interest on the carrying value of the deferred royalty obligations, and record interest expense using the imputed effective interest rate. To the extent our estimates of future net sales are greater or less than previous estimates or the estimated timing of such payments is materially different than previous estimates, we will account for any such changes by adjusting the effective interest rate on a prospective basis, with a corresponding impact to the reclassification of our deferred royalty obligations. The assumptions used in determining the expected repayment terms of the deferred royalty obligations and amortization period of the debt discount and issuance costs requires that we make estimates that could impact the classification of such costs, as well as the period over which such costs will be amortized.

Derivative Financial Instruments

The Company evaluates its debt or other funding agreements to determine if those agreements or embedded components of those agreements qualify as derivatives to be separately accounted for in accordance with ASC 815, *Derivatives and Hedging* and ASC 480, *Distinguishing Liabilities from Equity*. The result of this accounting treatment is that the fair value of the embedded derivative, if required to be bifurcated, is marked-to-market at each balance sheet date and recorded as a liability in “Deferred royalty obligations, net” on our consolidated balance sheets. The change in fair value is recorded in the accompanying consolidated statements of operations as a component of “Other income, net”. As of December 31, 2025 and 2024, the Company has an embedded derivative with a fair value of \$21.4 million and \$41.1 million, respectively, related to our deferred royalty obligation under the Funding Agreement. Refer to Note 3 and Note 10 for further details regarding our embedded derivative and deferred royalty obligations.

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Debt Issuance Costs

Debt issuance costs are amortized to interest expense over the estimated life of the related debt based on the effective interest method. In accordance with ASC 835, *Interest*, we present debt issuance costs on the consolidated balance sheets as a direct deduction from the associated debt.

Treasury Stock

Repurchased treasury stock is recorded at cost, including any commissions and fees.

Collaborative Agreements

We enter into collaboration arrangements with partners, under which we may grant licenses to further develop, manufacture and commercialize our drug compounds and/or product candidates. We may also perform research, development, manufacturing, commercialization, and supply activities under our collaboration agreements. Consideration under these arrangements may include, upfront payments, development and regulatory milestones, expense reimbursements, royalties based on net sales of commercial products, and commercial sales milestone payments.

When we enter into collaboration agreements, we assess whether the arrangements fall within the scope of ASC 808, *Collaborative Arrangements*, based on whether the arrangements involve joint operating activities and whether both parties have active participation in the arrangement and are exposed to significant risks and rewards. To the extent that the arrangement falls within the scope of ASC 808, we assess whether the payments between us and our partner fall within the scope of other accounting literature. If we conclude that payments from the partner to us represent consideration from a customer, such as license fees, contract manufacturing, and research and development activities, we account for those payments within the scope of ASC 606. However, if we conclude that our partner is not a customer for certain activities and associated payments, such as for certain collaborative research, development, manufacturing, and commercial activities, we record such payments as a reduction of research and development expense or selling, general and administrative expense, based on where we present the underlying expense. Additionally, if we reimburse our collaboration partners for these activities, we record such reimbursements as research and development expense or selling, general and administrative expense, depending upon the nature of the underlying expense.

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.

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- *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.

BRIDGEBIO PHARMA, INC.
Notes to Consolidated Financial Statements

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, health care 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 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 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 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.
- *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 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 consolidated balance sheets.

BRIDGEBIO PHARMA, INC.**Notes to Consolidated Financial Statements**

- *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 consolidated balance sheets in the period the related product revenue is recognized.

During the years ended December 31, 2025 and 2024, we recognized net product revenue of \$362.4 million and \$2.9 million, respectively, related to product sales of Attruby. There were no significant changes in estimates of variable considerations during the years ended December 31, 2025 and 2024.

As of December 31, 2024, our variable consideration reserves under ASC 606 totaled \$0.4 million, consisting of accrued rebates and other accruals of \$0.2 million and reserves against accounts receivable of \$0.2 million.

During the year ended December 31, 2025, we recorded \$150.1 million of reductions to current-year product revenue, primarily related to chargebacks and government rebates determined largely based on mandated discount rates under government programs.

During the same period, we recorded \$96.2 million of payments made or credits issued related to current-year product revenue, reflecting the utilization and settlement of previously recorded estimates of variable consideration.

As of December 31, 2025, our variable consideration reserves totaled \$54.3 million, consisting of \$46.0 million of accrued rebates and other accruals and \$8.3 million of reserves against accounts receivable, all of which are expected to be settled within the normal course of business.

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.

Accounts Receivable, net

Accounts receivable, net includes receivables from our product sales to customers, and from our collaboration partners as a result of licensing and collaboration agreements. Receivables from licensing and collaboration agreements represent valid claims against our collaboration partners, including unbilled receivables and royalty payments due from third parties for licensing our technology. Unbilled receivables include balances due from our collaboration partners related to development services and transition-related receivables that are recognized when the related costs are incurred for the partnered programs but prior to the achievement of contractual billing rights. Total receivables from our product sales to customers and licensing and collaboration agreements as of December 31, 2025 and 2024 are presented as “Accounts receivable, net” on our consolidated balance sheets.

We evaluate the collectability of our receivables based on historical collection trends, the financial condition of payment partners, and external market factors and provide for an allowance for potential credit losses based on management’s best estimate of the amount of probable credit losses. As of December 31, 2025 and 2024, we did not have an allowance for credit losses.

BRIDGEBIO PHARMA, INC.
Notes to Consolidated Financial Statements

Inventories

Inventory is recorded at the lower of cost or net realizable value. The cost of raw materials, work in process and finished goods are 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. Prior to regulatory approval of our product candidates, we record costs related to manufacturing and materials as "Research and development" expenses in the period incurred on the consolidated statements of operations, and therefore such costs are not included in cost of revenues. Subsequent to the FDA approval of Attruby in November 2024, the costs directly related to Attruby manufacturing were capitalized as inventory. 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. Provision for inventory reserves and write-downs are recorded within "Cost of revenues" on the consolidated statements of operations.

Inventories presented on the consolidated balance sheet consisted of the following balances:

	December 31, 2025
	(in thousands)
Raw materials	\$ 14,997
Work in process	6,104
Finished goods	6,509
Inventory reserve	(857)
Total inventories	\$ 26,753

Cost of Revenues

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

- *Cost of goods sold:* Cost of goods sold consists of 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 Beyontra to our collaboration partners, royalties owed to a third party on 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.

Research and Development Expenses

Research and development costs are expensed as incurred. Research and development expenses consist of salaries, benefits and other personnel-related costs including stock-based compensation expense, laboratory supplies, preclinical studies, clinical trials and related clinical manufacturing costs, costs related to manufacturing preparations, fees paid to other entities to conduct certain research and development activities on our behalf, and allocated facility and other related costs. Non-refundable advance payments for goods or services that will be used or rendered for future research and development activities are deferred and capitalized as prepaid expenses until the related goods are delivered or services are performed.

BRIDGEBIO PHARMA, INC.
Notes to Consolidated Financial Statements

Accrued Research and Development Liabilities

We record accruals for estimated costs of research and development activities conducted by third-party service providers, which include the conduct of preclinical studies, clinical trials, and contract manufacturing activities. We record the estimated costs of research and development activities based upon the estimated amount of services provided but not yet invoiced, and include these costs in “Accrued research and development liabilities” on the consolidated balance sheets and within “Research and development expenses” on the consolidated statements of operations. These costs are a significant component of our research and development expenses.

Examples of estimated research and development expenses that we accrue include:

- fees paid to CROs in connection with preclinical and toxicology studies and clinical trials;
- fees paid to investigative sites in connection with clinical trials;
- fees paid to CMOs in connection with the production of product and clinical trial materials; and
- professional service fees for consulting and related services.

We base our expense accruals related to clinical trials on our estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and CROs that conduct and manage clinical trials on our behalf. The financial terms of these agreements vary from contract to contract and may result in uneven payment flows. Payments under some of these contracts depend on factors, such as the successful enrollment of patients and the completion of clinical trial milestones. Our service providers generally invoice us monthly in arrears for services performed. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If we do not identify costs that we have begun to incur or if we underestimate or overestimate the level of services performed or the costs of these services, our actual expenses could differ from our estimates. We record advance payments to service providers as prepaid expenses.

We record accruals for the estimated costs of our contract manufacturing activities performed by third parties. The financial terms of these agreements are subject to negotiation, vary from contract to contract, and may result in uneven payment flows to our vendors. Payments under the contracts include upfront payments and milestone payments, which depend on factors such as the achievement of the completion of certain stages of the manufacturing process. For purposes of recognizing expense, we assess whether we consider the production process sufficiently defined to be considered the delivery of a good or the delivery of a service, where processes and yields are developing and less certain. If we consider the process to be the delivery of a good, we recognize expense when the drug product is delivered, or we otherwise bear risk of loss. If we consider the process to be the delivery of a service, we recognize expense based on our best estimates of the contract manufacturer’s progress towards completion of the stages in the contract. We base our estimates on the best information available at the time. However, additional information may become available to us which may allow us to make a more accurate estimate in future periods. In this event, we may be required to record adjustments to research and development expenses in future periods when the actual level of activity becomes more certain. Any increases or decreases in cost are generally considered to be changes in estimates and will be reflected in research and development expenses in the period identified.

Milestone and Royalty Payments Under In-licensing and Other Research & Development Agreements

Under our in-licensing and other research and development agreements, we could be required to pay development, regulatory, and sales-based milestone payments if certain substantive milestones are met. We generally expense development milestones as incurred. For regulatory or sales-based milestones that are associated with an approved asset, we capitalize the milestone payments related to the asset purchase as a finite-lived intangible asset provided that the milestone payment is recoverable based on our estimated projected cash flows and if the asset has alternative future use. Such intangible asset is amortized over its estimated useful life on a straight-line basis, beginning on the date the asset is acquired, which would generally be the regulatory approval date. We assess the carrying value of our finite-lived intangible assets for impairment whenever events or changes in circumstances indicate that the carrying value may not be fully recoverable. Recoverability of finite-lived intangible assets is measured by comparison of the carrying value of the asset to the future undiscounted cash flows the asset is expected to generate.

We could also be required to pay royalties based on actual net sales under in-licensing agreements. Such royalties are expensed in the period of sale of the product.

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Selling, general and administrative expenses

Selling, general and administrative expenses include all costs that are not directly related to revenue generating arrangements or research and development. Selling, general and administrative expenses include items for the Company's selling and administrative functions, such as pre-commercialization, finance, legal, human resources, and information technology support. These functions include costs for items such as salaries and benefits, stock-based compensation and other personnel-related costs, professional fees for external legal, accounting, and other consulting services, allocated facility costs, and depreciation and amortization expenses.

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 amounted to \$110.1 million and \$21.5 million for the years ended December 31, 2025 and 2024, respectively, and are included in "Selling, general and administrative expenses" on the consolidated statements of operations. Advertising costs for the year ended December 31, 2023 were immaterial. 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. The deferred advertising costs were nil as of December 31, 2025 and 2024, respectively.

Restructuring, Impairment, and Related Charges

Long-lived assets are reviewed for impairment annually or whenever events or changes in circumstances, including restructuring and exit activities, indicate that the carrying amount of an asset may not be recoverable. Recoverability is measured by comparison of the carrying amount of an asset group to the future net undiscounted cash flows that the assets are expected to generate. If the carrying amount of an asset group exceeds its estimated future cash flows, an impairment charge is recognized in the amount by which the carrying amount of the asset group exceeds the fair value of the asset group.

Costs related to contracts without future benefit or contract termination costs are recognized at the earlier of the contract termination or the cease-use dates. Employee severance costs are generally recognized when payments are probable and amounts are reasonably estimable. Other winding down and exit-related costs are recognized as incurred.

Stock-Based Compensation

Stock-based compensation arrangements include stock option grants, restricted stock awards ("RSAs"), and restricted stock units ("RSUs") under our equity incentive plans, as well as shares issued under our Employee Stock Purchase Plan ("ESPP"), through which employees may purchase our common stock at a discount to the market price.

We use the Black-Scholes option pricing model to estimate the fair value of options granted under our equity incentive plans and rights to acquire shares granted under our ESPP. The Black-Scholes option valuation model requires the use of assumptions, including the expected term of the award and the expected share price volatility. We use the "simplified" method to estimate the expected option term.

Stock-based compensation is measured at the grant date for all stock-based awards made to employees and consultants based on the fair value of the awards. Compensation expense for purchases under the ESPP is recognized based on the fair value of the award on the date of offering. Stock-based compensation is recognized as expense on a straight-line basis over the requisite service period, which is generally the vesting period.

The estimated fair value of equity awards that contain performance conditions is expensed using an accelerated method over the term of the award once we have determined that it is probable that performance milestones will be achieved. Compensation expense for equity-classified awards that contain performance conditions is measured based on the grant date fair value of the award. Compensation expense for liability-classified awards that contain performance conditions is initially measured based on the grant date fair value of the award and is remeasured at fair value at each reporting date until the date of settlement. Compensation expense is recorded over the requisite service period based on management's best estimate as to whether it is probable that the shares awarded are expected to vest. We assess the probability of the performance milestones being met on a continuous basis.

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We have elected to recognize the actual forfeitures by reducing the stock-based compensation in the same period as the forfeitures occur.

Market-based performance equity awards vest based on achievement of market targets, which are subject to the continued service of the employee through the vest date, and are subject to accelerated vesting upon a change in control event. The grant-date fair value of the market-based performance equity awards is determined using the Monte-Carlo valuation model and are recognized as compensation expense over the derived service period of the awards. The Monte-Carlo valuation model requires the use of assumptions, including but not limited to the expected volatility, risk-free rate, expected dividend yield, expected term and possible future market estimates over the derived service period based on historical stock prices and market data. Stock-based compensation expense will be recorded regardless of whether the market conditions are achieved or not. If the related market condition is achieved earlier than its estimated derived service period, the stock-based compensation expense will be accelerated, and a cumulative catch-up expense will be recorded during the period in which the market condition is met.

Stock-based compensation is recorded in cost of goods sold, research and development expense, and selling, general and administrative expense based on the function of the applicable employee and consultants.

Accrued Milestone Compensation Arrangements

We have performance-based milestone compensation arrangements with certain employees and consultants, whose vesting is contingent upon meeting various regulatory and development milestones, with fixed monetary amounts known at inception that can be settled in the form of (1) cash, (2) equity of BridgeBio, or (3) cash or equity of BridgeBio at our sole election, upon achievement of each contingent milestone. For arrangements that involve settlement by cash or equity of BridgeBio at our sole election, we will classify the milestone compensation arrangements as liability-classified awards when it is probable of achievement because of the possible fixed monetary amounts settlement outcomes. The arrangements would also result in settlement with a variable number of shares based on the then-current stock price at achievement date of each contingent milestone should we elect to settle in equity.

We record accruals for the compensation expense arising from each development milestone when the specific contingent development milestone is probable of achievement and such accruals are measured at each reporting period. We estimate the probability of achieving such milestones based on the progression and expected outcome of the related clinical programs. We base our estimates on the best available information at that time. However, additional information may become available to us which may allow us to make a more accurate estimate in future periods. In this event, we may be required to record adjustments to milestone compensation expenses in future periods. Any increases or decreases in such expenses are generally considered to be changes in estimates and will be reflected in the period identified.

Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax base and net operating loss and tax credit carryforwards. Deferred tax assets and liabilities are determined based upon the difference between the consolidated financial statement carrying amounts and the tax basis of assets and liabilities and are measured using the enacted tax rate expected to apply to taxable income in the years in which the differences are expected to be reversed. Deferred tax assets are reduced by a valuation allowance if it is more likely than not that some portion or all of the deferred tax asset will not be realized.

For U.S. federal income tax purposes, we are required to file a consolidated U.S. federal income tax return for the consolidated entities which meet the requirements as prescribed by the consolidated regulations. Those entities that do not meet the threshold to be included in the consolidated filing continue to file separate U.S. federal income tax returns. We are required to assess stand-alone valuation allowances separately in each entity even though we consolidate their financial results in the consolidated financial statements. We continue to file combined state tax returns in most jurisdictions. As a result, we continue to assess the state portion of valuation allowance for those jurisdictions on a consolidated basis. The Company also operates in various foreign jurisdictions and assesses stand-alone valuation allowances separately in each entity operating overseas.

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Current tax law in the United States imposes tax on U.S. stockholders for global intangible low-taxed income (“GILTI”) earned by certain foreign subsidiaries. The Company is required to make an accounting policy election of either: (1) treating taxes due on future amounts included in the U.S. taxable income related to GILTI as a current period tax expense when incurred (“the period cost method”); or (2) factoring such amounts into the Company’s measurement of its deferred tax expense (the “deferred method”). The Company has elected the period cost method for its accounting for GILTI.

We evaluate our deferred tax assets regularly to determine whether adjustments to the valuation allowance are appropriate due to changes in facts or circumstances, such as changes in expected future pre-tax earnings, tax law, interactions with taxing authorities and developments in case law. In making this evaluation, we rely on our recent history of pre-tax earnings. Our material assumptions are our forecasts of future pre-tax earnings and the nature and timing of future deductions and income represented by the deferred tax assets and liabilities, all of which involve the exercise of significant judgment. Although we believe our estimates are reasonable, we are required to use significant judgment in determining the appropriate amount of valuation allowance recorded against deferred tax assets.

We recognize uncertain income tax positions at the largest amount that is more likely than not to be sustained upon audit by the relevant taxing authority. Changes in recognition or measurement are reflected in the period in which judgment occurs. Our policy is to recognize interest and penalties related to the underpayment of income taxes as a component of the provision for income taxes. To date, there have been no interest or penalties recorded in relation to unrecognized tax benefits.

Net Loss per Share Attributable to Common Stockholders of BridgeBio

Basic net loss per share attributable to common stockholders of BridgeBio is calculated 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 RSUs and RSAs and performance-based milestone compensation awards, shares issuable under our ESPP and assumed conversion of our 2031 Notes, 2029 Notes, and 2027 Notes. 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. Since we were in a loss position for all periods presented, basic net loss per share attributable to common stockholders of BridgeBio is the same as diluted net loss per share attributable to common stockholders of BridgeBio since the effects of potentially dilutive securities are antidilutive.

Recently Adopted Accounting Pronouncement

In December 2023, the FASB issued Accounting Standards Update (“ASU”) 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*, which requires public companies on an annual basis to disclose specific categories in the income-tax rate reconciliation, provide information for reconciling items that meet a quantitative threshold, and disclose certain information about income taxes paid. We adopted this guidance for the year ended December 31, 2025, on a retrospective basis. There was no impact from the adoption of this ASU on our consolidated financial statements, however we included additional disclosures in our income tax disclosure. Refer to Note 17 for further discussions on income taxes.

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.

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In November 2024, the FASB issued 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 plans to adopt this standard effective January 1, 2026, and does not expect the adoption of this ASU to have a material 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 plans to adopt this standard effective January 1, 2026, and does not expect the adoption of this ASU to have a material impact on its 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 2029, 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 is currently evaluating the impact of the adoption of this new guidance 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.

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3. Fair Value Measurements

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

	December 31, 2025			
	Total	Level 1	Level 2	Level 3
	(in thousands)			
Assets				
Cash equivalents:				
Money market funds	\$ 132,602	\$ 132,602	\$ —	\$ —
Treasury bills	11,960	—	11,960	—
Agency discount notes	25,938	—	25,938	—
Total cash equivalents	170,500	132,602	37,898	—
Marketable securities:				
Treasury bills	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
	December 31, 2024			
	Total	Level 1	Level 2	Level 3
	(in thousands)			
Assets				
Cash equivalents:				
Money market funds	\$ 294,872	\$ 294,872	\$ —	\$ —
Treasury bills	20,714	—	20,714	—
Agency discount notes	44,205	—	44,205	—
Total cash equivalents	359,791	294,872	64,919	—
Total financial assets	\$ 359,791	\$ 294,872	\$ 64,919	\$ —
Liability				
Embedded derivative (included in “Deferred royalty obligations, net”)	\$ 41,091	\$ —	\$ —	\$ 41,091

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.

BRIDGEBIO PHARMA, INC.
Notes to Consolidated Financial Statements

Investment in Equity Securities

Our investment in equity securities, which only consisted of an investment in LianBio, had an aggregate fair value of nil as of December 31, 2025 and 2024 (refer to Note 6).

For the year ended December 31, 2025, we did not recognize any realized or unrealized gains or losses associated with investment in equity securities. For the year ended December 31, 2024, we recognized realized gains of \$8.1 million and no unrealized gains or losses associated with investment in equity securities. For the year ended December 31, 2023, we recognized realized gains of \$8.7 million and unrealized gains of \$9.6 million associated with investment in equity securities.

Notes

The fair values of our 1.75% convertible senior notes due 2031 (the “2031 Notes”), 2.25% convertible senior notes due 2029 (the “2029 Notes”) and our 2.50% convertible senior notes due 2027 (the “2027 Notes”) (collectively, the “Notes”, refer to Note 9), 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:

	December 31, 2025		December 31, 2024	
	Aggregate Face Values	Estimated Fair Values	Aggregate Face Values	Estimated Fair Values
	(in thousands)			
2031 Convertible Notes	\$ 575,000	\$ 1,003,783	\$ —	\$ —
2029 Convertible Notes	\$ 747,500	\$ 833,625	\$ 747,500	\$ 640,708
2027 Convertible Notes	\$ 550,000	\$ 1,019,975	\$ 550,000	\$ 578,087

Term Loan

The fair value of our outstanding term loan under the Amended Financing Agreement (as defined and discussed in Note 9) as of December 31, 2024 was estimated using the net present value of the payments, discounted at an interest rate that is consistent with a market interest rate, which is a Level 2 input. The estimated fair value of our outstanding term loan under the Amended Financing Agreement as of December 31, 2024 was \$461.8 million. The Company fully repaid the term loan under the Amended Financing Agreement in February 2025.

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 10, 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 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 consolidated statements of operations. The assumptions used in the option pricing Monte Carlo simulation model incorporates 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 Attriby and Beyontra; (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, net of the bifurcated embedded derivative liability, had an estimated fair value of \$565.5 million and \$446.0 million as of December 31, 2025 and 2024, respectively. For the year ended December 31, 2025 and for the period from November 22, 2024 through December 31, 2024, we recognized a \$19.7 million and \$1.6 million gain, respectively, for the change in fair value of the embedded derivative liability in “Other income (expense), net” on our consolidated statements of operations.

The deferred royalty obligation under the Royalty Purchase Agreement, as defined and discussed further in Note 10, had an estimated fair value of \$343.0 million as of December 31, 2025 based on the Monte Carlo simulation model.

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4. Cash Equivalents and Marketable Securities

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

Cash equivalents and marketable securities consisted of the following:

	December 31, 2025			
	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Estimated Fair Value
	(in thousands)			
Cash equivalents:				
Money market funds	\$ 132,602	\$ —	\$ —	\$ 132,602
Treasury bills	11,957	3	—	11,960
Agency discount notes	25,933	5	—	25,938
Total cash equivalents	\$ 170,492	\$ 8	\$ —	\$ 170,500
Marketable securities:				
Treasury bills	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
	December 31, 2024			
	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Estimated Fair Value
	(in thousands)			
Cash equivalents:				
Money market funds	\$ 294,872	\$ —	\$ —	\$ 294,872
Treasury bills	20,710	4	—	20,714
Agency discount notes	44,201	4	—	44,205
Total cash equivalents	\$ 359,783	\$ 8	\$ —	\$ 359,791

There were no marketable securities as of December 31, 2024.

5. Noncontrolling Interests

As of December 31, 2025 and 2024, we had both redeemable convertible noncontrolling interests and noncontrolling interests in consolidated partially-owned entities, for which BridgeBio is the primary beneficiary under the VIE model. These balances are reported as separate components outside stockholders' deficit in "Redeemable convertible noncontrolling interests" and as part of stockholders' deficit in "Noncontrolling interests" on the consolidated balance sheets.

We adjust the carrying value of noncontrolling interests to reflect the book value attributable to noncontrolling stockholders of consolidated partially-owned entities when there is a change in the ownership during the respective reporting period and such adjustments are recorded to additional paid-in capital. For the years ended December 31, 2025, 2024 and 2023, the adjustments in the aggregate amounted to \$(5.6) million, \$(5.8) million and \$(10.5) million, respectively. All such adjustments are disclosed within the "Transfers from (to) noncontrolling interests" line item on the consolidated statements of redeemable convertible noncontrolling interests and stockholders' deficit.

BRIDGEBIO PHARMA, INC.
Notes to Consolidated Financial Statements

6. Equity Method Investments and Other Equity Security Investment

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. On August 16, 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 third-party investors committed \$300.0 million of tranching financing to GondolaBio, of which \$60.0 million had been contributed as of September 30, 2024. 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%, which had a fair value of \$50.0 million, and will be subject to reduction as additional tranches of capital contributions are funded. As of December 31, 2025, the Company’s equity ownership percentage in GondolaBio was 27.5%.

On August 16, 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. On August 16, 2024, we recognized a \$52.0 million gain on deconsolidation, which is presented as part of “Gain on deconsolidation of subsidiaries” on our consolidated statements of operations.

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. BridgeBio’s equity investment in GondolaBio, valued at \$50.0 million upon deconsolidation, includes an implied difference of \$23.9 million between the fair value of the equity investment and the underlying equity in the net assets of GondolaBio (referred to as a “basis difference”) which was allocated to GondolaBio’s in-process research and development asset (“GondolaBio IPR&D asset”). The basis difference is amortized as a component of the net loss from equity method investment over the useful life of the GondolaBio IPR&D asset. The amortization of the GondolaBio IPR&D asset for the year ended December 31, 2025 was \$1.2 million. The amortization of the GondolaBio IPR&D asset for the period from August 16, 2024 through December 31, 2024 was \$0.4 million.

For the year ended December 31, 2025, the Company recognized a net loss from equity method investment of \$35.1 million. For the period from August 16, 2024 through December 31, 2024, the Company recognized a net loss from equity method investment of \$8.5 million. As of December 31, 2025 and 2024, the aggregate carrying amount of the Company’s equity method investment in GondolaBio was \$6.4 million and \$41.5 million, respectively, and is presented as part of “Equity method investments” on the consolidated balance sheets.

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Notes to Consolidated Financial Statements

In addition, on August 16, 2024, the Company and GondolaBio entered into a 24-month transition services agreement (the “GondolaBio Transition Services Agreement”) for the provision of certain transitional consulting services to be provided by the Company and GondolaBio. On November 4, 2025, the Gondola Transition Services Agreement was amended mainly to reflect the assignment of the GondolaBio Transition Services Agreement to GondolaBio ServiceCo, Inc. (a wholly-owned subsidiary of GondolaBio), extend the term for an additional 14 months, revise cost calculation methodologies, and update quarterly service schedules and related operating expense estimates. All other terms of the original agreement remain substantially unchanged. In October 2024, the Company and GondolaBio entered into an agreement for a partial sublease of a facility which was amended and renewed in October 2025 (“sublease agreement”). Under the GondolaBio Transition Services Agreement and the sublease agreement, the Company recognized \$11.7 million and \$1.3 million, respectively, in other income and \$5.1 million and \$0.8 million, respectively, of pass-through costs and sublease income recorded as an offset against operating expenses for the years ended December 31, 2025 and 2024. As of December 31, 2025 and 2024, the Company had \$4.5 million and \$3.2 million, respectively, in prepaid expenses and other current assets for transitional consulting services provided by BridgeBio to GondolaBio and for sublease income. The Company also recognized \$1.5 million and \$0.7 million in research and development expenses for the years ended December 31, 2025 and 2024, respectively, for transitional consulting services provided by GondolaBio to BridgeBio. As of December 31, 2025 and 2024, the Company also had \$1.5 million and \$1.2 million, respectively, in other current liabilities for transitional 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 and recognized a \$126.3 million gain on deconsolidation, which is presented as part of “Gain on deconsolidation of subsidiaries” on our consolidated statements of operations. The gain on deconsolidation represents the difference between BridgeBio’s equity investment in Legacy BBOT, valued at \$124.9 million upon deconsolidation and the carrying value of the net assets held by 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. BridgeBio’s equity investment in Legacy BBOT, valued at \$124.9 million upon deconsolidation, was compared to BridgeBio’s percentage of underlying equity in net assets of Legacy BBOT, which includes an implied difference of \$49.6 million between the fair value of the equity investment and the underlying equity in the net assets of Legacy BBOT (referred to as a “basis difference”). The basis difference was attributed to Legacy BBOT’s in-process research and development asset (“BBOT IPR&D asset”) and is amortized as a component of the net loss from equity method investment over the estimated useful life of the BBOT IPR&D asset. The amortization of the BBOT IPR&D asset for the year ended December 31, 2025 was \$2.4 million. The amortization of the BBOT IPR&D asset for the period from May 1, 2024 through December 31, 2024 was \$1.7 million.

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 December 31, 2025. BridgeBio continues to account for its retained investment in BBOT, for which it has significant influence, using the equity method of accounting.

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Notes to Consolidated Financial Statements

For the year ended December 31, 2025, we recognized a net loss from equity method investment of \$37.5 million. For the period from May 1, 2024 through December 31, 2024, we recognized a net loss from equity method investment of \$22.7 million. As of December 31, 2025 and 2024, the aggregate carrying amount of our equity method investment in BBOT was \$72.5 million and \$102.2 million, respectively, and is presented as part of “Equity method investments” on our consolidated balance sheets. As of December 31, 2025, the Level 1 fair value of our investment in BBOT was \$182.7 million based on the quoted market price for BBOT’s common stock as of December 31, 2025.

In addition, on April 30, 2024, the Company and Legacy BBOT entered into an 18-month transition service agreement (the “BBOT Transition Services Agreement”) for the provision of certain transitional consulting services to be provided by the Company and Legacy BBOT. Under the BBOT Transition Services Agreement, the Company recognized \$1.1 million and \$2.1 million, respectively, in other income and \$0.5 million and \$0.7 million, respectively, as an offset against operating expenses during the years ended December 31, 2025 and 2024. As of December 31, 2025 and 2024, the Company had \$0.6 million and \$0.5 million, respectively, in prepaid expenses and other current assets for transitional consulting services provided by BridgeBio to BBOT. The Company recognized an immaterial amount and \$0.8 million, respectively, in research and development expenses for the years ended December 31, 2025 and 2024 for transitional consulting services provided by BBOT to BridgeBio. As of December 31, 2025 and 2024, the Company also had immaterial amounts in accrued research and development liabilities for transitional consulting services provided by BBOT to BridgeBio.

In August 2025, the Company and BBOT entered into an amendment to the BBOT Transition Services Agreement, pursuant to which BBOT agreed to issue 784,720 shares of its common stock to the Company by October 31, 2025. The shares were issued on October 10, 2025. We recorded \$7.8 million as an increase to the value of our BBOT equity method investment on our consolidated balance sheets with a corresponding amount recognized in “Other income, net” on our consolidated statements of operations.

LianBio

In October 2019, our subsidiary, BridgeBio Pharma LLC (“BBP LLC”), entered into an exclusivity agreement with LianBio, an exempt company organized under the laws of the Cayman Islands (together with its subsidiaries, “LianBio”), pursuant to which BBP LLC received equity in LianBio (the “LianBio Exclusivity Agreement”). We accounted for BBP LLC’s equity interest in LianBio under ASC 321 as an investment in equity securities.

Pursuant to a License Agreement entered into in October 2019 between QED Therapeutics, Inc. (“QED”) and LianBio (the “QED-LianBio License Agreement”), QED also received warrants which entitle QED to purchase 10% of the then-fully diluted shares of one of the subsidiaries of LianBio upon achievement of certain contingent development milestones.

In October 2021, the warrants held by QED to purchase shares of one of the subsidiaries of LianBio were converted into a warrant (the “LianBio Warrant”), which entitles QED to purchase 347,569 shares of LianBio. The LianBio Warrant was measured at fair value on a recurring basis, with changes in fair value recognized in our consolidated statements of operations as part of “Other income (expense), net.” On February 20, 2024, QED exercised the 347,569 shares of the LianBio Warrant it held for an immaterial amount. Changes in fair value of the LianBio Warrant were not material for the years ended December 31, 2024 and 2023. The LianBio Warrant, which is presented as part of “Other assets” on our consolidated balance sheets, had a fair value of \$1.6 million as of December 31, 2023.

On February 13, 2024, LianBio announced plans to wind down its operations, including the sale of its remaining assets, delisting of its American Depository Shares from the Nasdaq Global Market, deregistration under Section 12(b) of the Securities Act of 1934, and workforce reductions. LianBio’s Board of Directors declared a special cash dividend of \$4.80 per ordinary share, net of applicable depository fees of \$0.05 per share held and applicable taxes. In March 2024, we received net proceeds of \$25.7 million in a special cash dividend and recognized net realized gains of \$1.8 million from our investment in LianBio equity securities. In June 2025, LianBio’s Board of Directors declared a special cash dividend of \$0.43 per ordinary share, net of applicable depository fees of \$0.05 per share held and applicable taxes. In July 2025, we received net proceeds of \$2.3 million in a special cash dividend, which we recognized as other income in “Other income (expense), net” on our consolidated statements of operations. As of December 31, 2025, the Company held 5,350,361 shares of LianBio common stock.

For the year ended December 31, 2023, we recorded an unrealized gain of \$14.2 million for the mark-to-market adjustments of our investment.

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7. Intangible Assets, net

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

	December 31, 2025		December 31, 2024	
	Weighted-average Estimated Useful Lives	Amount	Weighted-average Estimated Useful Lives	Amount
		(in thousands)		(in thousands)
Gross amount	13.7 years	\$ 39,400	10.0 years	\$ 32,500
Less accumulated amortization		(11,323)		(8,574)
Total		\$ 28,077		\$ 23,926

The Company's intangible assets primarily consist of acquired intellectual property rights, including patents and proprietary know-how, related to infigratinib, a compound targeting fibroblast growth factor receptor ("FGFR"). Following FDA approval of TRUSELTIQ™ in May 2021, these assets were initially recognized in relation to milestone payments made totaling \$32.5 million. While the FDA announced the withdrawal of the approval for TRUSELTIQ™ in May 2023, the intellectual property is still being utilized by the Company in its ongoing clinical investigations involving other FGFR-related conditions.

In addition, as a result of the regulatory milestone achieved in February 2025 under the Bayer License Agreement (as defined below) and the regulatory milestone achieved in May 2025 under the Eidos-Alexion Agreement (as defined below), we paid regulatory milestone fees to Leland Stanford Junior University ("Stanford University") in the aggregate amount of \$6.9 million during the year ended December 31, 2025. We capitalized these license fees as finite-lived intangible assets and amortize them over their estimated useful lives on a straight-line basis. Refer to Notes 11 and 12 for definitions and details regarding the Bayer License Agreement, the Eidos-Alexion License Agreement, and the Stanford License Agreement.

Amortization expense, recorded as part of "Cost of license, services, and royalty revenue" on our consolidated statements of operations for the years ended December 31, 2025, 2024, and 2023, was \$2.7 million, \$2.4 million and \$2.4 million, respectively. Estimated future amortization expense is \$2.9 million for each of the years from 2026 to 2030 and \$13.6 million thereafter.

8. Commitments and Contingencies

Milestone Compensation Arrangements

We have performance-based milestone compensation arrangements with certain employees and consultants, whose vesting is contingent upon meeting various 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 2020 Stock and Equity Award Exchange Program (the "Exchange Program", refer to Note 15). The compensation arrangements under the Exchange Program 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 RSAs. 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 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 December 31, 2025.

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Settlement Type	Potential Fixed Monetary Amount	Accrued Amount ⁽¹⁾
	(in thousands)	
Cash	\$ 805	\$ 78
Stock ⁽²⁾	14,432	—
Cash or stock at our sole discretion	53,763	1,003
Total	\$ 69,000	\$ 1,081

⁽¹⁾ Amount recorded for performance-based milestone awards that are probable of achievement.

⁽²⁾ Includes the performance-based milestone awards that were granted as part of the Exchange Program further discussed in Note 15.

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 products, contract research organizations for services related to clinical trials, CMOs for clinical supplies, and other vendors for preclinical studies, supplies, and other operating purposes. These contracts generally provide for termination on notice with potential termination charges. As of December 31, 2025 and 2024, 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 noncancellable 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 December 31, 2025, we have minimum noncancellable commitments in aggregate of \$110.2 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 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 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.

9. Debt

Notes

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 of 1933, as amended (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.

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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 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 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 2029 Notes and 2027 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.

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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 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.

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).

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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 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 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; 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 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.

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 semi-annually 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

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- Upon the occurrence of specified corporate events, as defined in the 2027 Notes Indenture.

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, regardless of the foregoing.

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 number of shares issuable should there be an increase in the conversion rate is 17,707,635 shares of BridgeBio's common stock.

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; 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 consolidated balance sheets and was amortized to interest expense using the effective interest method over the expected life of the 2027 Notes, which is approximately seven years.

As of December 31, 2025, the 2029 Notes were not convertible. The holders of the 2027 Notes and 2031 Notes, however, have the right to convert their notes during the period from January 1, 2026 through March 31, 2026 because an early conversion condition relating to the price of BridgeBio's common stock, as discussed above, was met, which resulted in the 2027 Notes and 2031 Notes becoming convertible for a limited period beginning January 1, 2026. Notwithstanding the satisfaction of this conversion condition, the 2027 Notes and 2031 Notes were classified as noncurrent liabilities as of December 31, 2025 because the Company has the ability to settle any conversions in shares of BridgeBio's common stock, as permitted under the terms of the 2027 Notes Indenture and 2031 Notes Indenture, respectively.

Additional Information Related to the Notes

The outstanding Notes' balances consisted of the following:

	December 31, 2025			December 31, 2024	
	2031 Notes	2029 Notes	2027 Notes	2029 Notes	2027 Notes
	(in thousands)			(in thousands)	
Principal	\$ 575,000	\$ 747,500	\$ 550,000	\$ 747,500	\$ 550,000
Unamortized debt discount and issuance costs	(10,435)	(6,610)	(2,985)	(8,628)	(4,827)
Net carrying amount	<u>\$ 564,565</u>	<u>\$ 740,890</u>	<u>\$ 547,015</u>	<u>\$ 738,872</u>	<u>\$ 545,173</u>

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

	Year Ended December 31, 2025			
	2031 Notes	2029 Notes	2027 Notes	Total
	(in thousands)			
Contractual interest expense	\$ 8,469	\$ 16,819	\$ 13,750	\$ 39,038
Amortization of debt discount and issuance costs	1,599	2,018	1,842	5,459
Total interest and amortization expense	<u>\$ 10,068</u>	<u>\$ 18,837</u>	<u>\$ 15,592</u>	<u>\$ 44,497</u>
Effective interest rate	2.1%	2.6%	2.8%	

	Year Ended December 31, 2024		
	2029 Notes	2027 Notes	Total
	(in thousands)		
Contractual interest expense	\$ 16,819	\$ 13,750	\$ 30,569
Amortization of debt discount and issuance costs	1,967	1,794	3,761
Total interest and amortization expense	<u>\$ 18,786</u>	<u>\$ 15,544</u>	<u>\$ 34,330</u>
Effective interest rate	2.6%	2.8%	

	Year Ended December 31, 2023		
	2029 Notes	2027 Notes	Total
	(in thousands)		
Contractual interest expense	\$ 16,819	\$ 13,750	\$ 30,569
Amortization of debt discount and issuance costs	1,917	1,745	3,662
Total interest and amortization expense	<u>\$ 18,736</u>	<u>\$ 15,495</u>	<u>\$ 34,231</u>
Effective interest rate	2.6%	2.8%	

As of December 31, 2025, interest payable on the 2031 Notes, 2029 Notes, and 2027 Notes amounted to \$3.4 million, \$7.0 million and \$4.0 million, respectively. As of December 31, 2024, interest payable on the 2029 Notes and 2027 Notes amounted to \$7.0 million and \$4.0 million, respectively. Such amounts are included in "Other current liabilities" on our consolidated balance sheets.

Future minimum payments under the Notes as of December 31, 2025 are as follows:

	2031 Notes	2029 Notes	2027 Notes	Total
	(in thousands)			
Year ending December 31:				
2026	\$ 10,063	\$ 16,819	\$ 13,750	\$ 40,632
2027	10,063	16,819	556,875	583,757
2028	10,063	16,819	—	26,882
2029	10,063	755,909	—	765,972
2030	10,063	—	—	10,063
Thereafter	580,031	—	—	580,031
Total future payments	630,346	806,366	570,625	2,007,337
Less amounts representing interest	(55,346)	(58,866)	(20,625)	(134,837)
Total principal amount	<u>\$ 575,000</u>	<u>\$ 747,500</u>	<u>\$ 550,000</u>	<u>\$ 1,872,500</u>

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Capped Call and Share Repurchase Transactions with Respect to the 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 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 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 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.

Additionally, we used approximately \$50.0 million and \$75.0 million of the net proceeds from the 2021 Note Offering and 2020 Note Offering to repurchase 759,993 shares and 2,414,681 shares, respectively, of our common stock concurrently with the closing of the Note Offerings from certain of the Notes’ Initial Purchasers in privately negotiated transactions. The agreed purchase price per share of common stock in the repurchases were \$65.79 and \$31.06, which were the last reported sale prices per share of our common stock on The Nasdaq Global Select Market, on January 25, 2021 and March 4, 2020, respectively. The shares repurchased were recorded as “Treasury stock” on our consolidated balance sheets and statements of redeemable convertible noncontrolling interests and stockholders’ deficit.

In February 2025, we used approximately \$48.3 million of the net proceeds from the 2025 Note Offering to repurchase 1,405,411 shares of our common stock concurrently with the closing of the 2025 Note Offering from certain of the 2031 Notes’ Initial Purchasers in privately negotiated transactions. The agreed purchase price per share of common stock in the repurchase was \$34.35, which was the last reported sale price per share of our common stock on the Nasdaq Global Select Market, on February 25, 2025. The shares repurchased were recorded as “Treasury stock” on our consolidated balance sheets and statements of redeemable convertible noncontrolling interests and stockholders’ deficit.

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. Refer to Note 19 for further details.

Term Loan, net

Loan and Security Agreement

In November 2021, we entered into a Loan and Security Agreement (the “Loan Agreement” and as amended by the First Amendment (as defined below) and the Second Amendment (as defined below), collectively the “Amended Loan Agreement”), by and among (i) U.S. Bank National Association, in its capacity as administrative agent and collateral agent, (ii) certain lenders, (iii) BridgeBio, as a borrower, and (iv) certain subsidiaries of BridgeBio, as guarantors. In May 2022, we entered into the First Amendment to the Loan Agreement (the “First Amendment”) and in November 2022, we entered into the Second Amendment to the Loan Agreement (the “Second Amendment”).

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Pursuant to the original terms and conditions of the Loan Agreement, the Lenders agreed to extend term loans to us in an aggregate principal amount of up to \$750.0 million, consisted of (i) a tranche 1 advance of \$450.0 million (the “Tranche 1 Advance”), and (ii) a tranche 2 advance of \$300.0 million (the “Tranche 2 Advance”) (collectively, the “Term Loan Advances”). The Tranche 1 Advance under the Loan Agreement was funded on November 17, 2021. The Tranche 2 Advance remained available for funding until December 31, 2023, which was available at our election after the occurrence of certain milestone events relating to data from our clinical trials. The First Amendment’s term included the reduction of the aggregate amount of the Tranche 2 Advance from \$300.0 million to \$100.0 million. The Second Amendment eliminated the \$100.0 million Tranche 2 Advance. As a result of the Second Amendment, the total aggregate principal amount of the loan was \$450.0 million before any mandatory prepayment.

We received net proceeds from the Tranche 1 Advance of \$431.3 million, after deducting debt discount and issuance costs of \$18.7 million, of which approximately \$1.1 million related to debt issuance costs.

Any outstanding principal on the Term Loan Advances accrued interest at a fixed rate equal to 9.0% per annum. 3.0% of which was eligible to be a payment-in-kind (“PIK”) until January 1, 2025. Pursuant to the terms of the Loan Agreement, we exercised our option to convert accrued interest into principal via PIK amounting to \$10.2 million for the year ended December 31, 2023.

On January 17, 2024, the Company fully repaid the Amended Loan Agreement for \$475.8 million, which consisted of \$455.4 million for the outstanding principal, \$9.1 million for the prepayment fee, \$8.6 million for the exit cost, \$2.4 million in accrued interest and \$0.3 million for transaction-related fees using the proceeds from the Financing Agreement (see below) and cash on hand, and recognized a loss on extinguishment of debt of \$26.6 million. For the period from January 1, 2024 through January 17, 2024, we recognized interest expense related to the Amended Loan Agreement of \$3.0 million, of which \$0.4 million related to amortization of debt discount and issuance costs. For the year ended December 31, 2023, we recognized interest expense related to the Amended Loan Agreement of \$46.3 million, of which \$5.2 million related to amortization of debt discount and issuance costs.

Financing Agreement

On January 17, 2024, the Company and each of the guarantors entered into a Financing Agreement, which was amended on February 12, 2024 (the “Financing Agreement”), with the lenders party thereto (the “Lenders”) and Blue Owl Capital Corporation, as administrative agent for the Lenders (the “Administrative Agent”). On June 20, 2024, the Company and each of the guarantors entered into the Second Amendment to the Financing Agreement (the Financing Agreement, as amended by the Second Amendment, the “Amended Financing Agreement”).

Pursuant to the terms and conditions of the Financing Agreement, the Lenders agreed to extend a senior secured credit facility to the Company in an aggregate principal amount of up to \$750.0 million, composed of (i) an initial term loan in an aggregate principal amount of \$450.0 million (the “Initial Term Loan”) and (ii) one or more incremental term loans in an aggregate amount not to exceed \$300.0 million (collectively, the “Incremental Term Loan,” and together with the Initial Term Loan, collectively, the “Term Loans”), subject to the satisfaction of certain terms and conditions set forth in the Financing Agreement.

In January 2024, we received net proceeds from the Initial Term Loan of \$434.0 million, after deducting debt discount and issuance costs of \$16.0 million.

On February 28, 2025, the Company fully repaid the Amended Financing Agreement for \$467.0 million, which consisted of \$450.0 million for the outstanding principal of the Initial Term Loan, \$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.

The balances of our borrowing under the Amended Financing Agreement consisted of the following:

	December 31, 2024
	(in thousands)
Principal value of term loan under the Amended Financing Agreement	\$ 450,000
Debt discount and issuance costs	(12,663)
Term loan, net	\$ 437,337

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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. For the year ended December 31, 2024, we recognized interest expense related to the Amended Financing Agreement of \$54.8 million, of which \$3.3 million relates to amortization of debt discount and issuance costs.

10. 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., a beneficial holder of the Company’s common equity and a related party, acquired a majority ownership interest in HCRx. Accordingly, HCRx became a related party of the Company following KKR & Co. Inc.’s acquisition of HCRx.

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 11), 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 obligation, net” on our 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.

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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 on November 22, 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 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 \$21.4 million and \$41.1 million as of December 31, 2025 and 2024, 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.

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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:

	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	<u>\$ 548,055</u>	<u>\$ 306,975</u>	<u>\$ 855,030</u>

(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.

	December 31, 2024	
	Funding Agreement	
	(in thousands)	
Carrying value of deferred royalty obligation, net	\$	507,114
Fair value of embedded derivative liability		41,091
Unamortized debt discount and issuance costs		(69,114)
Deferred royalty obligation, net	<u>\$</u>	<u>479,091</u>

The effective interest rate as of December 31, 2025 and 2024 was 22.2% and 19.3%, respectively, for the Funding Agreement. For the years ended December 31, 2025 and 2024, we recognized noncash interest expense related to the Funding Agreement of \$108.7 million and \$8.3 million, respectively, of which \$14.0 million and \$1.0 million, respectively, relates to amortization of debt discount and issuance costs. As of December 31, 2025 and 2024, the current portion of the deferred royalty obligation related to the Funding Agreement of \$8.2 million and \$0.1 million, respectively, is presented within “Other current liabilities” on our consolidated balance sheets.

The effective interest rate as of December 31, 2025 was 10.4% for Royalty Purchase Agreement. For the year ended December 31, 2025, we recognized noncash interest expense related to the Royalty Purchase Agreement of \$16.4 million, of which \$0.4 million relates to amortization of debt discount and issuance costs. As of December 31, 2025, the current portion of the deferred royalty obligation related to the Royalty Purchase Agreement of \$3.0 million is presented within “Other current liabilities” on our consolidated balance sheets.

11. 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”).

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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, which was received in full in May 2024, and will be eligible to receive up to \$150.0 million in regulatory and sales milestone payments through 2026 (of which a regulatory milestone of \$75.0 million was achieved in February 2025 upon EC approval of acoramidis under the brand name Beyontra and received in April 2025), and additional payments up to \$450.0 million subject to the achievement of certain sales milestones. 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 with 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 non-refundable 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 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. In February 2025, the EC granted marketing authorization in the EU for acoramidis, under the brand name Beyontra. 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 year ended December 31, 2025. We will continue to re-evaluate the transaction price at each reporting period and as uncertain events are resolved or other changes in circumstances occur. Upon receiving marketing authorization in the EU, Bayer began selling Beyontra, 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.

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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 \$0.6 million and \$1.0 million, respectively, of license and services revenue relating to this performance obligation during the years ended December 31, 2025 and 2024.

Under certain commercial and API supply agreements with an initial term ending in December 2026, we supplied \$7.6 million of product to Bayer during the year ended December 31, 2025, which are recorded in “License and services revenue” on our consolidated statements of operations. We did not supply any product under the Bayer Supply Agreements during the year ended December 31, 2024.

As of December 31, 2025 and 2024, there were \$5.0 million and nil, respectively, of outstanding receivables relating to the Bayer License Agreement on our consolidated balance sheets. During the years ended December 31, 2025 and 2024, we recognized license and services revenue and royalty revenue of \$93.8 million and \$131.5 million, respectively, under the Bayer License Agreement. Our 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. Our consolidated balance sheet as of December 31, 2024, includes a deferred revenue balance of \$3.5 million (\$1.3 million presented as “Deferred revenue, current portion” and \$2.2 million as “Deferred revenue, net of current portion”) related to our research and development services obligations.

Kyowa Kirin Exclusive License

On February 7, 2024, the Company’s subsidiary, 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, which was received in full in June 2024, and will be eligible to receive development and sales milestone payments up to \$81.4 million. 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 with 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.

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We determined the initial transaction price at inception of the KKC License Agreement to be \$100.0 million, which consisted of the fixed and non-refundable 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 December 31, 2025. 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 development services to extend through 2030. We recognized \$10.7 million and \$5.7 million of license and services revenue relating to this performance obligation during the years ended December 31, 2025 and 2024, respectively.

As of December 31, 2025 and 2024, there were immaterial amounts of outstanding receivables relating to the KKC License Agreement on our consolidated balance sheets. During the years ended December 31, 2025 and 2024, we recognized license and services revenue of \$12.3 million and \$76.2 million, respectively, under the KKC License Agreement. Our 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 and clinical supply. Our consolidated balance sheet as of December 31, 2024 includes a deferred revenue balance of \$25.2 million (\$10.3 million presented as "Deferred revenue, current portion" and \$14.9 million as "Deferred revenue, net of current portion") related to our research and development services obligation.

License, Development and Commercialization Agreement with BMS

On May 12, 2022, BridgeBio and our subsidiary, Navire Pharma, Inc. ("Navire"), entered into an exclusive license, development and commercialization agreement with Bristol-Meyers Squibb Company ("BMS") (the "Navire-BMS License Agreement"), pursuant to which Navire granted BMS exclusive rights to develop and commercialize Navire's product candidate, BBP-398, in all indications worldwide, except for the People's Republic of China, Macau, Hong Kong, Taiwan, Thailand, Singapore, and South Korea (collectively, the "Asia Region"). The Navire-BMS License Agreement expands an earlier agreement between Navire and BMS that was executed in July 2021 to study BBP-398 in a combination therapy trial to treat advanced solid tumors with KRAS mutations (the "2021 Navire-BMS Agreement"). The Navire-BMS License Agreement does not alter the terms of the 2021 Navire-BMS Agreement.

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In April 2024, Navire and BMS entered into a Clinical Collaboration Termination Agreement which terminated the 2021 Navire-BMS Agreement. Navire and BMS agreed to pursue reasonable efforts to wind down activities under both the Navire-BMS License Agreement and the 2021 Navire-BMS Agreement. In November 2025, the Navire-BMS License Agreement was formally terminated.

For the years ended December 31, 2024 and 2023, we recognized \$9.9 million and \$7.4 million, respectively, in license and services revenue relating to the Navire-BMS License Agreement. As of December 31, 2024, there were no remaining balances in deferred revenue on our consolidated balance sheets.

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, and in June 2025, Eidos received the \$30.0 million regulatory milestone payment. Under the Eidos-Alexion License Agreement, Eidos is eligible to receive royalties in the low-teens based on net sales 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.

In October 2024, Alexion initiated the ACT-EARLY clinical trial in Japan under the Eidos-Alexion License Agreement for an upfront payment of \$3.0 million. This initial payment was deferred upon receipt, and revenue is recognized over time relating to the research and development services for the ongoing clinical trial. During the years ended December 31, 2025 and 2024, we recognized \$0.2 million and nil, respectively, under the ACT-EARLY clinical trial in Japan.

As of December 31, 2025 and 2024, the receivables relating to the Eidos-Alexion License Agreement on our consolidated balance sheets were \$0.2 million and \$0.6 million, respectively. During the years ended December 31, 2025 and 2024, we recognized license and services and royalty revenue of \$33.3 million and \$0.6 million, respectively, under the Eidos-Alexion License Agreement. Our consolidated balance sheet as of December 31, 2025 includes a deferred balance of \$2.8 million (\$1.0 million presented as “Deferred revenue, current portion” and \$1.8 million presented as “Deferred revenue, net of current portion”) related to the ACT-EARLY clinical trial. Our consolidated balance sheet as of December 31, 2024 includes \$3.0 million presented as “Deferred revenue, current portion” related to the ACT-EARLY clinical trial as it was determined at that time the expenses would be incurred within a year.

12. 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 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 non-royalty revenue received by Eidos from its sublicensees, with the amount owed decreasing annually for three years based on when the applicable sublicense agreement is executed.

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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. For the year ended December 31, 2025, we incurred \$6.9 million of license fees due to Stanford University, which were related to the regulatory milestone achieved in February 2025 under the Bayer License Agreement (refer to Note 11) as well as the regulatory milestone achieved in May 2025 under the Eidos-Alexion License Agreement (refer to Note 11). These license fees were capitalized as finite-lived intangible assets (refer to Note 7). In addition, during the year ended December 31, 2025, we incurred \$6.8 million in royalties related to commercial sales of Attruby and Beyontra. For the year ended December 31, 2024, we incurred \$8.1 million of license fees due to Stanford University related to the Company entering into an exclusive license agreement with Bayer in March 2024 and an immaterial amount in royalties related to commercial sales of Attruby. For the year ended December 31, 2023, license fees incurred and due to Stanford University were immaterial.

Resilience Development and Manufacturing Service Agreements

In September 2023, BridgeBio Gene Therapy, LLC (“BBGT”), formerly Aspa Therapeutics, Inc., and Adrenas Therapeutics Inc. (“Adrenas”), each entered into a Development and Manufacturing Services Agreement (collectively the “Resilience DMSAs”) and a Project Agreement (collectively the “Resilience PAs”), (collectively the “Resilience Agreements”) with Resilience US, Inc. (“Resilience”), for Resilience to provide contract development, manufacturing, testing and related services with respect to therapeutic and pharmaceutical products for the clinical development applications of BBP-812 and BBP-631, respectively. BBP-812 is an intravenous Adeno-associated virus serotype 9 (“AAV9”) investigational drug product intended for the treatment of children with Canavan Disease, under the age of five years. BBP-631 is an intravenous adeno-associated virus 5 gene (“AAV5”) investigational drug product intended for the treatment of adults and children with congenital adrenal hyperplasia. The Resilience DMSAs have 10-year terms and may each be extended for additional two-year periods. Under the Resilience PAs, Resilience will provide BBGT with a cost-sharing credit of the lesser of a fixed percentage of certain agreed upon service costs or \$15.5 million. Under the Resilience PAs, Resilience will provide Adrenas with a cost-sharing credit of the lesser of a fixed percentage of certain agreed upon service costs or \$29.3 million. In addition to the payments for their share of services performed by Resilience, BBGT and Adrenas may each be required to make future payments of up to \$10.0 million upon achievement of certain development and approval milestone events, and royalty payments (mid-single digits for BBP-812 and low-single digits for BBP-631) based on achievement of certain net sales metrics.

In September 2024, we announced our decision to cease pursuing development of BBP-631, the Company’s investigational AAV5 gene therapy, for congenital adrenal hyperplasia (“CAH”), under our plans to reprioritize and advance our corporate strategy and development programs (Refer to Note 17 for additional details). In October 2024, Adrenas provided written notice to Resilience for the termination of the Development and Manufacturing Services Agreement and Project Agreement for the clinical application of BBP-631 effective October 2024, and all rights and obligations thereunder. In February 2025, BBGT provided written notice to Resilience for the termination of the Development and Manufacturing Services Agreement and Project Agreement for the clinical application of BBP-812 effective February 2025, and all rights and obligations thereunder.

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.

13. 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 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.

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The components of lease cost are as follows:

	Years Ended December 31,		
	2025	2024	2023
	(in thousands)		
Straight-line operating lease costs	\$ 4,902	\$ 4,110	\$ 4,032
Finance lease costs	367	395	420
Variable lease costs	4,417	6,305	6,844
Total lease cost	<u>\$ 9,686</u>	<u>\$ 10,810</u>	<u>\$ 11,296</u>

Supplemental cash flow information related to leases are as follows:

	Years Ended December 31,		
	2025	2024	2023
	(in thousands)		
Cash paid for amounts included in the measurement of lease liabilities:			
Operating cash flows for operating leases	\$ 6,547	\$ 5,092	\$ 4,829
Operating cash flows for finance lease	\$ 460	\$ 445	\$ 397
Operating lease right-of-use assets obtained in exchange for operating lease obligations	\$ 6,567	\$ 1,591	\$ 1,179

Supplemental information related to the remaining lease term and discount rate are as follows:

	December 31,		
	2025	2024	2023
Weighted-average remaining lease term (in years)			
Operating leases	2.9	3.6	4.7
Finance lease	0.1	1.1	2.1
Weighted-average discount rate			
Operating leases	6.8%	6.0%	6.0%
Finance lease	6.6%	6.6%	6.6%

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As of December 31, 2025, future minimum lease payments for our noncancelable operating leases are as follows. Future minimum lease payments under our finance lease are not material.

	<u>Amount</u>
	(in thousands)
Year ending December 31:	
2026	\$ 6,642
2027	1,320
2028	976
2029	494
2030	494
Thereafter	947
Total future minimum lease payments	10,873
Imputed interest	(870)
Total	<u>\$ 10,003</u>
Reported as of December 31, 2025	
Operating lease liabilities, current portion	\$ 6,192
Operating lease liabilities, net of current portion	3,811
Total operating lease liabilities	<u>\$ 10,003</u>

No impairment loss was recognized for the year ended December 31, 2025. The impairment loss recognized was immaterial for the years ended December 31, 2024 and 2023, respectively.

14. Public Offerings

2023 Follow-on Offering

In March 2023, we entered into an Underwriting Agreement (the “2023 Follow-on Agreement”) with Goldman Sachs & Co. LLC, Evercore Group L.L.C., Morgan Stanley & Co. LLC and KKR Capital Markets LLC (“KCM”), as representatives of several underwriters (collectively, the “Underwriters”), relating to an underwritten public offering (the “2023 Follow-on offering”) of 8,823,530 shares of the Company’s common stock, \$0.001 par value per share (the “Common Stock”), at a public offering price of \$17.00 per share. The Company also granted the Underwriters a 30-day option to purchase, at the public offering price less underwriting discounts and commissions, up to an additional 1,323,529 shares of Common Stock. The Company paid the Underwriters a commission of 4.3% of the aggregate gross proceeds received from all sales of the common stock under the 2023 Follow-on Agreement. The Underwriters included KCM, which is an affiliate of KKR Genetic Disorder L.P., a related party being a stockholder who beneficially owns greater than 5% of our outstanding securities. KCM received a commission of 0.315% of the aggregate gross proceeds received from all sales of the common stock under the 2023 Follow-on Agreement. On March 10, 2023, 8,823,530 shares were issued under the 2023 Follow-on Agreement, for net proceeds of \$143.0 million, after deducting underwriting fees and commissions of \$6.5 million (of which \$0.5 million related to commissions paid to KCM) and offering costs of \$0.5 million. On April 3, 2023, the Underwriters partially exercised their 30-day option to purchase additional shares, for which 63,470 shares were issued for net proceeds of \$1.0 million, after deducting underwriting fees and commissions of less than \$0.1 million.

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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 will pay 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. In 2023, 2,171,217 shares were issued under the ATM Agreement, for net proceeds of \$65.0 million, after deducting sales agent fees and commissions of \$1.0 million. In 2024, 1,061,991 shares were issued under the ATM Agreement, for net proceeds of \$38.1 million, after deducting sales agent fees and commissions of \$0.6 million. As of December 31, 2025, we are still eligible to sell up to \$345.3 million of our common stock pursuant to the ATM Agreement under the 2023 Shelf.

Securities Purchase Agreement and Private Placement

In September 2023, we and certain accredited investors (each an “Investor” and collectively, the “Investors”) entered into a securities purchase agreement pursuant to which we sold and issued to the Investors in a private placement (the “Private Placement”) an aggregate of 9,167,723 shares of our common stock, par value \$0.001 per share, at a purchase price of \$27.27 per share. We paid certain placement agents a commission based on the aggregate gross proceeds received from all sales of the common stock under the Private Placement. One of the placement agents in the Private Placement was KCM, which is an affiliate of KKR Genetic Disorder L.P., a related party being a stockholder who beneficially owns greater than 5% of our outstanding securities. KCM received a commission of \$1.8 million of the aggregate gross proceeds received from all sales of the common stock in the Private Placement. During the year ended December 31, 2024, we received net proceeds of \$240.8 million under the Private Placement offering, after deducting placement agent commissions of \$8.7 million and offering costs of \$0.5 million.

2024 Follow-on Offering

In March 2024, we entered into an Underwriting Agreement (the “2024 Follow-on Agreement”) with J.P. Morgan Securities LLC, Cantor Fitzgerald & Co. and Mizuho Securities USA LLC, as representatives of several underwriters (collectively, the “2024 Underwriters”), relating to an underwritten public offering (the “2024 Follow-on offering”) of 8,620,690 shares of the Company’s common stock, \$0.001 par value per share, at a public offering price of \$29.00 per share. The Company also granted the 2024 Underwriters a 30-day option to purchase, at the public offering price less underwriting discounts and commissions, up to an additional 1,293,103 shares of Common Stock, which the 2024 Underwriters exercised in full on the closing of the 2024 Follow-on offering. The Company paid the Underwriters a commission of 3.6% of the aggregate gross proceeds received from all sales of the common stock under the Follow-on Agreement. In March 2024, 9,913,793 shares (including the 1,293,103 shares issued upon exercise of the 2024 Underwriters’ option to purchase additional shares) were issued under the 2024 Follow-on Agreement, for net proceeds of \$276.6 million, after deducting underwriting fees and commissions of \$10.3 million and offering costs of \$0.6 million.

15. Stock-Based Compensation

Under each of the legal entity’s equity plans, we recorded stock-based compensation in the following expense categories on our consolidated statements of operations for employees and non-employees:

	Years Ended December 31,		
	2025	2024	2023
	(in thousands)		
Cost of goods sold	\$ 1,265	\$ —	\$ —
Research and development	49,267	49,844	61,647
Selling, general and administrative	84,656	63,862	53,369
Restructuring, impairment, and related charges	1,694	160	—
Total stock-based compensation	<u>\$ 136,882</u>	<u>\$ 113,866</u>	<u>\$ 115,016</u>

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We recorded \$3.9 million, \$18.1 million, and \$6.3 million of stock-based compensation expense for the years ended December 31, 2025, 2024 and 2023, respectively, for performance-based milestone awards that were achieved during the periods and were settled in cash. During the years ended December 31, 2025 and 2024, \$3.6 million, and an immaterial amount, respectively, of stock-based compensation expense were capitalized to inventories.

Equity-Based Awards of BridgeBio

In December 2023, the Amended and Restated 2019 Inducement Equity Plan (the “A&R 2019 Inducement Plan”) was amended and restated to increase the number of shares authorized for issuance from 2,000,000 shares to 3,750,000 shares. In June 2024, our stockholders approved an amendment and restatement of our 2021 Amended and Restated Stock Option and Incentive Plan (the “2021 A&R Plan”) to, among other things, increase the number of shares of common stock authorized for issuance by 6,500,000 shares. In June 2025, our stockholders further approved an amendment and restatement of the 2021 A&R Plan to, among other things, increase the number of shares of common stock authorized for issuance by 5,000,000 shares. As of December 31, 2025, 10,563,629 shares and 747,576 shares were reserved for future issuances under the 2021 A&R Plan and the A&R 2019 Inducement Plan, respectively. We also reserved 2,802,644 shares under the Eidos Award Exchange in 2021 (the “Eidos Award Exchange Plan”), all of which were issued upon execution of the Eidos Award Exchange as discussed below. The 2021 A&R Plan and the A&R 2019 Inducement Plan and the Eidos Award Exchange Plan are collectively referred herein as the “Plans.”

2020 Stock and Equity Award Exchange Program

On April 22, 2020, we completed our Exchange Program for certain subsidiaries, which was an opportunity for eligible controlled entities’ employees and consultants to exchange their subsidiary equity (including common stock, vested and unvested stock options and RSAs) for BridgeBio equity (including common stock, vested and unvested stock options and RSAs) and/or performance-based milestone awards tied to the achievement of certain development and regulatory milestones. The Exchange Program aligns our incentive compensation structure for employees and consultants across the BridgeBio group of companies to be consistent with the achievement of our overall corporate goals. In connection with the Exchange Program, we issued awards of BridgeBio equity under the 2019 Amended and Restated Stock Option and Incentive Plan (the “2019 A&R Plan”), which was amended and restated in December 2021 into the 2021 A&R Plan and further amended and restated in June 2024 and in June 2025, respectively, as mentioned above, to 149 grantees covering 554,064 shares of common stock, 1,268,110 stock options to purchase common stock, 50,145 shares of RSAs and 22,611 shares of performance-based RSAs. The exchange also included performance-based milestone awards of up to \$183.4 million to be settled in fully-vested RSAs in the future upon achievement of the milestones. In consideration for all the subsidiaries’ shares tendered, BridgeBio increased its ownership in controlled entities included in the Exchange Program and the corresponding noncontrolling interest decreased.

On November 18, 2020, we completed a stock and equity award under our Exchange Program for a subsidiary. We issued awards of BridgeBio equity under the 2019 A&R Plan to 16 grantees covering 24,924 shares of common stock, 70,436 stock options to purchase common stock, and 10,772 shares of performance-based stock options to purchase common stock. The exchange also included performance-based milestone awards of up to \$11.7 million to be settled in fully-vested RSAs in the future upon achievement of the milestones.

We evaluated the exchange of the controlled entities’ outstanding common stock and equity awards for BridgeBio awards as a modification under ASC 718, *Share Based Payments*. Under ASC 718, a modification is a change in the terms or conditions of a stock-based compensation award. In assessing the accounting treatment, we consider the fair value, vesting conditions and classification as an equity or liability award of the controlled entity equity before the exchange, compared to the BridgeBio equity received as part of the exchange to determine whether modification accounting must be applied. When applying modification accounting, we considered the type of modification to determine the appropriate stock-based compensation cost to be recognized on April 22 and November 18, 2020, (each the “Modification Date”), and subsequent to the Modification Date.

We considered the total shares of common stock and equity awards, whether vested or unvested, held by each participant in each controlled entity as the unit of account. The controlled entity’s common stock and equity awards in each unit of account was exchanged for a combination of BridgeBio’s common stock, time-based vesting equity awards and/or performance-based milestone awards. Other than the exchange of the controlled entity equity awards for performance-based milestone awards, all other exchanged BridgeBio equity awards retained the original vesting conditions. As a result, there was no incremental stock-based compensation expense resulting from the exchange of time-based equity awards.

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At the completion of the Exchange Program, we determined \$17.4 million of the performance-based milestone awards were probable of achievement and represented the incremental stock-based compensation cost resulting from the modification of time-based equity awards to performance-based milestone awards. These performance-based milestone awards were to be recognized over a period ranging from 0.7 years to 1.7 years. There was no incremental stock-based compensation cost arising from the completion of the Exchange Program on November 18, 2020. Under ASC 718, we account for such performance-based milestone awards as a liability in “Accrued compensation and benefits” and in “Other long-term liabilities” on the consolidated balance sheets due to the fixed milestone amount that will be converted into a variable number of shares of BridgeBio common stock to be granted upon the achievement date.

Stock Option Grants

The following table summarizes BridgeBio’s stock option activity under the Plans for the year ended December 31, 2025:

	Options Outstanding	Weighted-Average Exercise Price per Option	Weighted-Average Remaining Contractual Life (years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2024	12,499,883			
Regular equity program	11,172,627	\$ 25.76	6.2	\$ 78,764
Eidos Awards Exchange	1,014,175	\$ 14.18	4.3	\$ 13,734
Exchange Program	313,081	\$ 2.20	4.3	\$ 7,995
Granted	180,733			
Regular equity program	180,733	\$ 38.59		
Exercised	(1,180,825)			
Regular equity program	(835,876)	\$ 28.46		
Eidos Awards Exchange	(279,359)	\$ 13.96		
Exchange Program	(65,590)	\$ 0.68		
Cancelled	(7,583)			
Regular equity program	(7,583)	\$ 35.35		
Outstanding as of December 31, 2025	11,492,208			
Regular equity program	10,509,901	\$ 25.76	5.3	\$ 533,163
Eidos Awards Exchange	734,816	\$ 14.26	3.2	\$ 45,726
Exchange Program	247,491	\$ 2.61	3.5	\$ 18,285
Exercisable as of December 31, 2025	10,527,845			
Regular equity program	9,545,538	\$ 26.17	5.1	\$ 480,355
Eidos Awards Exchange	734,816	\$ 14.26	3.2	\$ 45,726
Exchange Program	247,491	\$ 2.61	3.5	\$ 18,285

The options granted to employees and non-employees are exercisable at the closing price as reported on the Nasdaq Global Select Market of BridgeBio’s common stock at the respective grant dates. The options granted have a service condition and generally vest over a period of three to four years.

The weighted-average grant date fair value of options granted during the year ended December 31, 2025 was \$30.15.

The aggregate intrinsic value of options outstanding and exercisable as of December 31, 2025 in the table above are calculated based on the difference between the exercise price and the current fair value of BridgeBio’s common stock. The total intrinsic value of options exercised for the years ended December 31, 2025, 2024 and 2023, was \$32.2 million, \$2.9 million and \$5.3 million, respectively.

As of December 31, 2025, there was \$11.7 million of total unrecognized compensation cost related to stock options under the Plans that is expected to be recognized over a weighted-average period of 1.3 years.

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Restricted Stock Units (RSUs) and Restricted Stock Awards (RSAs)

Time-Based RSUs

The following table summarizes BridgeBio's time-based RSU activity under the Plans for the year ended December 31, 2025:

	Unvested Shares of RSUs Outstanding	Weighted- Average Grant Date Fair Value
Balance as of December 31, 2024	10,272,798	\$ 21.91
Granted	4,383,339	\$ 35.20
Vested	(4,758,614)	\$ 23.64
Cancelled	(957,588)	\$ 23.77
Balance as of December 31, 2025	<u>8,939,935</u>	<u>\$ 27.31</u>

The time-based RSUs have a service condition and generally vest over a period of two to four years. As of December 31, 2025, there was \$229.0 million of total unrecognized compensation cost related to time-based RSUs under the Plans that is expected to be recognized over a weighted-average period of 2.2 years.

Performance-Based Milestone Awards

Apart from the milestone awards under the Exchange Program described above, we also have performance-based milestone compensation arrangements with certain employees and consultants whose vesting is contingent upon meeting various regulatory and development milestones, with fixed monetary amounts known at inception that can be settled in the form of cash or equity at our sole discretion, upon achievement of each contingent milestone. Upon achievement of a contingent milestone and if such performance-based milestone awards are settled in the form of equity, these are satisfied in the form of fully-vested RSAs. We recognize such contingent stock-based compensation expense when the milestone is probable of achievement. Refer to Note 8 for contingent compensation accrued associated with performance-based milestone awards that are determined to be probable as of December 31, 2025.

Performance-Based RSUs

The following table summarizes BridgeBio's performance-based RSU activity under the Plans for the year ended December 31, 2025:

	Unvested Shares of RSUs Outstanding	Weighted- Average Grant Date Fair Value
Balance as of December 31, 2024	3,326	\$ 18.71
Granted	194,650	\$ 33.75
Vested	(3,326)	\$ 18.71
Cancelled	—	\$ —
Balance as of December 31, 2025	<u>194,650</u>	<u>\$ 33.75</u>

In March 2025, the Company approved and granted RSUs under the 2021 A&R Plan to certain officers and employees with vesting based on achievement of positive top-line readout targets, which are subject to the continued service of the officers and employees through the applicable vesting date and are subject to accelerated vesting upon a change in control event ("performance-based RSUs"). We recognize such contingent stock-based compensation expense when the top-line readout targets are probable of achievement. As of the date of this report, the top-line readout targets were all achieved. As of December 31, 2025, there was \$6.5 million of total unrecognized compensation cost related to performance-based RSUs under the Plans that is expected to be recognized over a weighted-average period of 1.6 years.

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Market-Based RSUs

In December 2023, the Company approved and granted performance restricted stock units under the 2021 A&R Plan to certain employees with vesting based on achievement of market capitalization targets (“market-based RSUs”), which are subject to the continued service of the employees through the vest date and are subject to accelerated vesting upon a change in control event. The achievement of the market capitalization targets will be measured based on BridgeBio market capitalization data (available on the Nasdaq.com website) meeting the targets for 20-consecutive trading days during the performance period of up to six years from the date of grant.

The respective grant-date fair value of the market-based RSUs, which aggregated to \$10.8 million, was determined using the Monte Carlo valuation model and are recognized as compensation expense over the derived service period of the awards. The assumptions used in the Monte Carlo valuation included expected volatility ranging from 96.8% - 113.7%, risk-free rate ranging from 4.2% - 4.4%, no expected dividend yield, expected term of three to six years and possible future market capitalization over the derived service period based on historical stock prices and market capitalization.

As of December 31, 2025, 232,142 market-based RSUs were outstanding with a weighted average grant date fair value of \$28.97. As of December 31, 2025, there was no unrecognized compensation cost related to market-based RSUs under the Plans.

2019 Employee Stock Purchase Plan (ESPP)

On June 22, 2019, we adopted the 2019 Employee Stock Purchase Plan, which became effective on June 25, 2019 and was amended and restated effective as of December 12, 2019. The ESPP initially reserves and authorizes the issuance of up to a total of 2,000,000 shares of common stock to participating employees. The ESPP provides that the number of shares reserved and available for issuance will automatically increase each January 1, beginning on January 1, 2020, by the lower of: (i) 1% of the outstanding number of shares of common stock on the immediately preceding December 31, (ii) 2,000,000 shares or (iii) such lesser number of shares as determined by the Compensation Committee.

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

For the year ended December 31, 2025, employees purchased 261,422 shares for \$6.4 million under our ESPP. As of December 31, 2025, 3,100,352 shares were reserved for future issuance under the ESPP.

Valuation Assumptions

We used the Black-Scholes model to estimate the fair value of stock options and stock purchase rights under the ESPP. The following table presents the weighted-average assumptions used in the Black-Scholes calculations:

	Years Ended December 31,					
	2025		2024		2023	
	Stock Options	ESPP	Stock Options	ESPP	Stock Options	ESPP
Expected term (in years)	6.0	0.5	6.0	0.5	6.0	0.5
Expected volatility	94.0% - 94.7%	46.7% - 60.9%	92.0% - 93.1%	52.0% - 122.1%	66.2% - 67.5%	86.1% - 122.1%
Risk-free interest rate	4.1%	4.1% - 5.0%	3.8% - 4.3%	5.0% - 5.5%	3.9% - 4.1%	3.1% - 5.5%
Dividend yield	—	—	—	—	—	—
Weighted-average fair value of stock-based awards granted	\$ 30.15	\$ 14.09	\$ 21.28	\$ 11.34	\$ 8.48	\$ 8.22

16. 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.

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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.

“Restructuring, impairment, and related charges” included on our consolidated statements of operations for the years ended December 31, 2025, 2024 and 2023 consisted of the following:

	Years Ended December 31,		
	2025	2024	2023
	(in thousands)		
Winding down, exit and other related costs	\$ 16,680	\$ 10,255	\$ 7,211
Severance and employee-related costs	4,667	5,079	715
Long-lived assets impairments and write-offs	—	271	—
Total	<u>\$ 21,347</u>	<u>\$ 15,605</u>	<u>\$ 7,926</u>

The following table summarizes the activity related to the restructuring liabilities associated with our restructuring plans for the years ended December 31, 2025, 2024 and 2023:

	Years Ended December 31,		
	2025	2024	2023
	(in thousands)		
Beginning balance	\$ 1,848	\$ 55	\$ 6,826
Restructuring, impairment, and related charges	21,347	15,605	7,926
Cash payments	(14,478)	(13,374)	(14,697)
Noncash activities	(1,728)	(438)	—
Ending balance	<u>\$ 6,989</u>	<u>\$ 1,848</u>	<u>\$ 55</u>

Restructuring liabilities are presented on our consolidated balance sheets as follows:

	December 31, 2025		December 31, 2024	
	(in thousands)			
Accounts payable	\$	1,270	\$	330
Accrued compensation and benefits		2,045		332
Accrued research and development liabilities		3,584		1,020
Other current liabilities		90		166
Total	<u>\$</u>	<u>6,989</u>	<u>\$</u>	<u>1,848</u>

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17. Income Taxes

The following table presents the components of net loss before income taxes for the years ended December 31, 2025, 2024 and 2023:

	Years Ended December 31,		
	2025	2024	2023
	(in thousands)		
Domestic	\$ 437,614	\$ 207,795	\$ 565,840
Foreign	294,889	334,399	87,411
Total loss before income taxes	<u>\$ 732,503</u>	<u>\$ 542,194</u>	<u>\$ 653,251</u>

The following table presents the provision of income taxes for the years ended December 31, 2025, 2024 and 2023:

	Years Ended December 31,		
	2025	2024	2023
	(in thousands)		
Current:			
U.S. federal	\$ (78)	\$ 811	\$ —
State	—	—	—
Foreign	513	342	—
Total current	<u>435</u>	<u>1,153</u>	<u>—</u>
Deferred	—	—	—
Total provision for income taxes	<u>\$ 435</u>	<u>\$ 1,153</u>	<u>\$ —</u>

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The following table presents a reconciliation of the statutory federal rate and our effective tax rate (after the adoption of ASU 2023-09, on a retrospective basis) for the years ended December 31, 2025, 2024 and 2023:

	Years Ended December 31,					
	2025		2024		2023	
	Amount	Percentage	Amount	Percentage	Amount	Percentage
	(in thousands, except percentage data)					
U.S. federal statutory tax rate	\$ (153,830)	21.0 %	\$ (113,860)	21.0 %	\$ (137,110)	21.0 %
Foreign tax effects						
Switzerland						
Changes in valuation allowances	58,930	(8.1)%	39,800	(7.3)%	10,230	(1.6)%
Foreign rate differential	3,890	(0.5)%	30,300	(5.6)%	7,970	(1.2)%
Nontaxable or nondeductible items	—	— %	(170)	— %	200	— %
Other foreign jurisdictions	(380)	— %	630	(0.1)%	(40)	— %
Effect of cross-border tax laws						
Global intangible low-taxed income (GILTI)	—	— %	52,790	(9.7)%	—	— %
Other	—	— %	1,700	(0.3)%	—	— %
Tax credits						
Research and development tax credit	(15,880)	2.2 %	(14,780)	2.7 %	(13,230)	2.0 %
Orphan drug credit	(5,030)	0.7 %	(7,720)	1.4 %	(7,290)	1.1 %
Changes in valuation allowances	125,510	(17.1)%	(170)	— %	120,440	(18.4)%
Nontaxable or nondeductible items						
Disallowed executive compensation	9,120	(1.3)%	6,320	(1.2)%	5,130	(0.8)%
Excess tax benefit on stock awards	(30,850)	4.2 %	(7,350)	1.4 %	(3,590)	0.5 %
Other	(555)	0.1 %	1,693	(0.3)%	790	(0.1)%
Changes in unrecognized tax benefits	4,980	(0.7)%	4,020	(0.7)%	4,760	(0.7)%
Other adjustments						
Deconsolidation of subsidiaries	3,770	(0.5)%	7,630	(1.4)%	9,120	(1.4)%
Other	760	(0.1)%	320	(0.1)%	2,620	(0.4)%
Effective tax rate	<u>\$ 435</u>	<u>(0.1)%</u>	<u>\$ 1,153</u>	<u>(0.2)%</u>	<u>\$ —</u>	<u>— %</u>

The following table presents the income taxes paid for the years ended December 31, 2025, 2024 and 2023:

	Years Ended December 31,		
	2025	2024	2023
	(in thousands)		
Federal	\$ 1,000	\$ —	\$ —
State	—	—	—
Foreign:			
UK	198	—	—
Foreign subtotal	198	—	—
Total cash paid for income taxes (net of refunds)	<u>\$ 1,198</u>	<u>\$ —</u>	<u>\$ —</u>

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Significant components of our deferred tax assets and liabilities are as follows:

	December 31, 2025	December 31, 2024
	(in thousands)	
Deferred tax assets:		
Net operating loss carryforwards	\$ 490,732	\$ 379,019
Amortization	9,948	10,188
Accruals and reserves	11,251	7,787
Deferred revenue	3,856	—
Stock-based compensation	20,621	21,109
Equity method investments	16,110	2,998
Tax credits	139,489	117,020
Operating lease liabilities	1,944	2,200
Deferred income from asset sale	2,312	2,242
Capitalized research and experimental expenditures	157,931	150,520
Deferred interest expense	45,192	30,747
Property and equipment	712	918
Unrealized gains and losses	47	3,336
Deferred royalty obligations	69,427	—
Other	—	554
Gross deferred tax assets	969,572	728,638
Less valuation allowance	(968,021)	(727,326)
Deferred tax assets, net of valuation allowance	1,551	1,312
Deferred tax liabilities:		
Operating lease right-of-use assets	(1,465)	(1,312)
Other	(86)	—
Deferred tax liabilities	(1,551)	(1,312)
Net deferred tax assets (liabilities)	\$ —	\$ —

As of December 31, 2025, we have net operating loss carryforwards available to reduce future taxable income, if any, for federal and state income tax purposes of approximately \$1.7 billion and \$462.2 million, respectively.

The federal net operating losses generated prior to 2018 amounting to \$10.8 million will begin to expire in 2036, losses generated after 2018 amounting to \$1.6 billion will carry over indefinitely and will be subject to an 80% taxable income limitation in the year utilized. State net operating losses will generally begin to expire in 2036. We also have foreign net operating loss carryforwards of \$543.0 million available to reduce future taxable income, if any, which will begin to expire in 2030.

As of December 31, 2025, we have federal research and development and orphan drug credit carryforwards of approximately \$141.3 million, which will expire beginning in 2038 if not utilized.

As of December 31, 2025, we have California and other state research and development tax credit carryforwards of \$37.4 million. The state research and development tax credits will expire at various dates while the California research and development tax credits will carry over indefinitely.

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Beginning in 2022, the 2017 Tax Cuts and Jobs Act amended Section 174 of the Internal Revenue Code of 1986, as amended, to eliminate current-year deductibility of research and experimentation (“R&E”) expenditures and software development costs (collectively, “R&E expenditures”) and instead require taxpayers to charge their R&E expenditures to a capital account amortized over five years (15 years for expenditures attributable to R&E activity performed outside the U.S.). The Company generated a deferred tax asset for capitalized R&E expenditures for the year ended December 31, 2024 which was fully offset by a valuation allowance. On July 4, 2025, the current administration signed the One Big Beautiful Bill Act (“OBBBA”), which includes comprehensive U.S. corporate tax legislation. The OBBBA permanently reinstates the immediate deduction of domestic specified research and experimental expenditures. The Company continues to generate a deferred tax asset for foreign capitalized R&E expenditures for the year ended December 31, 2025 which is fully offset by a valuation allowance.

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

The valuation allowance increased by \$240.7 million, \$55.2 million and \$138.2 million for the years ended December 31, 2025, 2024 and 2023, respectively.

Utilization of the net operating loss and credit carryforwards may be subject to a substantial annual limitation due to an ownership change limitation as provided by Section 382 of the Internal Revenue Code of 1986, as amended, and similar state provisions. The annual limitation may result in the expiration of net operating losses and credits before utilization. In the event that we have a change of ownership, utilization of the net operating loss and tax credit carryforwards may be restricted.

As of December 31, 2025, we have an immaterial amount of undistributed earnings of our non-U.S. subsidiaries for which we have not provided for non-U.S. withholding taxes and state taxes because such earnings are intended to be reinvested indefinitely in international operations. The amount of applicable taxes due if such earnings were distributed would be immaterial. Accordingly, we have not provisioned U.S. state taxes and foreign withholding taxes on non-U.S. subsidiaries for which the earnings are permanently reinvested.

A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows:

	Years Ended December 31,	
	2025	2024
	(in thousands)	
Beginning balance	\$ 36,866	\$ 30,856
Additions of prior year positions	318	99
Reductions of prior year positions	—	(520)
Additions based on tax positions related to current year	6,795	6,431
Ending balance	<u>\$ 43,979</u>	<u>\$ 36,866</u>

As of December 31, 2025 and 2024, we have not recorded interest and penalties associated with our unrecognized tax benefits. Our policy is to recognize interest and penalties related to income tax matters in “Provision for income taxes” on our consolidated statements of operations.

Our unrecognized gross tax benefits would not reduce the annual effective tax rate if recognized because we have recorded a valuation allowance on our deferred tax assets.

We file federal and various income tax returns. We currently have no federal or state tax examinations in progress. All years are open for examination by federal, state and foreign authorities.

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Notes to Consolidated Financial Statements

18. Net Loss Per Share

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 by the weighted-average number of shares of common stock outstanding, plus all additional common shares that would have been outstanding, assuming dilutive potential common shares had been issued for other dilutive securities. For the years ended December 31, 2025, 2024 and 2023 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 anti-dilutive.

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 December 31,		
	2025	2024	2023
Unvested RSAs	—	—	85,453
Unvested RSUs	8,939,935	10,272,798	8,942,813
Unvested performance-based RSUs	194,650	3,326	3,326
Unvested market-based RSUs	232,142	375,000	375,000
Common stock options issued and outstanding	11,492,208	12,499,883	12,332,442
Estimated shares issuable under performance-based milestone compensation arrangements	913,176	2,558,295	4,865,250
Estimated shares issuable under the ESPP	105,232	122,268	75,889
Assumed conversion of 2027 Notes	12,878,305	12,878,305	12,878,305
Assumed conversion of 2029 Notes	7,702,988	7,702,988	7,702,988
Assumed conversion of 2031 Notes	11,544,448	—	—
	54,003,084	46,412,863	47,261,466

Our 2031 Notes, 2029 Notes, and 2027 Notes are convertible, based on the applicable conversion rate, into cash, shares of our common stock or a combination thereof, at our election.

As discussed in Notes 8 and 15, we have performance-based milestone compensation arrangements, whose vesting is contingent upon meeting various regulatory and development milestones, with fixed monetary amounts known at inception that can be settled in the form of cash or 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.

19. Subsequent Event

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. 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 will 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.

BRIDGEBIO PHARMA, INC.
Notes to Consolidated Financial Statements

We received net proceeds from the 2033 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.

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.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not applicable.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

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 December 31, 2025 and 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 were no changes in our internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act, during our most recently completed quarter that have materially affected or are reasonably likely to materially affect our internal control over financial reporting.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Exchange Act Rules 13a-15(f). Our internal control over financial reporting is a process designed under the supervision of our Chief Executive Officer and Chief Financial Officer to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our financial statements for external purposes in accordance with U.S. generally accepted accounting principles.

As of December 31, 2025, we assessed the effectiveness of our internal control over financial reporting based on the criteria for effective internal control over financial reporting under the 2013 "Internal Control — Integrated Framework," issued by the Committee of Sponsoring Organizations ("COSO"), of the Treadway Commission, under the supervision of, and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer. Based on that assessment, our management concluded that we maintained effective internal control over financial reporting as of December 31, 2025.

Deloitte & Touche LLP, an independent registered public accounting firm, audited the effectiveness of our internal control over financial reporting as of December 31, 2025, as stated in their attestation report, which is included herein.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the stockholders and the Board of Directors of BridgeBio Pharma, Inc.

Opinion on Internal Control over Financial Reporting

We have audited the internal control over financial reporting of BridgeBio Pharma, Inc. and its subsidiaries and controlled entities (the “Company”) as of December 31, 2025, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2025, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by COSO.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated financial statements as of and for the year ended December 31, 2025, of the Company and our report dated February 24, 2026, expressed an unqualified opinion on those financial statements.

Basis for Opinion

The Company’s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management’s Annual Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company’s internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control over Financial Reporting

A company’s internal control over financial reporting is a process designed 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. A company’s internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company’s assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Deloitte & Touche LLP

San Francisco, California

February 24, 2026

ITEM 9B. OTHER INFORMATION

Rule 10b5-1 Trading Plans

On November 14, 2025, Dr. Hannah A. Valentine, a member of our Board of Directors, adopted a trading plan (the “Valentine Trading Plan”) intended to satisfy the affirmative defense conditions of Securities Exchange Act Rule 10b5-1(c). The Valentine Trading Plan provides for the potential sale of a maximum of (i) 36,963 shares of our common stock underlying the stock options held by Dr. Valentine and (ii) 100% of net vested shares of our common stock to be issued to Dr. Valentine upon vesting of her restricted stock units (“RSUs”) on June 20, 2026. On the date when the Valentine Trading Plan was adopted, Dr. Valentine held no such net vested shares. Dr. Valentine’s net vested share amount will change as additional RSUs vest on the applicable vesting date. The aggregate number of net vested shares of common stock that will be available for sale by Dr. Valentine is not yet determinable because the shares available will be net of shares to be withheld to satisfy tax obligations in connection with the vesting of her RSUs on the vesting date. Dr. Valentine is not permitted to transfer, sell or otherwise dispose of any shares under the Valentine Trading Plan until the Earliest Sell Date, which is the later of (i) the 91st day after the adoption date of the Valentine 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 Valentine Trading Plan is adopted; or (b) the 121st day after the adoption date. The Valentine Trading Plan is expected to remain in effect until the earlier of (a) December 31, 2026; (b) the first date on which all trades have been executed or all trading orders relating to such trades set forth on Addendum A of the Valentine Trading Plan have expired; (c) as soon as practicable following the date on which Dr. Valentine gives written notice to Morgan Stanley Smith Barney LLC (“MSSB”) to terminate the Valentine 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 Valentine 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 Valentine 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. Valentine that would result in a modification or change to the amount, price or timing of the sale of shares under the Valentine Trading Plan but the requirements for a modification of the Valentine 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.

On December 3, 2025, Ms. Andrea J. Ellis, a member of our Board of Directors, adopted a trading plan (the “Ellis Trading Plan”) intended to satisfy the affirmative defense conditions of Securities Exchange Act Rule 10b5-1(c). The Ellis Trading Plan provides for the potential sale of an aggregate of 82,088 shares of our common stock underlying the stock options held by Ms. Ellis. Ms. Ellis is not permitted to transfer, sell or otherwise dispose of any shares under the Ellis Trading Plan until the Earliest Sell Date, which is the later of (i) the 91st day after the adoption date of the Ellis 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 Ellis Trading Plan is adopted; or (b) the 121st day after the adoption date. The Ellis Trading Plan is expected to remain in effect until the earlier of (a) November 30, 2026; (b) the first date on which all trades have been executed or all trading orders relating to such trades set forth on Addendum A of the Ellis Trading Plan have expired; (c) as soon as practicable following the date on which Ms. Ellis gives written notice to MSSB to terminate the Ellis 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 Ellis 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 Ellis 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 Ms. Ellis that would result in a modification or change to the amount, price or timing of the sale of shares under the Ellis Trading Plan but the requirements for a modification of the Ellis 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.

On December 4, 2025, Dr. Frank McCormick, a member of our Board of Directors, adopted a trading plan on behalf of the Francis P. McCormick Revocable Trust U/A DTD 1/27/2017, of which Dr. McCormick is a trustee, for the sale of a maximum of 200,000 shares of our common stock (the “McCormick Trading Plan”). The McCormick Trading Plan is intended to satisfy the affirmative defense conditions of the Securities and Exchange Act Rule 10b5-1(c) and is expected to take effect on March 6, 2026 and remain in effect until the earlier of (1) March 5, 2027 and (2) the date on which an aggregate of 200,000 shares of our common stock have been sold under such McCormick Trading Plan.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Except as set forth below, the information required by this Item is incorporated by reference from our definitive proxy statement for our 2026 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2025.

We have adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer, controller or persons performing similar functions. A current copy of the code is posted on the Corporate Governance section of our website, located at <https://investor.bridgebio.com/governance/governance-documents/default.aspx>. If we make any substantive amendments to, or grant any waivers from, the code of business conduct and ethics for our principal executive officer, principal financial officer, principal accounting officer, controller or persons performing similar functions, or any officer or director, we will disclose the nature of such amendment or waiver on our website or in a current report on Form 8-K.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item is incorporated by reference from our definitive proxy statement for our 2026 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2025, except as to information disclosed therein pursuant to Item 402(v) of Regulation S-K relating to pay versus performance.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this Item is incorporated by reference from our definitive proxy statement for our 2026 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2025.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this Item is incorporated by reference from our definitive proxy statement for our 2026 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2025.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this Item is incorporated by reference from our definitive proxy statement for our 2026 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2025.

PART IV**ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES**

(a) The following documents are filed as part of this Annual Report on Form 10-K:

1. Financial Statements:

The following financial statements and schedules of the Registrant are contained in Part II, Item 8, “Financial Statements and Supplementary Data” of this Annual Report on Form 10-K:

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Report of Independent Registered Public Accounting Firm	149
Consolidated Balance Sheets as of December 31, 2025 and 2024	151
Consolidated Statements of Operations for the years ended December 31, 2025, 2024 and 2023	152
Consolidated Statements of Comprehensive Loss for the years ended December 31, 2025, 2024 and 2023	153
Consolidated Statements of Redeemable Convertible Noncontrolling Interests and Stockholders’ Deficit for the years ended December 31, 2025, 2024 and 2023	154
Consolidated Statements of Cash Flows for the years ended December 31, 2025, 2024 and 2023	155
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2. Financial Statement Schedules:

All schedules have been omitted because of the absence of conditions under which they are required or because the required information, where material, is shown in the financial statements, financial notes or supplementary financial information.

(b) Exhibits required by Item 601 of Regulation S-K:

The exhibits listed in the accompanying Exhibit Index are filed as part of, or incorporated by reference into, this Annual Report on Form 10-K.

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 Therapeutic, 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 SEC on October 6, 2020).	8-K	001-38959	2.1	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
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 shareholders.	S-1	333-231759	4.3	June 24, 2019
4.3	Description of Securities.	10-K	001-38959	4.3	February 25, 2022

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4.4	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
4.5	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	4.1	March 10, 2020
4.6	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
4.7	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	4.1	January 29, 2021
4.8	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
4.9†	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
4.10	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
4.11	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	4.1	February 28, 2025
4.12	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
4.13	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
10.1#	Amended and Restated 2021 Stock Option and Incentive Plan and forms of award agreements thereunder.	10-Q	001-38959	10.1	August 1, 2024
10.2#	Amended and Restated 2019 Employee Stock Purchase Plan.	10-Q	001-38959	10.1	November 4, 2021
10.3#	Senior Executive Cash Incentive Bonus Plan.	S-1	333-231759	10.3	June 24, 2019
10.4#	Form of Indemnification Agreement, between the Registrant and each of its directors.	S-1	333-231759	10.4	June 24, 2019
10.5#	Form of Indemnification Agreement, between the Registrant and each of its executive officers.	S-1	333-231759	10.5	June 24, 2019
10.6†	Exclusive (Equity) Agreement, by and between Eidos Therapeutics, Inc. and the Board of Trustees of the Leland Stanford Junior University, effective as of April 10, 2016, as amended by Amendment No. 1 effective September 25, 2017.	S-1	333-231759	10.9	May 24, 2019

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10.7†	License Agreement, between QED Therapeutics, Inc. and Novartis International Pharmaceutical Ltd., dated as of January 29, 2018.	S-1	333-231759	10.10	May 24, 2019
10.8†	Asset Purchase Agreement, among BridgeBio Pharma LLC, Origin Biosciences, Inc., and Alexion Pharma Holding Unlimited Company, dated as of June 7, 2018.	S-1	333-231759	10.11	May 24, 2019
10.9†	Cell Line License Agreement, by and between Life Technologies Corporation and BridgeBio Services, Inc., effective as of November 15, 2018.	S-1	333-231759	10.17	May 24, 2019
10.10#	Offer Letter, between BridgeBio Services, Inc. and Neil Kumar, dated December 14, 2017.	S-1	333-231759	10.19	June 11, 2019
10.11#	Offer Letter, between BridgeBio Services, Inc. and Brian Stephenson, dated October 28, 2018.	S-1	333-231759	10.20	June 11, 2019
10.12#	Offer Letter, between BridgeBio Services, Inc. and Charles Homcy, dated February 20, 2019.	S-1	333-231759	10.22	June 11, 2019
10.13#†	Consulting Agreement between Frank McCormick and the Registrant, effective as of January 1, 2021.	10-K	001-38959	10.16	February 23, 2023
10.14#†	Amendment No. 1 to Consulting Agreement between Frank McCormick and the Registrant, effective as of March 3, 2022.	10-K	001-38959	10.17	February 23, 2023
10.15#†	Amendment No. 2 to Consulting Agreement between Frank McCormick and the Registrant, effective as of March 3, 2023.	10-K	001-38959	10.18	February 23, 2023
10.16#†	Amendment No. 3 to Consulting Agreement between Frank McCormick and the Registrant, effective as of March 4, 2024.	—	—	—	Filed herewith
10.17#†	Amendment No. 4 to Consulting Agreement between Frank McCormick and the Registrant, effective as of March 4, 2025.	—	—	—	Filed herewith
10.18	Form of Tax Sharing Agreement, between the Registrant and each of its subsidiaries.	S-1	333-231759	10.27	June 24, 2019
10.19	Indemnification Agreement, between BridgeBio Pharma LLC and KKR Genetic Disorder, L.P., dated March 26, 2016.	S-1	333-231759	10.28	June 24, 2019
10.20†	License Agreement, by and between Eidos Therapeutics, Inc. and Alexion Pharma International Operations Unlimited Company, dated September 9, 2019.	10-Q	000-38959	10.1	November 8, 2019
10.21#	BridgeBio Pharma, Inc. Amended and Restated 2019 Inducement Equity Plan.	S-8	333-276393	99.1	January 5, 2024
10.22#	Form of Restricted Stock Unit Award Agreement under BridgeBio Pharma, Inc. Amended and Restated 2019 Inducement Equity Plan (2023 Form).	10-Q	000-38959	10.3	August 3, 2023
10.23#	Form of Restricted Stock Award Agreement under BridgeBio Pharma, Inc. Amended and Restated 2019 Inducement Equity Plan (2023 Form).	10-Q	000-38959	10.4	August 3, 2023

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10.24#	Form of Non-Qualified Stock Option Agreement under BridgeBio Pharma, Inc. Amended and Restated 2019 Inducement Equity Plan (2023 Form).	10-Q	000-38959	10.5	August 3, 2023
10.25#	Amended and Restated Director Compensation Policy.	—	—	—	Filed herewith
10.26†	Letter Agreement, Amendment #1 thereto, and Amendments to License Agreement between QED Therapeutics, Inc. and Novartis International Pharmaceutical Ltd., dated May 4, 2018.	10-K	001-38959	10.31	February 22, 2024
10.27†	License, Development and Commercialization Agreement, dated May 11, 2022, by and among the Registrant, Navire Pharma, Inc. and Bristol-Myers Squibb Company.	10-Q	001-38959	10.1	August 4, 2022
10.28	Equity Distribution Agreement dated May 4, 2023, by and among the Company and Goldman Sachs & Co. LLC and SVB Securities LLC.	S-3ASR	333-271650	1.2	May 4, 2023
10.29†	Second Amendment, effective as of August 15, 2023, to the Exclusive (Equity) Agreement, by and between Eidos Therapeutics, Inc. and the Board of Trustees of the Leland Stanford Junior University, effective as of April 10, 2016, as amended by Amendment No. 1, effective September 25, 2017.	10-Q	001-38959	10.1	November 2, 2023
10.30#†	Amendment to Employment Agreement, between BridgeBio Services, Inc. and Brian Stephenson, dated February 21, 2024.	10-K	001-38959	10.39	February 22, 2024
10.31	Form of Confirmation for Capped Call Transactions.	8-K	001-38959	10.1	March 10, 2020
10.32	Form of Confirmation for Capped Call Transactions.	8-K	001-38959	10.1	January 29, 2021
10.33†	First Amendment to Financing Agreement, dated as of February 12, 2024, by and among the Registrant, the Guarantors party thereto, the Lenders party thereto, and Blue Owl Capital Corporation as Administrative Agent.	10-Q	001-38959	10.3	May 2, 2024
10.34†	Funding Agreement, dated January 17, 2024, by and among LSI Financing 1 Designated Activity Company and CPPIB Credit Europe S.À R.L. as Purchasers, the Registrant and certain subsidiaries of the Registrant as Seller Parties, and Alter Domus (US) LLC as Collateral Agent.	10-Q	001-38959	10.4	May 2, 202
10.35†	Exclusive License Agreement, dated March 1, 2024, by and among Eidos Therapeutics, Inc., BridgeBio International GmbH, BridgeBio Europe B.V., and Bayer Consumer Care AG.	10-Q	001-38959	10.5	May 2, 2024
10.36†	Amendment No. 3, effective as of March 1, 2024, to Exclusive (Equity) Agreement effective April 10, 2016, by and between Eidos Therapeutics, Inc. and the Board of Trustees of the Leland Stanford Junior University.	10-Q	001-38959	10.6	May 2, 2024

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10.37#†	Amendment No. 3 to Consulting Agreement between Frank McCormick and the Registrant, effective as of March 4, 2024.	10-Q	001-38959	10.7	May 2, 2024
10.38†	Second Amendment to Financing Agreement, dated as of June 20, 2024, by and among the Registrant, the Guarantors party thereto, the Lenders party thereto, and Blue Owl Capital Corporation as Administrative Agent.	10-Q	001-38959	10.1	August 1, 2024
10.39**	Transaction Agreement, dated as of August 16, 2024, by and among BridgeBio Pharma, Inc., Viking Global Opportunities Illiquid Investments Sub-Master LP, Viking Global Opportunities Drawdown (Aggregator) LP, Patient Square Bravo Aggregator, LP, SC US/E GROWTH FUND X MANAGEMENT, L.P., SC US/E Venture Fund XVIII Management, L.P., Frazier Life Sciences XI, L.P., Frazier Life Sciences Public Fund, L.P., Frazier Life Sciences Public Overage Fund, L.P., Cormorant Private Healthcare Fund IV, LP, Cormorant Private Healthcare Fund V, LP, Cormorant Global Healthcare Master Fund, LP, Aisling V Bridge Splitter LP, Kumar Haldea Revocable Trust and GondolaBio, LLC.	8-K	001-38959	10.1	August 21, 2024
10.40**	Amended and Restated Limited Liability Company Agreement of GondolaBio, LLC, dated as of August 16, 2024.	8-K	001-38959	10.2	August 21, 2024
10.41#†	Employment Agreement between BridgeBio Services, Inc. and Thomas Trimarchi, dated October 10, 2024.	10-K	001-38959	10.41	February 20, 2025
10.42#	Consulting Agreement, dated March 17, 2025, between BridgeBio Pharma, Inc. and Brian Stephenson.	10-Q	001-38959	10.1	April 29, 2025
10.43†	Royalty Interest Purchase and Sale Agreement, dated June 27, 2025, by and among BridgeBio Pharma, Inc. Acoramidis Royalty SPV, LP and LSI Financing Fund, LP.	10-Q	001-38959	10.1	August 5, 2025
10.44†	First Amendment to Funding Agreement, dated as of June 27, 2025, by and among LSI Financing 1 Designated Activity Company and CPPIB Credit Europe S.À R.L. as Purchasers, the BridgeBio Pharma, Inc. and certain subsidiaries of BridgeBio Pharma, Inc. as Seller Parties, and Alter Domus (US) LLC as Collateral Agent.	10-Q	001-38959	10.2	August 5, 2025
10.45#	BridgeBio Pharma, Inc. Second Amended and Restated 2021 Stock Option and Incentive Plan and form award agreements thereunder.	8-K	001-38959	10.1	June 23, 2025
19	Amended and Restated Insider Trading Policy.	10-K	001-38959	19	February 22, 2024
21	List of Subsidiaries of the Registrant.	—	—	—	Filed herewith
23.1	Consent of Independent Registered Public Accounting.	—	—	—	Filed herewith
24	Power of Attorney (reference is made to signature page hereto).	—	—	—	Filed herewith

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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
97	Compensation Clawback Policy.	10-K	001-38959	97	February 22, 2024
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 with applicable taxonomy extension information contained in Exhibits 101).	—	—	—	Filed herewith

* This certification is deemed to accompany this Annual Report on Form 10-K and 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 of the exhibits and schedules to this Exhibit have been omitted in accordance with Regulation S-K Item 601(a)(5).

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

† Certain confidential portions (indicated by brackets and asterisks) have been omitted from this exhibit in accordance with the rules of the Securities and Exchange Commission because such information (i) is not material and (ii) is the type that the registrant treats as private or confidential.

ITEM 16. FORM 10-K SUMMARY

None.

<hr/> <i>/s/ Fred Hassan</i> <hr/> Fred Hassan	Director	February 24, 2026
<hr/> <i>/s/ Charles Homcy</i> <hr/> Charles Homcy, M.D.	Director	February 24, 2026
<hr/> <i>/s/ Andrew W. Lo</i> <hr/> Andrew W. Lo, Ph.D.	Director	February 24, 2026
<hr/> <i>/s/ Frank P. McCormick</i> <hr/> Frank P. McCormick, Ph.D.	Director	February 24, 2026
<hr/> <i>/s/ James C. Momtazee</i> <hr/> James C. Momtazee	Director	February 24, 2026
<hr/> <i>/s/ Ali J. Satvat</i> <hr/> Ali J. Satvat	Director	February 24, 2026
<hr/> <i>/s/ Randal W. Scott</i> <hr/> Randal W. Scott, Ph.D.	Director	February 24, 2026
<hr/> <i>/s/ Hannah A. Valentine</i> <hr/> Hannah A. Valentine, M.D.	Director	February 24, 2026

AMENDMENT No. 3 TO CONSULTING AGREEMENT

THIS AMENDMENT No. 3 TO CONSULTING AGREEMENT (“Amendment No. 3”) is effective as of March 4, 2024 (hereinafter “**Effective Date**”) by and between BridgeBio Pharma, Inc. (hereinafter “**Company**”), a Delaware corporation with offices at 3160 Porter Drive, Suite 250, Palo Alto, California 94304, and Frank McCormick (hereinafter “**Consultant**”), located at [***] (each herein referred to as a “**Party**” and collectively as “**Parties**”).

WHEREAS, the Parties wish to amend that certain Consulting Agreement (the “**Agreement**”) dated March 3, 2021 and amended March 3, 2022 and March 3, 2023, by and between Company and Consultant to incorporate certain changes to the Services as set forth below.

NOW, THEREFORE, in consideration of the foregoing and the mutual covenants and premises set forth herein and other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, the Parties agree as follows:

1. Exhibit A to the Agreement is hereby amended and replaced as set forth in Appendix A hereto.
2. Except as expressly modified hereby, the Agreement shall continue in full force according to its terms.
3. Capitalized terms not otherwise defined in this Amendment No. 3 shall have the meaning ascribed to such term in the Agreement.
4. This Amendment No. 3 shall be effective from the Effective Date.
5. This Amendment No. 3 shall inure to the benefit of, and be binding upon, the Parties hereto and their respective heirs, successors, trustees, transferees, and assigns.
6. This Amendment No. 3 may be executed in any number of counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

IN WITNESS WHEREOF, the parties hereto, intending to be legally bound hereby, have caused this Amendment No. 3 and any attachments related thereto to be executed and delivered by their proper and duly authorized officers.

Frank McCormick

/s/ Frank McCormick

Date: March 4, 2024

BridgeBio Pharma, Inc.

/s/ Neil Kumar

By: Neil Kumar

Title: CEO

Date: March 4, 2024

Appendix A

Services. Consultant shall provide consulting services to the Company generally in the area of oncology and pipeline development matters.

Fees and Payment Terms. For 2024, Company shall pay Consultant a cash fee of \$500,000.00. Once this agreement is effective, Consultant shall submit an invoice for the payment of the fee, which will be payable within 30 days of receipt.

Reimbursable Expenses. So long as Company's prior written approval has been obtained, Consultant shall be entitled to be reimbursed for any reasonable, out-of-pocket travel lodging and incidental travel expenses incurred in performing the Services, as evidenced by a valid receipt.

AMENDMENT No. 4 TO CONSULTING AGREEMENT

THIS AMENDMENT No. 4 TO CONSULTING AGREEMENT (“Amendment No. 3”) is effective as of March 4, 2025 (hereinafter “**Effective Date**”) by and between BridgeBio Pharma, Inc. (hereinafter “**Company**”), a Delaware corporation with offices at 3160 Porter Drive, Suite 250, Palo Alto, California 94304, and Frank McCormick (hereinafter “**Consultant**”), located at [***] (each herein referred to as a “**Party**” and collectively as “**Parties**”).

WHEREAS, the Parties wish to amend that certain Consulting Agreement (the “**Agreement**”) dated March 3, 2021 and amended March 3, 2022, March 3, 2023, and March 4, 2024, by and between Company and Consultant to incorporate certain changes to the Services as set forth below.

NOW, THEREFORE, in consideration of the foregoing and the mutual covenants and premises set forth herein and other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, the Parties agree as follows:

1. Exhibit A to the Agreement is hereby amended and replaced as set forth in Appendix A hereto.
2. Except as expressly modified hereby, the Agreement shall continue in full force according to its terms.
3. Capitalized terms not otherwise defined in this Amendment No. 4 shall have the meaning ascribed to such term in the Agreement.
4. This Amendment No. 4 shall be effective from the Effective Date.
5. This Amendment No. 4 shall inure to the benefit of, and be binding upon, the Parties hereto and their respective heirs, successors, trustees, transferees, and assigns.
6. This Amendment No. 4 may be executed in any number of counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

IN WITNESS WHEREOF, the parties hereto, intending to be legally bound hereby, have caused this Amendment No. 4 and any attachments related thereto to be executed and delivered by their proper and duly authorized officers.

Frank McCormick

/s/ Frank McCormick

Date: February 26, 2025

BridgeBio Pharma, Inc.

/s/ Neil Kumar

By: Neil Kumar

Title: CEO

Date: February 26, 2025

Appendix A

Services. Consultant shall provide consulting services to the Company generally in the area of oncology and pipeline development matters.

Fees and Payment Terms. For 2025, Company shall pay Consultant a cash fee of \$500,000.00. Once this agreement is effective, Consultant shall submit an invoice for the payment of the fee, which will be payable within 30 days of receipt.

Reimbursable Expenses. So long as Company's prior written approval has been obtained, Consultant shall be entitled to be reimbursed for any reasonable, out-of-pocket travel lodging and incidental travel expenses incurred in performing the Services, as evidenced by a valid receipt.

BridgeBio Pharma, Inc.

Amended and Restated Director Compensation Policy

Effective Date: December 11, 2025

The purpose of this Amended and Restated Director Compensation Policy (this “Policy”) of BridgeBio Pharma, Inc., a Delaware corporation (the “Company”), is to provide a total compensation package that enables the Company to attract, retain and motivate on a long-term basis, high-caliber directors and the type of qualified individuals who it believes are necessary and desirable to serve on the Company’s Board of Directors and its committees and to work in the best interests of the Company and its stockholders. This Policy will become effective as of December 11, 2025 (the “Effective Date”) and will remain in effect until amended or terminated by the Board of Directors of the Company. In furtherance of the purpose stated above, all members of the Company’s Board of Directors who are not serving as the Chief Executive Officer of the Company (“Outside Directors”) shall be paid compensation for services provided to the Company as set forth below:

I. Cash Retainers

Annual Retainer for Board Membership: \$50,000 for general availability and participation in meetings and conference calls of the Board of Directors. No additional compensation will be paid for attending individual Board meetings, serving on committees of the Board of Directors or attending committee meetings.

All cash retainers will be paid quarterly, in arrears, or upon the earlier resignation or removal of the Outside Director. Cash retainers owing to Outside Directors shall be annualized, meaning that with respect to directors who join the Board of Directors during the calendar year, such amounts shall be pro-rated based on the number of calendar days served by such director.

II. Equity Retainers

All grants of equity retainer awards to Outside Directors pursuant to this Policy will be automatic and nondiscretionary and will be made in accordance with the following provisions:

- (a) Value. For purposes of this Policy, “Value” means with respect to (i) any award of stock options the grant date fair value of the option (*i.e.*, Black-Scholes Value) determined in accordance with the reasonable assumptions and methodologies employed by the Company for calculating the fair value of options under ASC 718 (or any successor provision); and (ii) any award of restricted stock and restricted stock units the product of (A) the closing price of a share of the Company’s common stock on the date of grant (and in all events calculated consistent with calculating the fair value of stock awards under ASC 718 or its successor provision), and (B) the aggregate number of shares pursuant to such award.
 - (b) Revisions. The Compensation Committee in its discretion may change and otherwise revise the terms of awards to be granted under this Policy, including, without limitation, the number of shares subject thereto, for awards of the same or
-

- (c) different type granted on or after the date the Compensation Committee determines to make any such change or revision.
- (d) Sale Event Acceleration. In the event of a Sale Event (as defined in the Company's 2019 Stock Option and Incentive Plan (as amended and/or restated from time to time, the "2019 Plan")), the equity retainer awards granted to Outside Directors pursuant to this Policy shall become 100% vested and exercisable.
- (e) Initial Grant. Upon initial election to the Board of Directors, each Outside Director will receive (i) an initial, one-time grant of a non-statutory stock option ("Initial Stock Option") with a Value of \$345,000, with an exercise price per share equal to the closing price of a share of the Company's common stock on the date of grant and a term of ten years; and (ii) a grant of restricted stock units ("Initial RSU Grant") with a Value of \$345,000, each of which will vest in three equal annual installments over three years, the Initial Stock Option together with the Initial RSU Grant ("Initial Grant"); provided, however, that all vesting ceases if the director resigns from the Company's Board of Directors or otherwise ceases to serve as a director, unless the Board of Directors determines that the circumstances warrant continuation of vesting.
- (f) Annual Grant. On the date of the Company's Annual Meeting of Stockholders, each Outside Director who will continue as a member of the Board of Directors following such Annual Meeting of Stockholders and who has not received the Initial Grant in the same calendar year as such Annual Meeting will receive (i) a grant of a non-statutory stock option on the date of such Annual Meeting with a Value of \$230,000, with an exercise price per share equal to the closing price of a share of the Company's common stock on the date of grant and a term of ten years, and (ii) a grant of restricted stock units on the date of such Annual Meeting with a Value of \$230,000, each of which will vest in full on the one year anniversary of the grant; provided, however, that all vesting ceases if the director resigns from the Company's Board of Directors or otherwise ceases to serve as a director, unless the Board of Directors determines that the circumstances warrant continuation of vesting.

III. Expenses

The Company will reimburse all reasonable out-of-pocket expenses incurred by Outside Directors for their attendance at meetings of the Board of Directors or any Committee thereof.

IV. Maximum Annual Compensation

The aggregate amount of compensation, including both equity compensation and cash compensation, (i) awarded to any Outside Director in any calendar year shall not exceed \$1,250,000 (or such other limits as may be set forth in Section 3(b) of the 2019 Plan or any similar provision of a successor plan), and (ii) awarded to any Outside Director in any calendar year subsequent to the calendar year in which such Outside Director was first elected to the Board of Directors will not exceed \$600,000 (in each case, or such other limit as may be set forth in any successor to the 2019 Plan) (each of the foregoing, a "Maximum Annual Compensation Limit"). For this purpose, the "amount" of equity compensation paid in a calendar year shall be determined based on the grant date fair value thereof, as determined in accordance with ASC 718

or its successor provision, but excluding the impact of estimated forfeitures related to service-based vesting conditions.

V. Amendment

This Policy may be amended, revised or terminated by the Board of Directors at any time in its sole discretion; provided, however that the Maximum Annual Compensation Limits may not be increased without the approval of the Company's stockholders.

List of Subsidiaries

Entity name	Place of Incorporation	Ownership % as of December 31, 2025
BB Square Capital Investors I, LP	Delaware	100.0%
BB Square Capital, LLC	Delaware	100.0%
BB Square Holdings, LLC	Delaware	100.0%
BB Square Investors GP I, LLC	Delaware	100.0%
BB Square LP Investment, LLC	Delaware	100.0%
BridgeBio Chemistry, Inc.	Delaware	100.0%
BridgeBio Gene Therapy LLC	Delaware	100.0%
BridgeBio Gene Therapy Research, Inc.	Delaware	100.0%
BridgeBio Pharma LLC	Delaware	100.0%
BridgeBio Services Inc.	Delaware	100.0%
Calcilytix Therapeutics, Inc.	Delaware	100.0%
Cyan Therapeutics, Inc.	Delaware	100.0%
DTD Therapeutics, Inc.	Delaware	100.0%
Eidos Therapeutics, Inc.	Delaware	100.0%
CoA Therapeutics, Inc.	Delaware	99.9%
Origin Biosciences, Inc.	Delaware	99.9%
Adrenas Therapeutics, Inc.	Delaware	99.3%
QED Therapeutics, Inc.	Delaware	99.3%
Sub22, Inc.	Delaware	98.5%
Ferro Therapeutics, Inc.	Delaware	98.2%
Eulamin Therapeutics, Inc.	Delaware	98.0%
Cantero Therapeutics, Inc.	Delaware	96.5%
Venthera, Inc.	Delaware	96.2%
G Protein Therapeutics, Inc.	Delaware	94.6%
Molecular Skin Therapeutics, Inc.	Delaware	91.5%
Phoenix Tissue Repair, Inc.	Delaware	86.6%
Navire Pharma, Inc.	Delaware	81.5%
ML Bio Solutions, Inc.	Delaware	89.5%
Sen Therapeutics, Inc.	Delaware	89.8%
Audition Therapeutics, Inc.	Delaware	37.5%
BridgeBio Pharma Canada, ULC	Canada	100.0%
BridgeBio Pharma Cayman	Cayman Islands	100.0%
BridgeBio France SAS	France	100.0%
BridgeBio Germany GmbH	Germany	100.0%
BridgeBio Pharma (HK) Limited	Hong Kong	100.0%
BridgeBio Europe B.V.	Netherlands	100.0%
BridgeBio International GmbH	Switzerland	100.0%
BridgeBio UK Limited	United Kingdom	100.0%
Evanesco Therapeutics, Inc.	Delaware	100.0%
BridgeBio Pharma Europe B.V.	Netherlands	100.0%

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the following Registration Statements:

- Registration Statement Nos. 333-289268 on Form S-8 pertaining to the 2021 Amended and Restated BridgeBio Pharma, Inc. Stock Option and Incentive Plan
- Registration Statement Nos. 333-271656 and 333-276393 on Form S-8 pertaining to the Amended and Restated 2019 Inducement Equity Plan
- Registration Statement Nos. 333-281190, 333-269600 and 333-263009 on Form S-8 pertaining to the 2021 Amended and Restated Stock Option and Incentive Plan
- Registration Statement Nos. 333-232491 and 333-236872 on Form S-8 pertaining to the 2019 Stock Option and Incentive Plan and 2019 Employee Stock Purchase Plan
- Registration Statement No. 333-234803 on Form S-8 pertaining to the 2019 Inducement Equity Plan
- Registration Statement No. 333-239718 on Form S-8 pertaining to the Amended and Restated 2019 Stock Option and Incentive Plan
- Registration Statement No. 333-252393 on Form S-8 pertaining to the Eidos Therapeutics, Inc. Amended and Restated 2018 Stock Option and Incentive Plan and Eidos Therapeutics, Inc. Amended and Restated 2016 Equity Incentive Plan
- Registration Statement No. 333-252394 on Form S-8 pertaining to the Amended and Restated 2019 Stock Option and Incentive Plan and Amended and Restated 2019 Employee Stock Purchase Plan
- Registration Statement Nos. 333-271650, 333-273452 and 333-275280 on Form S-3ASR

of our reports dated February 24, 2026, relating to the consolidated financial statements of BridgeBio Pharma, Inc. and the effectiveness of BridgeBio Pharma, Inc.'s internal control over financial reporting appearing in this Annual Report on Form 10-K for the year ended December 31, 2025.

/s/ Deloitte & Touche LLP

San Francisco, California
February 24, 2026

**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 Annual Report on Form 10-K 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: February 24, 2026

By:

/s/ Neil Kumar

Neil Kumar, Ph.D.

**Chief Executive Officer and Director
(Principal Executive Officer)**

**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 Annual Report on Form 10-K 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: February 24, 2026

By:

/s/ Thomas Trimarchi

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

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

In connection with the Annual Report of BridgeBio Pharma, Inc. (the "Company") on Form 10-K for the period ended December 31, 2025, 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: February 24, 2026

By:

/s/ Thomas Trimarchi

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

