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, 2024

or

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

For the transition period from to

Commission File No. 001-38959

BridgeBio Pharma, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**84-1850815**
State or other jurisdiction of incorporation or organization	(I.R.S. Employer Identification No.)
3160 Porter Drive, Suite 250, Palo Alto, CA	**94304**
(Address of principal executive offices)	(Zip Code)

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

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

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

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

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

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

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

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

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

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

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

Indicate by check mark whether the registrant 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, 2024 was approximately $3,729.4 million. 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 13, 2025, there were 190,188,626 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, 2024, 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.
2024 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 is our registered trademark in the United States. BRIDGEBIO, ATTRUBY and BEYONTTRA are our registered trademarks in the European Union. 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, ADH1 and LGMD2I/R9 development programs, we refer to our product candidates by their scientific (or generic) name or BridgeBio Pharma ("BBP") developmental designation. Where referring to our commercial product that has been approved in both the United States and European Union, we use both names Attruby™/Beyonttra™ – e.g., "Our commercial organization focuses on supporting the appropriate use of ATTRUBY and BEYONTTRA in the markets where this product has been approved."

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:

- our ability to successfully commercialize Attruby™ (acoramidis), including our ability to successfully establish and maintain commercial manufacturing and supply chains for Attruby, and 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, our ongoing Phase 2 and planned Phase 3 clinical trials of low-dose infigratinib, our planned Phase 3 clinical trials of BBP-418, and our ongoing Phase 2b and Phase 3 clinical trials of encaleret, a Phase 1/2 study for BBP-812 for Canavan disease, 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 timing of our submissions to the U.S. Food and Drug Administration (the "FDA"), and any review or comments on data that we will need to generate to file our Investigational New Drug applications ("INDs") including pending or new clinical hold notices;
- 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 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 restructuring plans we commenced in 2024 and any future restructuring plans that we may pursue;
- 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;
- 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.

- Drug development is a highly uncertain undertaking and involves a substantial degree of risk. We have incurred significant losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future. We have not generated significant revenue since inception, which, together with our limited operating history, may make it difficult for you to assess our future viability.
- We may encounter substantial delays in clinical trials for a variety of reasons, including difficulties in patient enrollment, and we 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.
- 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.
- Interim, "top-line," and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available or as additional analyses are conducted, and as the data are subject to audit and verification procedures that could result in material changes in the final data.
- 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 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.
- Even if we obtain FDA approval for any of our current 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.
- Even though we may apply for orphan drug designation for our product candidates, we may not be able to obtain orphan drug marketing exclusivity.
- Attruby™ 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.
- 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.
- 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 rely entirely on third parties for the manufacturing of Attruby and Beyonttra and our product candidates that we may develop for preclinical studies and clinical trials. 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.

- Significant political, trade, regulatory developments, and other circumstances beyond our control could have a material adverse effect on our financial condition or results of operations.
- If we are unable to obtain and maintain sufficient intellectual property protection for Attruby and our product candidates, 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.
- 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.
- 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.
- Our business is substantially dependent on our ability to successfully commercialize Attruby and Beyonttra, and the commercial success of Attruby and Beyonttra or any other product candidates, if approved, will depend upon the degree of market acceptance by physicians, patients, healthcare payors, and others in the medical community.
- If our sales and marketing capabilities for Attruby and Beyonttra are not effective or we are unable to establish sales and marketing capabilities or enter into and maintain our agreements with third parties to sell and market Attruby and Beyonttra or any future product candidates approved for commercial sale, we may be unsuccessful in our commercial efforts.
- Our profitability will depend significantly on our ability to sell enough product at competitive prices and on the availability of adequate coverage and reimbursement through governmental or private third-party payors.
- We face significant competition in an environment of rapid technological and scientific change, and there is a possibility that our competitors may achieve regulatory approval before us or develop therapies that are safer, more advanced or more effective than ours, which may ultimately harm our financial condition.
- Adverse developments affecting the financial services industry could adversely affect our current and projected business operations, financial condition and results of operations.
- Our future success depends on our ability to retain key employees, directors, consultants and advisors and to attract, retain and motivate qualified personnel.
- 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 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.
- 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.
- The Funding Agreement contains certain conditions to the Purchasers' funding obligations and various covenants and restrictions on our operations that, if violated, may adversely affect our financial condition and operating results.

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PART I

ITEM 1. BUSINESS

Overview

BridgeBio Pharma, Inc. is a new type of biopharmaceutical company founded to discover, create, test and deliver transformative medicines to treat patients who suffer from genetic diseases. BridgeBio's pipeline of development programs ranges from early science to advanced clinical trials. BridgeBio was founded in 2015 and our team of experienced drug discoverers, developers and innovators are committed to applying advances in genetic medicine to help patients as quickly as possible. Since inception, BridgeBio has created 19 Investigational New Drug applications ("INDs") and received approval from the U.S. Food and Drug Administration (the "FDA") for three of our products. We have worked across over 20 disease states at various stages of development. Several of our programs target indications that we believe present the potential for our product candidates, if approved, to target portions of market opportunities of at least $1.0 billion in annual sales.

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

We believe we have developed a world-class product platform that supports the continued growth of our Company and the advancement of our pipeline.

Recent Developments

On November 22, 2024, the FDA approved Attruby™ (acoramidis), an orally-administered near-complete (≥90%) stabilizer of transthyretin (TTR) for the treatment of adults with ATTR-CM to reduce cardiovascular death and cardiovascular-related hospitalization. Following the receipt of FDA approval, we commercially launched Attruby in the United States (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. On February 10, 2025, the European Commission ("EC") approved acoramidis for the treatment of ATTR-CM in Europe. We have licensed commercial rights in Europe to Bayer Consumer Care AG, a wholly-owned subsidiary of Bayer AG ("Bayer"), who plans to commercialize acoramidis following approval under the brand name Beyonttra™ as a treatment for transthyretin amyloidosis in all EU member states as well as all member and extension states of the European Patent Organization as of the effective date of the license agreement. We anticipate Bayer will commercially launch Beyonttra in Europe during the first half of 2025. Please see the disclosures below in this Part I, Item 1 of this Annual Report on Form 10-K for further discussion of these recent developments.

Our Commercial Product and Late-Stage Clinical Pipeline

Our late-stage clinical pipeline has successfully resulted in the approval of our commercial product Attruby by the FDA on November 22, 2024 for the treatment of ATTR-CM in adults to reduce cardiovascular death and cardiovascular-related hospitalization and the approval of Beyonttra (acoramidis) by the EC on February 10, 2025. Over the next year, this pipeline is also expected to deliver Phase 3 clinical trial results in three additional programs in potential markets of $1.0 billion dollars or more. The following table summarizes our commercial product

Attruby/Beyonttra (acoramidis) and the three clinical product candidates in our late-stage development pipeline along with their target indications, drug mechanism, estimated patient population, and development status:

Product Name	Target Indication	Drug Mechanism	Patient Population (US + EU)	Development Stage
Commercial Product				
Attruby (US) & Beyonttra (EU) (acoramidis)	ATTR-CM[1]	TTR stabilizer	>400,000	Approved in US & EU
Products in Phase 3 Development				
Infigratinib	Achondroplasia	Low-dose FGFRi[4]	7,000 - 10,000[5]	Phase 3 Fully Enrolled
Encaleret	ADH1[2]	CaSR antagonist	20,000 - 25,000[6]	Phase 3 Fully Enrolled
BBP-418	LGMD2I/R9[3]	Glycosylation substrate	7,000	Fully Enrolled

[1] Transthyretin amyloid cardiomyopathy
[2] Autosomal Dominant Hypocalcemia Type 1
[3] Limb Girdle Muscular Dystrophy Type 2I
[4] Oral FGFR1-3 selective tyrosine kinase inhibitor
[5] Treatable population
[6] Carriers

Commercial Product-Attruby (U.S.)/ Beyonttra (EU) for the Treatment of TTR Amyloidosis

Summary

Our product, Attruby (acoramidis), previously known as AG10, a next-generation oral small molecule near-complete TTR stabilizer, was approved by the FDA in November 2024 for the treatment of cardiomyopathy of wild-type or variant transthyretin-mediated amyloidosis (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 December 2024, acoramidis received a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) recommending the approval of acoramidis in the European Union (EU) based on positive results from the Phase 3 ATTRibute-CM study. On February 10, 2025, the European Commission approved acoramidis for the treatment of ATTR-CM in Europe. We have licensed commercial rights in Europe to Bayer who following approval will commercialize acoramidis under the name Beyonttra as a treatment for transthyretin amyloidosis in all EU member states as well as all member and extension states of the European Patent Organization as of the effective date of the license agreement. We anticipate Bayer will commercially launch Beyonttra in Europe during the first half of 2025.

The FDA's approval of Attruby was based on positive data from our Phase 3 ATTRibute-CM clinical trial of acoramidis for patients with ATTR-CM. In July 2023, we announced that the primary endpoint (a hierarchical analysis inclusive of all-cause mortality and frequency of cardiovascular-related hospitalization) was met (win ratio of 1.8) with a highly statistically significant p-value ($p<0.0001$). This primary endpoint result consistently favored acoramidis treatment across key subgroups, including across both variant and wild-type ATTR patients as well as across New York Heart Association (NYHA) Class I, II, and III patients. Absolute values observed across all-cause mortality (ACM), cardiovascular mortality (CVM) and cardiovascular-related hospitalization (CVH) showed that over 30 months, patients survived more and were hospitalized less than, to our knowledge, has been seen in prior controlled studies of ATTR-CM. Acoramidis was well-tolerated, with no safety signals of potential clinical concern identified. In additional results from ATTRibute-CM presented on November 12, 2023, the placebo and acoramidis time-to-first event Kaplan-Meier curves for a composite of ACM and CVH separated beginning at month 3, representing the most rapid and sustained clinical benefit known to us on the composite endpoint of ACM and CVH in ATTR-CM patients through month 30.

In March 2024, we entered into an exclusive license agreement with Bayer Consumer Care AG ("Bayer"), a wholly-owned subsidiary of Bayer AG (the "Bayer License Agreement"), to commercialize acoramidis in Europe. Following approval, Bayer will commercialize acoramidis under the name Beyonttra. Under the Bayer License Agreement, we 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 (of which $75.0 million is for a regulatory milestone dependent upon receipt of EC approval of Beyonttra on or before December 31, 2025). We are also eligible to receive up to $450.0 million in additional sales milestones along with quarterly royalty payments according to a tiered structure starting in the low-thirties percent on net sales by Bayer of Beyonttra, subject to reduction under

certain circumstances as provided in the Bayer License Agreement. The condition for the $75.0 million regulatory-based milestone payment was achieved upon the EC approval of Beyonttra on February 10, 2025. We anticipate receiving this milestone payment from Bayer in April 2025.

In September 2019, through our subsidiary Eidos Therapeutics, Inc. ("Eidos"), we entered into a license agreement (the "Eidos-Alexion License Agreement"), with Alexion Pharma International Operations Unlimited Company, a subsidiary of Alexion Pharmaceuticals, Inc. (together, "Alexion"), to develop and commercialize Beyonttra in Japan. Under the Eidos-Alexion License Agreement, we are eligible to receive $30.0 million in regulatory milestone payments and royalties in the low-teens based on net sales of Beyonttra in Japan. Refer to the section titled "Our Material Agreements" below, and Note 11 of Part II - Item 8. Financial and Supplementary Data - Notes to Consolidated Financial Statements of this Annual Form 10-K for further details regarding the Bayer License Agreement and Eidos-Alexion License Agreement.

We presented results from the open label extension (OLE) of ATTRibute-CM in 2024, which confirmed sustained benefit of acoramidis on cardiovascular outcomes, including statistically significant reduction in ACM within 36 months. The continued curve separation of the composite endpoint of ACM and recurrent CVH emphasizes the importance of early intervention resulting in early and sustained clinical benefits.

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, and that the potential total global addressable market could reach as high as $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 2024. 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 (Attruby/Beyonttra). We believe acoramidis (Attruby/Beyonttra) will also be an important treatment option for patients inadequately managed by the current treatment. Further, we believe that acoramidis (Attruby/Beyonttra) 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.

Disease 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 essential hormones and vitamins. In ATTR, TTR tetramers become destabilized due to a mutation in the TTR gene or as part of the natural aging process. Destabilized TTR dissociates into monomers, self-aggregates, and assembles into fibrils 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. Only when TTR destabilizes to release its monomers, which may then re-aggregate and misfold into amyloid fibrils, does the ATTR disease process begin.

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. 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.

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 (Attruby/Beyonttra) 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 TTR monomer formation.

TTR is a protein which 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.

Clinical Data

Phase 2 Data

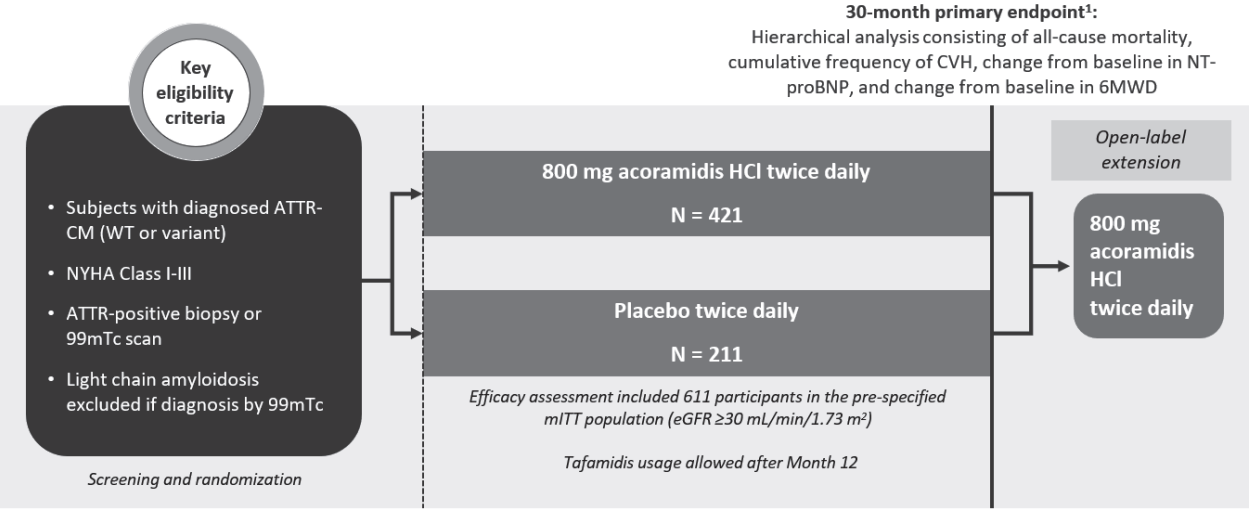
In November 2018, we announced Phase 2 data for acoramidis in symptomatic patients with ATTR-CM. The randomized, placebo-controlled, dose-ranging clinical trial included 49 patients with symptomatic ATTR-CM, of which 14 had ATTR-CM. Eligible patients were randomized in a 1:1:1 ratio to placebo or 400 milligrams or mg, or 800 mg of acoramidis twice daily over 28 days. Overall, acoramidis was well-tolerated in symptomatic ATTR-CM subjects with no safety signals of potential clinical concern attributed to study drug. Acoramidis significantly raised serum TTR concentrations ($p < 0.0001$) by 50% and 36% in subjects administered 800 mg twice daily and 400 mg twice daily, respectively, at day 28. Normalized serum TTR levels were observed in all actively treated subjects at day 28.

In November 2019, we announced data from our Phase 2 open-label extension ("OLE"), suggesting long-term tolerability of acoramidis and stabilization of ATTR-CM disease measures. Acoramidis was well-tolerated in the OLE and no safety signals of potential clinical concern were attributed to study drug. In an exploratory analysis of OLE participants following a median of 15 months since Phase 2 initiation, the rate of all-cause mortality (including either death or cardiac transplantation) was 8.5% and cardiovascular-related hospitalizations (proportion experiencing at least one event) was 25.5%.

In October 2023, we presented updated results from our Phase 2 OLE, demonstrating continued long-term tolerability of acoramidis and stabilization of ATTR-CM disease measures. With a median of 55 months of continuous treatment, acoramidis was generally well-tolerated in the OLE and no safety signals of potential clinical concern were attributed to study drug. In patients with symptomatic ATTR-CM, long-term treatment with acoramidis is associated with both stable median NT-proBNP levels and sustained increases in serum TTR. In this ongoing open-label study, at least 53% of patients with ATTR-CM and NYHA Class II or III at entry to the Phase 2 trial have survived for a median follow-up of 4.6 years.

Phase 3 Data

In February 2019, we initiated ATTRibute-CM, a global Phase 3 randomized, placebo-controlled clinical trial of acoramidis in ATTR-CM. ATTRibute-CM enrolled 632 subjects with symptomatic ATTR-CM, associated with either wild-type or variant TTR and NYHA Class I-III symptoms. Subjects were randomized 2:1 between treatment (acoramidis 800 mg) and placebo twice daily in a two-part trial. In Part A, change in 6MWD at 12 months was compared between treatment and placebo groups as a potential registrational endpoint. In Part B, the hierarchical composite primary endpoint including all-cause mortality and cardiovascular hospitalizations will be compared between treatment and control groups at 30 months. Secondary endpoints include quality of life as assessed by the KCCQ-OS, safety parameters, serum TTR levels, a measure of TTR stabilization, and NT-proBNP levels, a cardiac biomarker. In Part B, concomitant use of tafamidis was allowed. A schematic of the trial design is shown below:



6MWD = Six-minute walk distance; NYHA = New York Heart Association; 99mTc = Technetium labeled pyrophosphate (PYP) or bisphosphonate (e.g., DPD); mITT = Modified intent-to-treat. eGFR = Estimated glomerular filtration rate.

[1] Primary analysis assessed using the Finkelstein-Schoenfeld method.

On December 27, 2021, we reported topline data from Part A of the ATTRibute-CM trial, which did not meet its primary endpoint of change from baseline in 6MWD ($p = 0.76$). Mean observed 6MWD decline for the acoramidis and placebo arms were 9 meters and 7 meters, respectively. Decline observed in both arms of ATTRibute-CM was similar to expected functional decline in healthy elderly adults at 12 months. We observed improvements in acoramidis-treated participants relative to placebo-treated participants at Month 12 on secondary and exploratory endpoints including NT-proBNP, serum TTR concentration and KCCQ-OS.

On July 17, 2023, we announced positive data from our Phase 3 ATTRibute-CM clinical trial of acoramidis for patients with ATTR-CM. The primary endpoint (a hierarchical analysis inclusive of all-cause mortality and frequency of cardiovascular-related hospitalization) was met (win ratio of 1.8) with a highly statistically significant p-value ($p<0.0001$). This primary endpoint result consistently favored acoramidis treatment across key subgroups, including across both variant and wild-type ATTR patients as well as across NYHA Class I, II, and III patients. In particular, consistency against cardiovascular-related hospitalizations (CVH) was observed across all prespecified subgroups at 30 months. Absolute values observed across all-cause mortality (ACM), cardiovascular mortality (CVM) and CVH

showed that over 30 months, patients survived more and were hospitalized less than has been seen in prior controlled studies of ATTR-CM to the Company's knowledge. Assessment of measures of disease progression in the trial suggest that of participants assigned to receive acoramidis treatment who completed a month 30 visit, 45% experienced an improvement from baseline in N-terminal prohormone of brain natriuretic peptide (NT-proBNP), 40% experienced an improvement from baseline on 6-minute walk distance (6MWD), and 13% experienced an improvement from baseline in NYHA class. The placebo and acoramidis time-to-first event Kaplan-Meier (K-M) curves for a composite of all-cause mortality (ACM) and cardiovascular-related hospitalization (CVH) separated beginning at Month 3, representing rapid and sustained clinical benefit on the composite endpoint of ACM and CVH in ATTR-CM patients through Month 30 (Hazard Ratio = 0.645, 95% CI: 0.500-0.832). Acoramidis was well-tolerated, with no safety signals of potential clinical concern identified.

On September 27, 2024, we announced a post-hoc analysis of ATTRibute-CM demonstrating a 42% reduction in composite ACM and recurrent CVH events at 30 months observed with acoramidis treatment compared to placebo by applying a negative binomial regression model (p=0.0005). A 42% reduction in the total number of ACM and recurrent CVH events per patient was also observed over 30 months with acoramidis treatment compared to placebo.

On November 18, 2024, we announced acoramidis demonstrated statistically significant risk reduction in the OLE of 36% on ACM alone at Month 36 (p=0.009) and 34% by Month 42 (p=0.006), as assessed by the Stratified Cox proportional hazards model. A significant reduction of composite ACM and CVH by 46% at Month 36 (p<0.0001) and 48% at Month 42 (p<0.0001) was also assessed by negative binomial regression. Acoramidis continued to be well tolerated, with no new clinically significant safety signals identified in this long-term evaluation.

ACT-EARLY Prevention Study

ACT-EARLY, the first Phase 3 clinical trial to evaluate prophylactic acoramidis therapy for the prevention or delay of ATTR amyloidosis in asymptomatic pathogenic TTR variant carriers, was initiated in 2024.

Competition

Attruby/Beyonttra (acoramidis) for the treatment of adults with ATTR-CM will compete 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. We also expect Attruby/Beyonttra to face competition from Alnylam Pharmaceuticals, Inc.'s Vutrisiran, if approved by the FDA for the ATTR-CM indication, which is anticipated in March 2025.

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.

Products in Clinical Development

Starting with our three late-stage assets, the following section summarizes the products that we have in clinical development and that we believe have the greatest potential to drive significant near-term value for us due to a combination of factors, including their stage of development, potential availability of expedited development pathways, degree of unmet medical need and potential market size in the applicable target indication.

Low-dose Infigratinib for the treatment of FGFR-driven skeletal dysplasias

Summary

We are developing low-dose infigratinib, an oral FGFR1-3 selective tyrosine kinase inhibitor ("TKI") for the treatment of children with achondroplasia and hypochondroplasia. On January 13, 2025, we announced full enrollment of PROPEL 3, a Phase 3, multicenter, double-blinded, placebo-controlled pivotal study of low-dose infigratinib at a dose level of 0.25 milligrams per kilogram per day (mg/kg/day) in children with achondroplasia. We are also currently enrolling patients in ACCEL, a prospective natural history study in children with hypochondroplasia.

On June 4, 2024, we announced positive sustained results from PROPEL 2, our Phase 2 clinical trial of infigratinib in children with achondroplasia. In the highest dose level (Cohort 5, 0.25mg/kg/day), an increased annualized height velocity was observed, which persisted throughout the duration of the study, with a mean change

from baseline at 18 months of 2.50 centimeters per year (p = 0.001). The mean change from baseline in height z score was 0.54 (95% CI, 0.35 to 0.72) relative to an untreated achondroplasia reference population at 18 months; the mean change from baseline in the upper-to-lower body segment ratio was −0.12 (mean change from baseline, p=0.001). Infigratinib demonstrated clear dose-responsiveness when given as a single daily oral dose and was well-tolerated with no treatment-related adverse events ("AEs") assessed in Cohort 5.

Infigratinib is the first-ever investigational therapeutic option for achondroplasia, which has been awarded the breakthrough therapy designation by the FDA. In addition, infigratinib has also received Orphan Drug Designation and Rare Pediatric Disease Designation for achondroplasia from the FDA, and Fast Track Designation for both achondroplasia and hypochondroplasia from the FDA.

On February 7, 2024, our subsidiary, QED, granted Kyowa Kirin an exclusive license to develop, manufacture, and commercialize infigratinib for achondroplasia, hypochondroplasia, and other skeletal dysplasias in Japan for an upfront payment of $100.0 million that was received in June 2024. In addition, the Company will be eligible to receive royalties up to the mid-twenties percent on sales of infigratinib in Japan, with the potential to receive up to $81.4 million in development and sales-based milestone payments. 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 regarding the Kyowa Kirin license agreement.

Market Opportunity

We believe that achondroplasia and other FGFR-driven skeletal dysplasias represent a potentially over $5.0 billion total global market opportunity. The achondroplasia market alone has grown steadily since the end of 2021, driven by a newly available therapy driving children to seek treatment, as well as growing awareness of the new treatment among pediatric endocrinologists. 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.

Condition Overview

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

Achondroplasia is an autosomal dominant condition caused by a gain-of-function point mutation in the FGFR3 gene. Approximately 97% of cases are due to G380R substitution and 80% of cases are the result of *de novo* mutations. FGFR3 is expressed in osteoblasts and chondrocytes where it plays a critical role in regulating bone growth through the MAPK pathway, which drives hypertrophic differentiation, and through the STAT1 pathway, which drives chondrocyte proliferation. Apart from growth hormones, which are approved in Japan, there is only one medicine approved for marketing by the FDA, the European Medicines Agency ("EMA"), and the Pharmaceuticals and Medical Devices Agency ("PMDA"), for the treatment of achondroplasia: Voxzogo (vosoritide), a C-type natriuretic peptide ("CNP"), analog which activates the MAPK pathway but not the STAT1 pathway.

Design Criteria

We are developing low-dose infigratinib based upon two key design principles – we seek to target achondroplasia and hypochondroplasia at their source (FGFR3 gain-of-function mutations) in order to maximize clinical activity against all manifestations of the condition, not just height; and we seek to provide a tolerable oral treatment option in order to provide a reduced burden of treatment versus injection for children and their families. We believe low-dose infigratinib is the only investigational therapy in late-stage clinical development that incorporates both of these design principles.

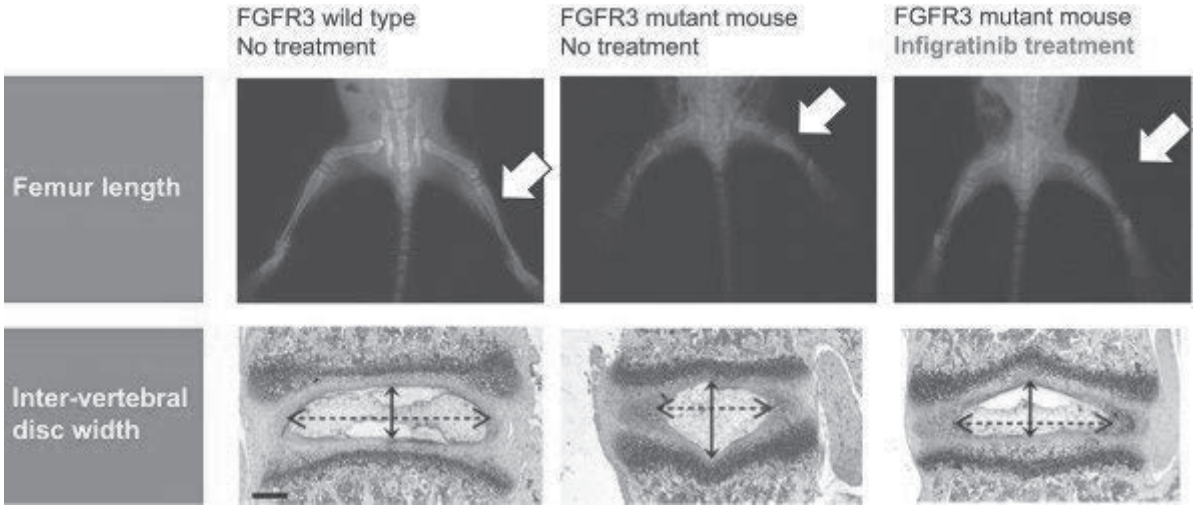
Low-dose infigratinib is designed to directly target FGFR3 gain-of-function mutations, which are the drivers behind the pathophysiology of achondroplasia and hypochondroplasia. As an FGFR1-3 inhibitor, we believe that low-dose infigratinib has the potential to decrease pathologic signaling downstream of FGFR3 and treat both conditions at the source. Unlike potentially competitive CNP mimetic approaches, which only inhibit MAPK signaling, our approach is aimed at also inhibiting STAT1 signaling.

Low-dose infigratinib is also designed for an oral route of administration. Blinded market research indicates that oral administration is the preferred route of administration amongst healthcare providers who treat children with achondroplasia.

Preclinical Data

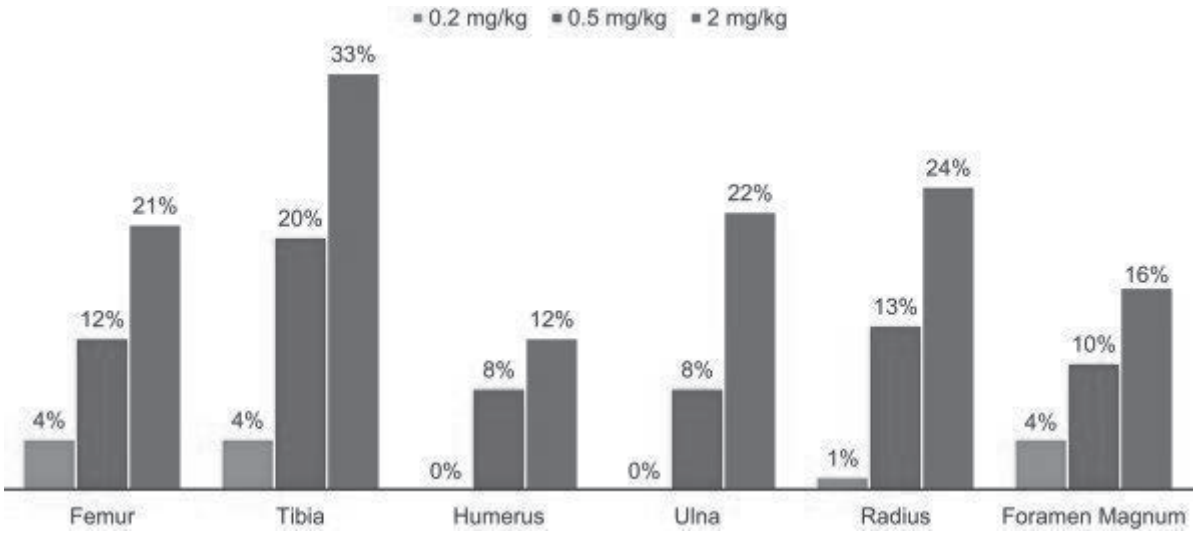
Low-dose infigratinib has been studied preclinically in a mouse model of achondroplasia that recapitulates anomalies of the growth plates, vertebrae, and intervertebral discs. Investigators observed that low-dose infigratinib rescued *ex vivo* bone growth of mutant mouse embryo femurs after six days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

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



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

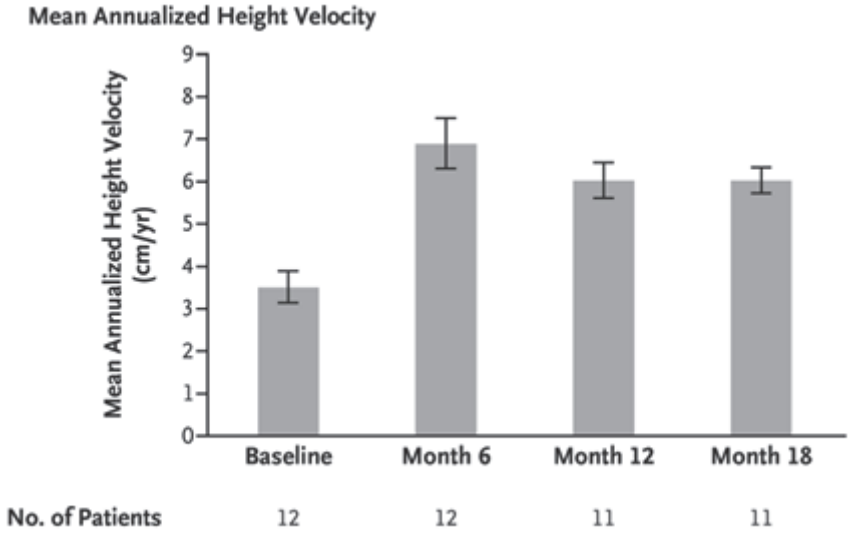
Increase in length compared to non-treated mouse (%)



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

Clinical Development Plan

Following positive feedback on the regulatory path to approval from the FDA and EMA, we continued to enroll patients in PROPEL 3 and we announced full enrollment of this study. This is a pivotal Phase 3 double-blinded, 2:1 randomized, placebo-controlled pivotal study of low-dose infigratinib at a dose level of 0.25 mg/kg/day in children with achondroplasia. The primary endpoint is change from baseline in AHV and the secondary endpoints include safety, proportionality, and height for age z-score.



Key Competitors

Low-dose infigratinib is the only oral direct FGFR1-3 inhibitor that has been publicly disclosed in clinical development for the treatment of achondroplasia. There are three other identified companies in clinical development for the treatment of achondroplasia: Ascendis Pharma A/S (TransCon CNP), Tyra Biosciences Inc., (TYRA-300), and Ribomic (RBM-007). If approved, infigratinib would face competition from BioMarin's Voxzogo (vosoritide), a CNP analog, for the treatment of achondroplasia, Voxzogo is approved in the U.S., Europe, Japan, Brazil and Australia.

Low-dose Infigratinib: Hypochondroplasia

We are also developing low-dose infigratinib as a treatment option for children living with hypochondroplasia, a skeletal dysplasia closely related to achondroplasia and similarly driven by FGFR3 gain-of-function variants. We are also committed to exploring the potential of infigratinib on the wider medical and functional impacts of hypochondroplasia, which hold significant unmet needs for families.

Market Opportunity

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.

Condition Overview

Hypochondroplasia is a rare, autosomal dominant skeletal dysplasia manifesting with disproportionate short stature, rhizomelic or mesomelic limb shortening, relative macrocephaly, and occasional mild orthopedic manifestations such as tibial bowing and limited elbow extension. Activating mutations in the FGFR3 gene have been shown to be the molecular source of the condition. The prevalence of hypochondroplasia is estimated to approach that of achondroplasia at one in 15,000 – 40,000. The average height is approximately 4'7" for a male and 4'3" for a female with hypochondroplasia. Medical complications common to achondroplasia (e.g., spinal stenosis, tibial bowing, obstructive apnea) occur less frequently in hypochondroplasia with reports in the literature of cases of temporal lobe dysgenesis and epilepsy. Apart from growth hormone, which is approved in Japan, there are no approved treatments for hypochondroplasia.

Preclinical Data

Low-dose infigratinib has been studied preclinically in a mouse model of hypochondroplasia (Fgfr3N534K/+ mice) that exhibits progressive dwarfism, impairment of the synchondroses of the cranial base resulting in defective formation of the foramen magnum. Mice treated with 1 mg/kg infigratinib daily for a total of 21 days showed a statistically significant increase in appendicular and axial skeleton (tibia +3.18%, femur +3.16%, humerus +3.04%, ulna +2.94%, radius +3.01%). Treatment with infigratinib modified skull shape, length of the mandible, and foramen magnum length (+3.72%). Cartilage growth plate organization, in particular the hypertrophic chondrocyte area, was modified, indicating that chondrocyte differentiation is improved. Low-dose treatment with infigratinib in the Fgfr3N534K/+ HCH mouse model ameliorated the clinical hallmarks of human pathology and significantly lengthened the axial skeleton, the appendicular skeleton and improved foramen magnum length. These findings support the rationale for targeting FGFR3 with a specific TKI such as infigratinib for the treatment of children with HCH.

Clinical Development Plan

We are currently enrolling children living with hypochondroplasia in ACCEL, an observational study for infigratinib in hypochondroplasia. The study will establish annualized height velocity ("AHV"), for each child for a minimum period of six months. ACCEL is designed to provide baseline measurements for children that we anticipate enrolling in the interventional study, ACCEL 2/3. This is a Phase 2/3, multicenter, open-label phase followed by a double-blind, randomized, placebo-controlled study to evaluate the efficacy and safety of infigratinib in children with hypochondroplasia.

Key Competitors

Low-dose infigratinib is the only oral direct FGFR1-3 inhibitor that has been publicly disclosed in clinical development for the treatment of hypochondroplasia. BioMarin Pharmaceutical Inc. is developing Voxzogo (vosoritide), a CNP analog, for the treatment of hypochondroplasia.

Encaleret for the treatment of Autosomal Dominant Hypocalcemia Type 1 and Hypoparathyroidism

Summary

Encaleret is an oral small molecule antagonist of the calcium sensing receptor ("CaSR") that we are developing for the treatment of Autosomal Dominant Hypocalcemia Type 1 ("ADH1"). We are currently studying encaleret in an ongoing Phase 3 clinical trial (NCT05680818) as a potential treatment for patients with ADH1. We reported results from the Phase 2b study of encaleret in ADH1 (NCT04581629) in 2022 and published the results from the same study in the New England Journal of Medicine in September 2023. In 13 participants in the Phase 2b trial, treatment with encaleret resulted in rapid and sustained restoration of normal mineral homeostasis, with mean values of blood calcium, urinary calcium, and blood parathyroid hormone ("PTH") within the normal range by day 5 of therapy and sustained at 24 weeks, and was well-tolerated without any reported serious adverse events.

We are also currently studying encaleret in an ongoing Phase 2 clinical trial (NCT05735015) as a potential treatment for patients with post-surgical hypoparathyroidism, in collaboration with clinical researchers at the National Institutes of Health. Preliminary results from this ongoing Phase 2 study were reported at the American Society for Bone Mineral Research annual meeting in September 2024.

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.

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 post-surgical hypoparathyroidism given its profile as an orally administered therapy.

Design Criteria

Encaleret is an investigational, orally administered, small molecule antagonist of the CaSR. It has been studied in more than 1,200 human subjects in its prior development and was observed to increase serum calcium in a dose-dependent manner. The rationale for developing encaleret as a potential treatment for patients with ADH1 is based on both non-clinical and clinical evidence. Antagonists of the CaSR have been shown *in vitro* to shift the aberrant CaSR "set-point" back towards a normal IC_{50} for calcium and *in vivo* to increase PTH secretion, elevate blood calcium concentrations, and reduce urinary calcium excretion. By selectively antagonizing the CaSR, encaleret may restore normal CaSR function in individuals with ADH1 and may address symptoms associated with hypocalcemia and hypercalciuria.

Clinical Data

On June 13, 2022, we reported positive data from our Phase 2b clinical trial of encaleret in patients with ADH1. Thirteen adults with ADH1 caused by nine unique *CASR* variants participated in the three-period, Phase 2b, open-label, dose-ranging clinical trial. Oral calcium and activated vitamin D supplements were discontinued prior to encaleret initiation. Periods 1 and 2 each evaluated encaleret over the course of five inpatient days and Period 3 included a 24-week outpatient evaluation. Based on 24-week outpatient data, we observed:

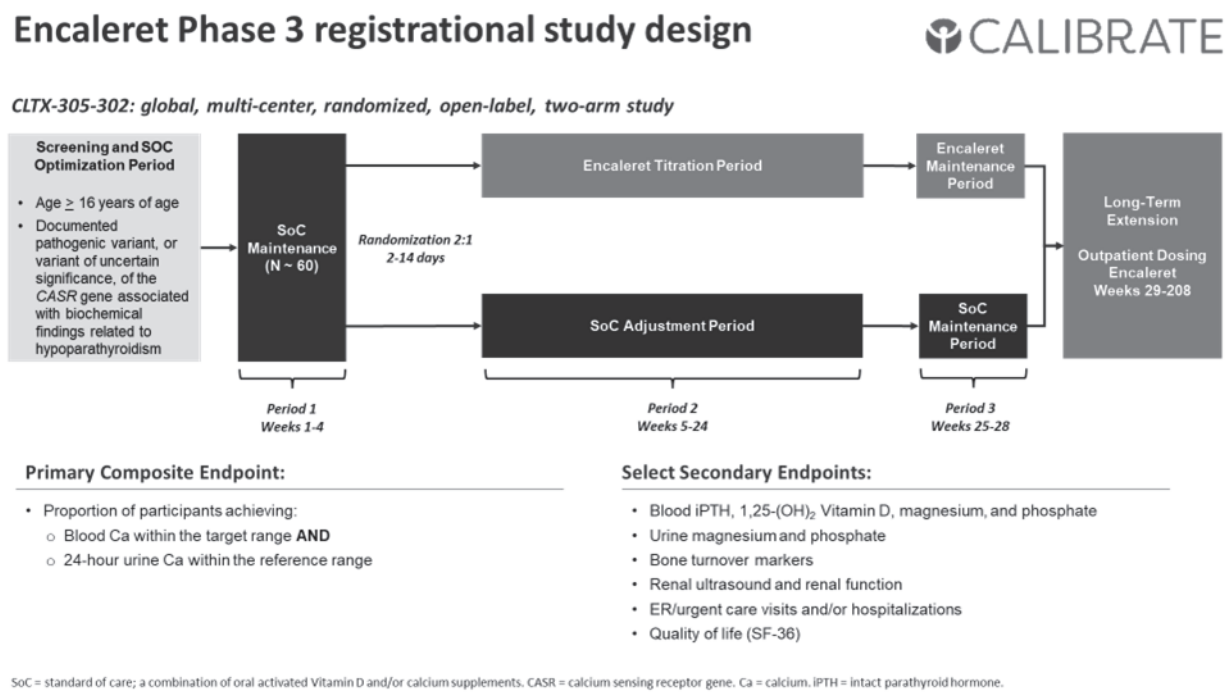
- Mean values of blood calcium, urinary calcium, and blood parathyroid hormone, key biochemical parameters of mineral homeostasis, were normalized by Period 2, Day 5 and were sustained through Period 3, Week 24 of the trial.

- At Week 24 of encaleret treatment, 92% (12/13) of participants had achieved normal trough blood calcium levels in the absence of extra-dietary calcium supplements and active vitamin D, and 77% (10/13) of participants had normal urinary calcium excretion.
- Encaleret was well-tolerated with no serious adverse events reported; there were no treatment discontinuations or study withdrawals.

The participants who completed Period 3 of the Phase 2b study were eligible to continue in an open-label extension of up to 25 months. The results of the study were published in the New England Journal of Medicine in September 2023.

In September 2024, we reported preliminary results from an ongoing Phase 2 clinical study of encaleret in participants in post-surgical hypoparathyroidism. Encaleret was found to simultaneously normalize blood and urine calcium levels in 86% (6 of 7) participants evaluated within 5 days of treatment. Encaleret was well-tolerated without any reported serious adverse events.

In December 2022, we also announced the initiation of our Phase 3 registrational trial of encaleret in ADH1 and completed screening for this study in November 2024. Topline results from this Phase 3 registrational study are anticipated in the second half of 2025. A schematic of this Phase 3 trial is shown below:



Key Competitors

We believe encaleret is the only molecule that has been publicly disclosed to be in development specifically for the treatment of ADH1. There are other identified companies developing compounds for the treatment of hypoparathyroidism using recombinant parathyroid hormone analogs or PTH receptor agonists: Ascendis Pharma A/S (palopegteriparatide), AstraZeneca PLC (eneboparatide), Amolyt Pharma (AZP-3601), EnteraBio Ltd. (EB612), Extend Biosciences Inc. (EXT608), and MBX Biosciences, Inc. (MBX 2109), and Septerna Inc. (SEP-786). Palopegteriparatide is currently being marketed as Yorvipath in certain territories, including in the United States and in Europe, for the treatment of hypoparathyroidism.

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

BBP-418 is an investigational, orally administered, small molecule substrate supplementation therapy that we are developing for the treatment of LGMD2I, also known as LGMDR9 FKRP-related. In October 2023, we shared positive long-term data from our Phase 2 trial in patients with LGMD2I, including that early assessment of increased glycosylated αDG may predict subsequent ambulatory improvements at later time points, supporting the use of glycosylated αDG levels as a potential surrogate endpoint in LGMD2I. We are currently studying BBP-418 in FORTIFY, an ongoing global registrational Phase 3 clinical trial in patients with LGMD2I. We believe there is potential to pursue accelerated approval in the United States for BBP-418 based on recent interactions with the FDA discussing the use of glycosylated αDG as a surrogate endpoint, the validated bioassay and the interim analysis approach.

Disease Overview

LGMD2I 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 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.

Design Criteria

The rationale for developing BBP-418 as a potential treatment for LGMD2I 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, 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 by supplying supra-physiological levels of BBP-418 upstream to drive residual activity of the mutant FKRP enzyme and potentially increase glycosylated αDG levels.

Clinical Data

On October 9, 2023, we shared positive long-term results from our ongoing Phase 2 clinical trial of BBP-418 in patients with LGMD2I. Based on the data after 21 months of treatment, we observed:

- Increased glycosylated αDG levels from baseline observed as early as three months and sustained with treatment
- Large (≥80%), sustained reduction in creatine kinase observed over an extended (up to 21-months) treatment period
- Stabilization in NSAD scores and ambulatory measures observed over 21-months of BBP-418 treatment
- BBP-418 continues to be well-tolerated with longer-term treatment
- No treatment-related serious adverse events ("SAEs") or dose limiting toxicities observed with 21-months of BBP-418 dosing

Clinical Development Plan

Following the release of top-line data from our Phase 2 trial, we engaged with regulatory authorities to align on a Phase 3 trial design, including an interim analysis at 12 months on study intended to support accelerated approval. Our Phase 3 trial, FORTIFY, was initiated in the U.S., with the first patient enrolled in June 2023. The FORTIFY study announced enrollment surpassed the interim analysis target in June 2024. The FORTIFY study was fully enrolled in September 2024 and is now closed for enrollment. Top-line data from the FORTIFY interim analysis is expected in the second half of 2025.

Key Competitors

We believe BBP-418 is the only late-stage oral therapy in clinical development for potentially disease-modifying treatment of LGMD2I. Edgewise Therapeutics is developing an oral small molecule therapy (sevasemten) for adults with LGMD2I. Asklepios Biopharmaceutical, Inc. (AB-1003 also known as LION-101) and Atamyo Therapeutics (ATA-100) are two other companies that are developing gene therapies for the treatment of LGMD2I.

Other Development

Our robust late-stage pipeline is supported by our productive early-stage research engine, which has produced 19 INDs since our inception. We recently announced in the fourth quarter of 2024 a new trial ACT-EARLY, the first Phase 3 clinical trial to evaluate prophylactic acoramidis therapy for the prevention or delay of ATTR amyloidosis in asymptomatic pathogenic TTR variant carriers. In addition to this Phase 3 study, our clinical product pipeline includes a Phase 2 study (ACCEL) for infigratinib for hypochondroplasia that is currently enrolling. The dosing of the first patient is anticipated in the middle of 2025. We also have an ongoing Phase 2 clinical trial for encaleret for postsurgical hypoparthyroidism. We anticipate formalizing plans to advance development of encaleret in this indication by the end of 2025. We are also conducting a Phase 1/2 study (CANaspire) for BBP-812 for Canavan disease.

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 Attruby and Beyonttra 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., which began following the FDA approval of Attruby on November 22, 2024. In June 2024, BridgeBio Europe B.V. ("BridgeBio B.V.") entered into a commercial supply agreement with Bayer ("Bayer 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 the use in the commercialization of Beyonttra in Europe under the Bayer License Agreement. As of December 31, 2024, there have been no commercial product supply sales to Bayer. In addition, during the year ended December 31, 2024, we have supplied $0.6 million of commercial product to Alexion in Japan under a commercial supply agreement. 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. Attruby, Beyonttra and several of our development candidates have or are in the near term expected to have redundant and overlapping drug substance and drug product supply chains. 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 regarding the Bayer Supply Agreement.

Commercialization and Product Support

U.S. Launch of Attruby (acoramidis)

We have built our own commercial organization in the U.S. to support the commercialization of Attruby in the U.S. Following the receipt of FDA approval in November 2024, we commercially 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. Attruby was approved by the FDA for the treatment of ATTR-CM in adults to reduce cardiovascular death and cardiovascular-related hospitalization. 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.

To prepare for this sizable market opportunity, commercial readiness efforts for Attruby began well in advance of its FDA approval. Our pre-launch activities, including claims analytics and disease state educational programs for healthcare providers, helped identify key stakeholders and ensure a smooth transition post-approval in November 2024.

Attruby has already demonstrated category-leading results including:

- Effect on hard clinical outcomes and quality of life (QoL) observed as early as three months
- 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. For Medicare patients, the Inflation Reduction Act (IRA) limited out-of-pocket costs (OOP) and capped OOP at $2,000 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 per month, inclusive of all Part D medications. Dual-eligible and Low-Income Subsidy patients will pay no more than $13 per month. 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.

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 (3PL) 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 Beyonttra in Europe and Alexion for commercialization of acoramidis in Japan if approved. We plan to leverage a full-service distribution partnership to support commercialization of acoramidis in rest of world markets.

We 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.

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 13, 2025, our intellectual property portfolio is composed of over 100 issued patents and over 400 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 to two issued U.S. patents, and related pending and issued foreign patents and patent applications in Australia, Canada, China, Europe, Japan and Mexico, as well as in other countries in Asia and in South America, that are directed to compositions of matter of 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 to 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 four pending U.S. patent applications, two pending Patent Cooperation Treaty ("PCT") patent applications, and related pending foreign patent applications in Australia, Canada, China, Europe, Japan and Mexico, as well as in other countries in Asia, that are directed to methods of treating various cancers or skeletal disorders using infigratinib. If any patents issue from these patent applications, such patents would be expected to expire between 2040 and 2044.

For our subsidiary Eidos Therapeutics, Inc., we license rights from the Board of Trustees of the Leland Stanford Junior University, or Stanford, to 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.

In addition, we own five issued U.S. patents, six pending U.S. patent applications, 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 to one issued U.S. patent and two foreign patents in Europe and Japan that are directed to compositions of matter of encaleret. The U.S. patent is expected to expire in 2025, and the foreign patents expired in 2024. In addition, Calcilytix owns four pending U.S. patent applications, and thirty one 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 encaleret. 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 to seven issued U.S. patents, one pending U.S. patent application, 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, not including any potential patent term extension. The pending U.S. and foreign patent applications, if issued, are expected to expire in 2040 or 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. Upon approval of acoramidis, patent term extension applications were timely filed for multiple U.S. patents licensed from Stanford.

Our Material Agreements

Acoramidis (Attruby/Beyonttra)

License Agreement with Bayer

In March 2024, certain of our subsidiaries, including Eidos Therapeutics, Inc. ("Eidos"), BridgeBio International GmbH and BridgeBio Europe B.V. ("BridgeBio B.V."), entered into an exclusive license agreement (the "Bayer License Agreement") with Bayer, to develop and commercialize acoramidis (Beyonttra) as a treatment for ATTR-CM in all EU member states as well as all member and extension states of the European Patent Organization as of effective date of the license agreement (the "Licensed Territory").

Under the terms of the Bayer License Agreement, Eidos granted Bayer an exclusive license, to certain of Eidos' intellectual property rights to develop, manufacture and commercialize Beyonttra in the Licensed Territory. Under the Bayer License Agreement, we 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 (of which $75.0 million is for a regulatory milestone dependent upon receipt of EC approval of Beyonttra on or before December 31, 2025). We are also eligible to receive up to $450.0 million in additional sales milestones along with quarterly royalty payments according to a tiered structure starting in the low-thirties percent on net sales by Bayer of Beyonttra.

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 Beyonttra under certain circumstances or challenges the validity or enforceability of Eidos' patent rights.

In June 2024, BridgeBio B.V. entered into the Bayer 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 the use in the commercialization in the Licensed Territory under the Bayer License Agreement. Under the Bayer Supply Agreement, Bayer shall pay to BridgeBio B.V. a commercial product per unit price equal to the applicable fully burdened manufacturing cost per unit of product, which shall include the cost of the active

pharmaceutical ingredient ("API") used to manufacture the product and the packaging price. As of December 31, 2024, there have been no commercial product supply sales to Bayer.

The condition for the $75.0 million regulatory-based milestone payment was achieved upon the EC approval of Beyonttra on February 10, 2025. We anticipate receiving this milestone payment from Bayer in April 2025.

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 Unlimited Company, a subsidiary of Alexion Pharmaceuticals, Inc. (together, "Alexion"), to develop and commercialize Beyonttra in Japan. Additionally, in September 2019, Eidos entered into a stock purchase agreement with Alexion, pursuant to which Eidos sold to Alexion 556,173 shares of its common stock for aggregate cash proceeds of $25.0 million. Under the terms of the Eidos-Alexion License Agreement, Eidos granted Alexion an exclusive license to certain of our intellectual property rights to develop, manufacture and commercialize Beyonttra in Japan. In consideration for the license grant, Eidos received an upfront payment of $25.0 million in 2019, with the potential for an additional one-time payment of $30.0 million subject to the achievement of a regulatory milestone. In addition, Eidos is entitled to receive royalties in the low double-digits on net sales by Alexion of Beyonttra 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 Beyonttra 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, to be used by Eidos to cover any out-of-pocket costs and employee costs incurred by Eidos in connection with the clinical trial in Japan.

In November 2024, BridgeBio and Alexion entered into a commercial supply agreement for the manufacture and supply of the Licensed Product (as defined in the agreement) for commercial use in the Territory (as defined in the agreement). BridgeBio entered into the agreement as BridgeBio is the entity responsible for the manufacture of the Licensed Product. Under the commercial supply agreement, Alexion shall pay to BridgeBio a commercial product per unit price equal to the applicable fully burdened manufacturing cost per unit of product. BridgeBio has supplied $0.6 million of commercial products to Alexion during the year ended December 31, 2024.

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.

During 2024, we incurred and paid $8.1 million of licensing fees due to Stanford related to the Company entering into the Bayer License Agreement in March 2024, recognized a milestone payable to Stanford of $0.5 million upon the receipt of FDA approval for Attruby, and recognized an immaterial amount of royalty payable to Stanford from net product sales of Attruby.

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.

Infigratinib

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 CCA, UC and achondroplasia. We refer to this agreement as the Novartis License.

Pursuant to the Novartis License, we obtained a license to research, develop, make, have made, use, import, offer for sale, sell, have sold and otherwise commercialize 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 TRUSELTIQ™ 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:

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.

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 Attruby 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.

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 a New Drug Application ("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, and may overlap.

- Phase 1 clinical trials generally involve a small number of healthy volunteers or disease-affected patients who are initially exposed to a single dose and then multiple doses of the product candidate. The primary purpose of these clinical trials is to assess the metabolism, pharmacologic action, side effect tolerability and safety of the product candidate.
- Phase 2 clinical trials involve studies in disease-affected patients to evaluate proof of concept and/or determine the dose required to produce the desired benefits. At the same time, safety and further PK and PD information is collected, possible adverse effects and safety risks are identified, and a preliminary evaluation of efficacy is conducted.

- Phase 3 clinical trials generally involve a large number of patients at multiple sites and are designed to provide the data necessary to demonstrate the effectiveness of the product for its intended use, its safety in use and to establish the overall benefit/risk relationship of the product and provide an adequate basis for product labeling.

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. 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 of life-threatening manifestations primarily affect individuals aged from birth to 18 years and the disease affects fewer than 200,000 individuals in the United States or affects more than 200,000 in the United States and for which there is no reasonable expectation that the cost of developing and making in the United States a drug for such disease or condition will be received from sales in the United States of such drug. The sponsor of a product candidate for a rare pediatric disease may be eligible for a voucher that can be used to obtain a priority review for a subsequent human drug or biologic application after the date of approval of the rare pediatric disease drug product, referred to as a 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. The FDA's rare pediatric disease priority voucher program began to sunset on December 20, 2024, on failure to pass a continuing resolution package that included its reauthorization. Under the amended statutory sunset provisions, after December 20, 2024, the FDA may award a PRV for an approved rare pediatric disease product application only if the sponsor has rare pediatric disease designation for the drug and if that designation was granted by December 20, 2024. After September 30, 2026, the FDA may not award any rare pediatric disease PRVs. Congress may vote to reauthorize this program, but its future remains unknown at this time.

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 PHSA and 21 CFR Part 1271. This program is intended to facilitate efficient development and expedite review of regenerative medicine therapies, which are intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition and qualify for RMAT designation. A 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 DSCSA mandates phased-in and resource-intensive obligations for pharmaceutical manufacturers, wholesale distributors, and dispensers over a 10-year period that culminated in November 2023. The FDA established a one-year stabilization period from November 2023 to November 2024 for trading partners to continue to build and validate interoperable systems and processes to meet certain requirements of the DSCSA. In late 2024, the FDA announced it is allowing a further exemption period for eligible trading partners who have successfully completed or made documented efforts to complete data connections with their immediate trading partners, but still face challenges exchanging data. The exemption period for eligible manufacturers and repackagers now extends until May 27, 2025. The law's requirements 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 System Regulation, or QSR, which requires manufacturers to follow design, testing, control, documentation and other quality assurance procedures. The FDA's review of an initial PMA application is required by statute to take between six to ten months, although the process typically takes longer, and may require several years to complete. If the FDA evaluations of both the PMA application and the manufacturing facilities are favorable, the FDA will either issue an approval letter or an approvable letter, which usually contains a number of conditions that must be met in order to secure the final approval of the PMA 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 PHSA, in part, attempts to minimize duplicative testing. Biosimilarity, which requires that the biological product be highly similar to the reference product notwithstanding minor differences in clinically inactive components and that there be no clinically meaningful differences between the product and the reference product in terms of safety, purity and potency, can be shown through analytical studies, animal studies and a clinical trial or trials. Interchangeability requires that a biological product be biosimilar to the reference product and that the product can be expected to produce the same clinical results as the reference product in any given patient and, for products administered multiple times to an individual, that the product and the reference product may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biological product without such alternation or switch. Complexities associated with the larger, and often more complex, structure of biological products as compared to small molecule drugs, as well as the processes by which such products are manufactured, pose significant hurdles to implementation that are still being worked out by the FDA.

A reference biological product is granted four and twelve year exclusivity periods from the time of first licensure of the product. 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"), which took effect on January 1, 2020 imposed many new requirements on businesses that process the personal information of California residents. Many of the CCPA's requirements are similar to those found in the General Data Protection Regulation (the "GDPR"), including requiring businesses to provide notice to data subjects regarding the information collected about them and how such information is used and shared, and providing data subjects the right to request access to such personal information and, in certain cases, request the erasure of such personal information. The CCPA also affords California residents the right to opt-out of "sales" or "sharing" of their personal information. The CCPA contains significant penalties for companies that violate its requirements. In November 2020, California voters passed a ballot initiative for the California Privacy Rights Act ("CPRA"), which went into effect on January 1, 2023, and significantly expanded the CCPA to incorporate additional GDPR-like provisions including requiring that the use, retention, and sharing of personal information of California residents be reasonably necessary and proportionate to the purposes of collection or processing, granting additional protections for certain sensitive personal information, and requiring greater disclosures related to notice to residents regarding retention of information. The CPRA also created a new enforcement agent—the California Privacy Protection Agency—whose sole responsibility is to enforce the CPRA, which will further increase compliance risk. The provisions in the CPRA may apply to some of our business activities.

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). Some of the provisions of these laws may apply to our business activities. Such proposed legislation, if enacted, may add additional complexity, variation in requirements, restrictions and potential legal risk, require additional investment of resources in compliance programs, impact strategies and the availability of previously useful data and could result in increased compliance costs and/or

changes in business practices and policies. The existence of comprehensive privacy laws in different states in the country would 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

Further, Congress has also been debating passing a federal privacy law. There are also states that are specifically regulating health information that may affect our business. For example, Washington's My Health My Data Act, which went into effect on March 31, 2024, regulates the collection and sharing of 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. State laws are changing rapidly and there has been discussion in the U.S. Congress of a new comprehensive federal data privacy law to which we may likely become subject, if enacted. 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. In addition, 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.

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, orphan drugs are exempted from the Medicare drug price negotiation program, but only if they have one orphan designation and for which the only approved indication is for that disease or condition. If a product receives multiple orphan designations or has multiple approved indications, it will not qualify for the orphan drug exemption. The implementation of the IRA is currently subject to ongoing litigation challenging the constitutionality of the IRA's Medicare drug price negotiation program. The effects of the IRA on our business and the healthcare industry in general is not yet known.

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. President Biden has also issued multiple executive orders that have sought to reduce prescription drug costs. In February 2023, HHS also issued a proposal in response to an October 2022 executive order from President Biden that includes a proposed prescription drug pricing model that will test whether targeted Medicare payment adjustments will sufficiently incentivize manufacturers to complete confirmatory trials for drugs approved through FDA's accelerated approval pathway. 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. 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 two types of MAs.

- 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 Member States 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, who makes the final decision to grant an MA, which is issued within 67 days of receipt of the EMA's recommendation. Accelerated assessment might 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 ten-year period will be extended to a maximum of 11 years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are determined to bring a significant clinical benefit in comparison with currently approved therapies. 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." 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 approval. 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 is eligible for six months' 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 Beyonttra 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 Beyonttra. 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 Beyonttra 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 Statue prohibition in the United States, the provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the European Union. The provision of benefits or advantages to 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). The European Commission has provided the legislative proposals to the European Parliament and the European Council for their review and approval, and, in April 2024, the European Parliament proposed amendments to the legislative proposals. Once the European Commission's legislative proposals are approved (with or without amendment), they will be adopted into EU law.

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

The UK formally left the EU on January 31, 2020, and 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.

At present, EU laws which have been transposed into UK law through secondary legislation continue to be applicable as "retained EU law". However, new EU legislation, such as the EU Clinical Trials Regulation, is not applicable. The UK government has passed the Medicines and Medical Devices Act 2021, which introduced delegated powers in favor of the Secretary of State (or for Northern Ireland, the Department of Health in Northern Ireland) 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.

As a result of the Northern Ireland protocol, following Brexit, the EMA remained responsible for approving novel medicines for supply in Northern Ireland under the EU centralized procedure, and a separate authorization was required to supply the same medicine in Great Britain (England, Wales and Scotland). However, on February 27, 2023, the UK government and the European Commission announced a political agreement in principle to replace the Northern Ireland Protocol with a new set of arrangements, known as the "Windsor Framework". This new framework fundamentally changes the existing system under the Northern Ireland Protocol, including with respect to the regulation of medicinal products in the UK. In particular, the MHRA is now responsible for approving all medicinal products destined for the UK market (i.e., Great Britain and Northern Ireland), and the EMA will no longer have any role in approving medicinal products destined for Northern Ireland under the EU centralized procedure. A single UK-wide marketing authorization will be granted by the MHRA for all 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 all medicines placed on the UK market to be labelled "UK only", indicating they are not for sale in the EU. The medicinal product aspects of the Windsor Framework have applied since January 1, 2025.

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, 2024, we had 725 full-time employees and 5 part-time employees. Of these, 391 focus on driving forward research and development programs and 202 focus on our commercialization efforts, either directly or through our affiliates, and 137 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 in 2025 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 our ability to successfully commercialize Attruby™ and Beyonttra™, and the commercial success of Attruby and Beyonttra or any other product candidates, if approved, will depend upon the degree of market acceptance by physicians, patients, healthcare payors, and others in the medical community.

Our business depends heavily on our ability to successfully commercialize Attruby and Beyonttra. The commercial success of Attruby and Beyonttra or our other product candidates, if approved, will depend upon their degree of market acceptance by physicians, patients, third-party payors, and others in the medical community. Our product candidates, if approved, may nonetheless fail to gain sufficient market acceptance by physicians, patients, healthcare payors, and others in the medical community. The degree of market acceptance of Attruby and Beyonttra or any other of our product candidates we may develop, if approved for commercial sale, will depend on a number of factors, including:

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

Sales of medical products also depend on the willingness of physicians to prescribe the treatment, which is likely to be based on a determination by these physicians that the products are safe, therapeutically effective and cost effective. In addition, the inclusion or exclusion of products from treatment guidelines established by various

physician groups and the viewpoints of influential physicians can affect the willingness of other physicians to prescribe the treatment. We cannot predict whether physicians, physicians' organizations, hospitals, other healthcare providers, government agencies or private insurers will determine that our products are safe, therapeutically effective and cost effective as compared with competing treatments. If any product candidates we develop do not achieve an adequate level of acceptance, we may not generate significant product revenue, and we may not become profitable.

If our sales and marketing capabilities for Attruby and Beyonttra are not effective or we are unable to establish sales and marketing capabilities or enter into and maintain our agreements with third parties to sell and market Attruby and Beyonttra or any future product candidates approved for commercial sale, we may be unsuccessful in our commercial efforts.

To achieve commercial success for Attruby and Beyonttra and any other approved product for which we retain sales and marketing responsibilities, we must continue to develop a sales and marketing organization or outsource these functions to third parties. In the future, we may choose to grow our focused sales, marketing, and commercial support infrastructure to market and sell our product candidates, if and when they are approved. We may also elect to enter into collaborations or strategic partnerships with third parties to engage in commercialization activities with respect to selected product candidates, indications or geographic territories, including territories outside the United States, as we have done with Bayer in the case of Beyonttra once it was approved, 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.

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 of any approved products by us or a commercial partner;
- the failure to obtain the necessary regulatory approvals, state licenses, wholesale distribution licenses or other registrations that are required to ship an approved product to a customer or commercial partner;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent commercialization organization.

If we enter into arrangements with third parties to perform sales, marketing, commercial support, and distribution services, our product revenue or the profitability of product revenue may be lower than if we were to market and sell any products we may develop internally. In addition, we may not be successful in entering into arrangements with third parties to commercialize, if approved, our product candidates or may be unable to do so on terms that are favorable to us or them. We may have little control over such third parties, and any of them may fail

to devote the necessary resources and attention to sell and market our products effectively or may expose us to legal and regulatory risk by not adhering to regulatory requirements and restrictions governing the sale and promotion of prescription drug products, including those restricting off-label promotion. Even if we enter into a commercial partnership with a third party, we may have manufacturing, supply chain or distribution disruptions that delay or prevent the commercial launch of an approved product by our partner. There is also a risk that one of our commercial partners decides to terminate our agreement due to a change in its business priorities or financial condition, or due to other circumstances may no longer be able to fulfill its obligations under our agreement, which would negatively impact our ability to sell our products in certain markets and to generate revenues from product sales. If we do not continue to build on our commercialization capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing Attruby and Beyonttra and our product candidates, if approved.

Our profitability will depend significantly on our ability to sell enough product at competitive prices and on the availability of adequate coverage and reimbursement through governmental or private third-party payors. The insurance coverage and reimbursement status of newly-approved products is uncertain. Our product candidates may become subject to unfavorable pricing regulations, third-party coverage and reimbursement practices, or healthcare reform initiatives, which would harm our business. Failure to obtain or maintain adequate coverage and reimbursement for new or current products could limit our ability to market those products and decrease our ability to generate revenue.

The regulations that govern marketing approvals, pricing, coverage, and reimbursement for new drugs vary widely from country to country. In the 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. In particular, the list price of Attruby in the United States is $18,759.12 for a 28-day supply and 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 other 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, 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.

Additionally, we may develop companion diagnostic tests for use with Attruby and Beyonttra and our product candidates. We, or our collaborators, may be required to obtain coverage and reimbursement for these tests separate and apart from the coverage and reimbursement we seek for our product candidates, once approved. Even if we obtain regulatory approval or clearance for such companion diagnostics, there is significant uncertainty regarding our ability to obtain coverage and adequate reimbursement for the same reasons applicable to our product candidates. Medicare reimbursement methodologies, whether under Part A, Part B, or clinical laboratory fee

schedule may be amended from time to time, and we cannot predict what effect any change to these methodologies would have on any product or product candidate or companion diagnostic for which we receive approval. Our inability to promptly obtain coverage and adequate reimbursement from both third-party payors for the companion diagnostic tests that we develop and for which we obtain regulatory approval could have a material and adverse effect on our business, financial condition, results of operations and prospects.

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

We have partnered with Bayer to commercialize Beyonttra in Europe and we plan to commercialize Attruby and Beyonttra in other foreign markets. In June 2024, BridgeBio B.V. entered into the Bayer 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 of Beyonttra in Europe under the Bayer License Agreement. 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 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;
- longer accounts receivable collection times;
- longer lead times for shipping;
- language barriers for technical training;
- reduced protection of intellectual property rights in some foreign countries, and related prevalence of bioequivalent or generic alternatives to therapeutics;
- foreign currency exchange rate fluctuations;
- potential resource constraints, including with respect to patients' ability to obtain reimbursement for our products in foreign markets; and
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute.

Any of these factors could impair our ability to commercialize Attruby and Beyonttra and any future drugs we may develop or for which we obtain commercial rights outside the 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 that may be adopted in other jurisdictions exemplifies the vulnerability of our business to the evolving regulatory environment related to personal data and protected health information. Compliance with U.S. and international data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Failure to comply with these laws and regulations could result in government enforcement actions (which could include civil, criminal and administrative penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects, employees and other individuals about whom we or our potential collaborators obtain personal information, as well as the providers who share this information with us, may limit our ability to collect, use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

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 Beyonttra and our other 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. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for Attruby and Beyonttra and our other 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 other 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.

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 other 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 regulatory approval or commercial success before us or develop therapies that are safer, more advanced or more effective than ours, which may negatively impact our ability to successfully market or commercialize any product candidates we may develop and ultimately harm our financial condition.

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

There are a number of large pharmaceutical and biotechnology companies that are currently pursuing the development and commercialization of products for the treatment of the indications that our core value drivers 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 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 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. We have not generated significant revenue since inception, which, together with our limited operating history, may make it difficult for you to assess our future viability.

Pharmaceutical and biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We are a newly commercial-stage biopharmaceutical company with a limited operating history upon which you can evaluate our business and prospects. Our subsidiaries, on whose success we largely rely, are primarily early-stage biopharmaceutical companies. To date, we have focused principally on identifying, acquiring or in-licensing and developing our product candidates at the subsidiary level, almost all of which are in discovery, lead optimization, preclinical or clinical development. In November 2024, Attruby was approved for commercial sale in the United States. In February 2025, Beyonttra was approved for commercial sale in Europe. Our pipeline of product candidates will require substantial additional development time, including extensive 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, 2024, 2023 and 2022 were $543.3 million, $653.3 million and $484.7 million, respectively. As of December 31, 2024, we had an accumulated deficit of $3.1 billion. In November 2024, Attruby was approved for commercial sale in the United States, and to date, we have not yet generated substantial revenue from sales of Attruby. 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 financed operations solely through the sale of equity securities, debt financings, royalty financing, and the sale of certain assets. Sentynl purchased the global rights to NULIBRY in March 2022 and Helsinn, who is the principal selling party of TRUSELTIQ™, discontinued selling TRUSELTIQ™ in March 31, 2023. We continue to incur significant research and development ("R&D"), costs for the commercialization of Attruby, 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 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 a marketable drug 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.

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. For instance, in January 2021, we completed our acquisition of all of the outstanding shares of common stock of Eidos that were not previously owned by us or our subsidiaries, to which we refer as the Eidos Merger. In connection with the Eidos Merger and our integration of Eidos' historical operations into our business, the attention of certain members of each company's management and each company's resources were diverted from day-to-day business operations. Additionally, the interests of our stockholders were diluted as a result of our issuance of shares of our common stock to Eidos' stockholders and our assumption of certain equity awards of Eidos in connection with the transaction. We may engage in similar discussions in the future with respect to other potential transactions that may divert our time and resources from our ongoing operations. 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 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") including for our ongoing Phase 3 clinical trial of low-dose infigratinib, our ongoing Phase 2 and planned Phase 3 clinical trials of BBP-418, and our ongoing Phase 3 clinical trial of encaleret, 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. Given that our Phase 2 dose-escalation and expansion study of low-dose infigratinib in children with achondroplasia, or PROPEL 2, was designed as an open-label trial, the results from this clinical trial may not be predictive of future clinical trial results with this or other product candidates for which we include an open-label clinical trial when studied in a controlled environment with a placebo or active control.

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

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

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

- the size and nature of a patient population;
- the patient eligibility criteria defined in the applicable clinical trial protocols, which may limit the patient populations eligible for clinical trials to a greater extent than competing clinical trials for the same indication;
- the size of the study population required for analysis of the trial's primary endpoints;
- the severity of the disease under investigation;
- the proximity of patients to a trial site;
- the design of the trial;
- the ability to recruit clinical trial investigators with the appropriate competencies and experience;
- the approval or concurrent enrollment of clinical trials involving competing product candidates currently under development for Mendelian diseases or genetically driven cancers, or competing clinical trials for similar therapies or targeting patient populations meeting our patient eligibility criteria;
- clinicians' and patients' perceptions as to the potential advantages and side effects of the product candidate being studied in relation to other available therapies and product candidates;
- the ability to obtain and maintain patient consents; and
- the risk that patients enrolled in clinical trials will not complete such trials for any reason.

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

Use of our product candidates could be associated with side effects, adverse events or other properties or safety risks, which could delay or halt their clinical development, prevent their regulatory approval, cause us to suspend or discontinue clinical trials, abandon a product 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.

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

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. 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

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

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidates in humans. To date, we have focused substantially all of our efforts and financial resources on identifying, acquiring, and developing our product candidates, including conducting lead optimization, nonclinical studies, preclinical studies and clinical trials, and providing general and administrative support for these operations. We cannot be certain that any clinical trials will be conducted as planned or completed on schedule, if at all. Our inability to successfully complete preclinical and clinical development could result in additional costs to us and negatively impact our ability to generate revenue. Our future success is dependent on our ability to successfully develop, obtain regulatory approval for, and then successfully commercialize product candidates. While Attruby was approved for commercial sales in November 2024 and we previously had two products approved for sale, we have not yet generated significant revenue from sales of drugs, and we may never be able to successfully commercialize a marketable drug.

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. Many of our product candidates are in early-stage research or translational phases of development, and the risk of failure for these programs is high. We cannot be certain that 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 received FDA approval for commercial sale in the United States in November 2024, we cannot be certain that any of our other product candidates will receive regulatory approval or that Attruby, or any of our other product candidates, 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 as inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. 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 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 marketing exclusivity.

Our business strategy focuses on the development of product candidates for the treatment of genetic diseases, which may be eligible for FDA or 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: Attruby for the treatment of transthyretin amyloidosis; low-dose infigratinib for the treatment of achondroplasia; encaleret for the treatment of autosomal dominant hypocalcemia (including ADH type 1 and ADH type 2); and BBP-812 for the treatment of Canavan Disease. We have obtained from the EMA and European Commission, orphan drug designation for: Attruby 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 August 3, 2017, Congress passed the FDA Reauthorization Act of 2017 ("FDARA"). FDARA, among other things, codified the FDA's pre-existing regulatory interpretation to require that a sponsor demonstrate the clinical superiority of an orphan drug that is otherwise the same as a previously approved drug for the same rare disease in order to receive orphan drug exclusivity. The legislation reverses prior precedent holding that the Orphan Drug Act unambiguously requires that the FDA recognize the orphan exclusivity period regardless of a showing of clinical superiority. Moreover, in the Consolidated Appropriations Act of 2021, Congress did not further change this interpretation when it clarified that the interpretation codified in FDARA would apply in cases where FDA issued an orphan designation before the enactment of FDARA but where product approval came after the enactment of FDARA. 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-812 for the treatment of Canavan Disease. However, a marketing application for BBP-812 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-812 for the treatment of Canavan Disease. 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, Drugs, and Cosmetic Act ("FDCA"), we will need to request a rare pediatric disease PRV, in our original NDA for BBP-812. The FDA may determine that an NDA for BBP-812, if approved, does not meet the eligibility criteria for a PRV, including for the following reasons:

- achondroplasia 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 BBP-812 is designated (for example, if BBP-812 is approved for an indication based on specific genetic alterations that would be inclusive of, but not limited to, BBP-812).

The FDA's rare pediatric disease priority voucher program began to sunset on December 20, 2024, on failure to pass a continuing resolution package that included its reauthorization. Under the amended statutory sunset provisions, after December 20, 2024, the FDA may award a PRV for an approved rare pediatric disease product application only if the sponsor has rare pediatric disease designation for the drug and if that designation was granted by December 20, 2024. After September 30, 2026, the FDA may not award any rare pediatric disease PRVs. Congress may vote to reauthorize this program, but its future remains unknown at this time. Absent such legislative reauthorization of the program, if an NDA for BBP-812 is not approved prior to September 30, 2026 for any reason, regardless of whether it meets the criteria for a rare pediatric disease PRV, it will not be eligible for a PRV.

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. We may seek approval of additional product candidates, where applicable, under 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 1; organizational commitment involving senior managers; and eligibility for rolling review and priority review.

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

We may also seek RMAT designation for one or more of our product candidates. 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,
- encaleret 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.

We may seek designation for our platform technology as a designated platform technology, but we might not receive such designation, and even if we do, such designation may not lead to a faster development or regulatory review or approval process.

We may seek designation for our platform technology as a designated platform technology. 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. Even if we believe our platform technology meets the criteria for such designation, the FDA may disagree and instead determine not to grant such designation. In addition, the receipt of such designation for a platform technology does not ensure that a drug will be developed more quickly or receive a faster FDA review process or ultimate FDA approval. Moreover, the FDA may revoke a designation if the FDA determines that a designated platform technology no longer meets the criteria for such designation. See the section titled, "*Business — Government Regulation — Expedited Development and Review Programs*."

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. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty.

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

If competitors are able to obtain marketing approval for biosimilars referencing any of our product candidates, our products may become subject to competition from such biosimilars, which would impair our ability to successfully commercialize and generate revenues from sales of such products.

Attruby and Beyonttra and our current product candidates, if approved, will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

Attruby and Beyonttra and our current product candidates, if approved, will be subject to ongoing regulatory requirements and review by the FDA and other applicable regulatory authorities for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies, and submission of safety, efficacy, and other post-market information, including both federal and state requirements in the 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 placing the product on a list of discontinued products, which would revoke the product's ability to be marketed.

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

The holder of an approved NDA, BLA or MAA must submit new or supplemental applications and obtain approval for certain changes to the approved product, product labeling, or manufacturing process. We could also be asked to conduct post-marketing clinical trials to verify the safety and efficacy of our products, 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 regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.

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

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 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 not distribute a lot until the agency authorizes its release. Slight deviations in the manufacturing process, including those affecting quality attributes and stability, may result in unacceptable changes in the product that could result in lot failures or product recalls. Lot failures or product recalls could cause us to delay product launches or clinical trials, which could be costly to us and otherwise harm our business, financial condition, results of operations and prospects.

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

Any problems in our CMOs' manufacturing process or facilities could result in delays in planned clinical trials and increased costs, and could make us a less attractive collaborator for potential partners, including larger biotechnology companies and academic research institutions, which could limit access to additional attractive development programs. Problems in our manufacturing process could 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 a novel adeno-associated virus ("AAV") gene therapy technology with which there is limited clinical or regulatory experience to date, which makes it difficult to predict the time and cost of product candidate development and subsequently obtaining regulatory approval.

Certain of our product candidates are based on gene therapy technology and our future success depends on the successful development of this novel therapeutic approach. We cannot assure you that any development problems we or other gene therapy companies experience in the future related to gene therapy technology will not cause significant delays or unanticipated costs in the development of our product candidates, or that such development problems can be solved. In addition, the clinical study requirements of the FDA, 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 governs the approval of gene therapies in the European Union and may issue new guidelines concerning the development and marketing authorization for gene therapy products and require that we comply with these new guidelines.

These regulatory review committees and advisory groups and the new guidelines they promulgate may lengthen the regulatory review process, require us to perform additional studies or trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post-approval limitations or restrictions. As we advance our product candidates, we will be required to consult with these regulatory and advisory groups and comply with applicable guidelines. If we fail to do so, we may be required to delay or discontinue development of such product candidates. These additional processes may result in a review and approval process that is longer than we otherwise would have expected. Delays as a result of an increased or lengthier regulatory approval process or further restrictions on the development of our product candidates can be costly and could negatively impact our ability to complete clinical trials and commercialize our current and future product candidates, 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. While new AAV vectors have been developed to reduce these side effects, gene therapy is still a relatively new approach to disease treatment and additional adverse side effects could develop. There also is the potential risk of delayed AEs following exposure to gene therapy products due to persistent biologic activity of the genetic material or other components of products used to carry the genetic material.

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

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

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

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

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

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

- reliance on the third party for sourcing of raw materials, components, and such other goods as may be required for execution of its manufacturing processes and the oversight by the third party of its suppliers;
- reliance on the third party for regulatory compliance and quality assurance for the manufacturing activities each performs;
- the possible breach of the manufacturing agreement by the third party;

- the possible misappropriation of proprietary information, including trade secrets and know-how; and
- the possible termination or non-renewal of the agreement by the third party at a time that is costly or inconvenient for us.

Furthermore, all of our CMOs are engaged with other companies to supply and/or manufacture materials or products for such companies, which exposes our manufacturers to regulatory risks for the production of such materials and products. The facilities used by our contract manufacturers to manufacture our product candidates are subject to review by the FDA pursuant to inspections that will be conducted after we submit an NDA or BLA to the FDA. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with the regulatory requirements, known as 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 other product candidates that receive marketing approval, our results could be materially impacted.

Our product candidates may compete with other 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 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 under development and manufacturing contracts and services and quality agreements and purchase orders. We do not currently have any other suppliers for the drug substance or drug product of these product candidates and, although we believe that there are alternate sources of supply that could satisfy our clinical and commercial requirements, we cannot assure you that identifying alternate sources and establishing relationships with such sources would not result in significant delay in the development of our product candidates.

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

- our suppliers may cease or reduce production or deliveries, raise prices or renegotiate terms;
- delays caused by supply issues may harm our reputation; and

- our ability to progress our business could be materially and adversely impacted if our single-source suppliers upon which we rely were to experience a significant business challenges, disruption or failures due to issues such as financial difficulties or bankruptcy, issues relating regulatory or quality compliance issues, or other legal or reputational issues.

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

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

All entities involved in the preparation of products for commercial sale or product candidates for clinical trials, including our existing CMOs for Attruby and Beyonttra and all of our product candidates, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical trials must be manufactured in accordance with cGMP, or similar regulatory requirements outside the 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 Beyonttra as a treatment for ATTR-CM in the European Union and all member states of the European Patent Organization; Eidos is also a party to a license agreement with Alexion Pharma International Operations Unlimited Company ("Alexion") pursuant to which we depend on Alexion for the clinical development and commercialization of Beyonttra in Japan; QED is party to an exclusive license with Kyowa Kirin to develop, manufacture, and commercialize infigratinib for achondroplasia, hypochondroplasia, and other skeletal dysplasias in Japan; and QED was previously party to a license and collaboration agreement with Helsinn Healthcare S.A. and Helsinn Therapeutics (U.S.), Inc., to which we refer collectively as Helsinn, pursuant to which QED granted to Helsinn exclusive licenses to develop, manufacture and commercialize QED's product candidate, infigratinib, in selected indications and geographic territories. The collaboration with Helsinn, was terminated effective in March 2023 pursuant to a mutual termination agreement. 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 Beyonttra 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. For example, our license and collaboration agreement with Helsinn for the development and commercialization of QED's product candidate, infigratinib, in selected indications and geographic territories was terminated for convenience by Helsinn effective in March 2023, citing commercial considerations.

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

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain sufficient intellectual property protection for Attruby 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 other product candidates we may identify and pursue. Our license agreement with Stanford imposes, and we expect that future license agreements will impose, various development, diligence, commercialization, and other obligations on us. 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, low-dose infigratinib, BBP-418, encaleret or other product candidates that we may identify may be subject to claims of infringement of the patent rights of third parties.

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

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

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

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

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 and may in the future lead to market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank ("SVB") was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation ("FDIC") as receiver. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each swept into receivership and thereafter, First Republic Bank on May 1, 2023. In these cases, borrowers under credit agreements, letters of credit and certain other financial instruments with SVB, Signature Bank or any other 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. In this regard, counterparties to SVB credit agreements and arrangements, and third parties such as beneficiaries of letters of credit (among others), may experience direct impacts from the closure of SVB, or the sale of its assets, and uncertainty remains over liquidity concerns in the broader financial services industry. Similar impacts have occurred in the past, such as during the 2008-2010 financial crisis.

Inflation and rapid increases in interest rates have led to a decline in the trading value of previously issued government securities with interest rates below current market interest rates. Although the U.S. Department of Treasury, FDIC and Federal Reserve Board have announced a program to provide up to $25 billion of loans to financial institutions secured by certain of such government securities held by financial institutions to mitigate the risk of potential losses on the sale of such instruments, widespread demands for customer withdrawals or other liquidity needs of financial institutions for immediate liquidity may exceed the capacity of such program. Additionally, there is no guarantee that the U.S. Department of Treasury, FDIC and Federal Reserve Board will provide access to uninsured funds in the future in the event of the closure of other banks or financial institutions, or that they would do so in a timely fashion.

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.

Our corporate restructuring initiatives, including any associated workforce reductions or reorganizations, may not result in the full anticipated savings and may disrupt operations.

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 initiative 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, 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.

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, 2024, we had 730 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.

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

Inadequate funding for the FDA, the SEC and other government agencies, including from government shut downs, or other disruptions to these agencies' operations, 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 business functions on which the operation of our business may rely, which could negatively impact our business.

Currently, federal agencies in the United States are operating under a continuing resolution that is set to expire on March 14, 2025. Without appropriation of additional funding to federal agencies, our business operations related to our product development activities for the U.S. market could be impacted. The ability of the FDA to review and approve new products or take action with respect to other regulatory matters can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept payment of user fees, the availability of personnel and other resources, and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved, or for other actions to be taken, by relevant government agencies, which would adversely affect our business. If a prolonged government shutdown or disruption to the operations of the FDA or other regulatory authorities occurs, 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. 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. Future government shutdowns and similar events could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

We will need to expand our organization and we may experience difficulties in managing this growth, which could disrupt our operations.

As of December 31, 2024, we had 725 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 and genetically driven cancers, regardless of the treatment modality or the particular target indication within this space. Because we have limited financial and personnel resources, we may 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 are conducting clinical trials internationally through a global CRO, and our business strategy incorporates potential international expansion to target patient populations outside the United States. If we receive regulatory approval for and commercialize any of our product candidates in patient populations outside the United States, we may hire sales representatives and conduct physician and patient association outreach activities outside of the United States. Doing business internationally involves a number of risks, including, but not limited to:

- multiple, conflicting, and changing laws and regulations such as privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements, and other governmental approvals, permits, and licenses;
- failure by us to obtain and maintain regulatory approvals for the use of our products in various countries;
- additional potentially relevant third-party patent rights;
- complexities and difficulties in obtaining protection and enforcing our intellectual property;
- difficulties in staffing and managing foreign operations;
- complexities associated with managing multiple payor reimbursement regimes, government payors, or patient self-pay systems;
- limits in our ability to penetrate international markets;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our products, and exposure to foreign currency exchange rate fluctuations;
- natural disasters, political and economic instability, including wars, terrorism, and political unrest, 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, 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, artificial intelligence presents risks and challenges that could impact our business. The use of certain artificial intelligence technology can give rise to intellectual property risks, including compromises to proprietary intellectual property and intellectual property infringement. Additionally, we expect to see increasing government and supranational regulation related to artificial intelligence use and ethics, which may

also significantly increase the burden and cost of research, development and compliance in this area. For example, the EU's Artificial Intelligence Act ("AI Act") — the world's first comprehensive AI law — was entered into force on August 1, 2024, and most provisions of which will become effective on August 2, 2026. This legislation 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. We may adopt and integrate generative artificial intelligence tools into our systems for specific use cases reviewed by legal and information security.

If we develop or use AI systems that are governed by the AI Act, it may necessitate ensuring higher standards of data quality, transparency, and human oversight, as well as adhering to specific and potentially burdensome and costly ethical, accountability, and administrative requirements. The rapid evolution of artificial intelligence will require the application of significant resources to design, develop, test and maintain our products and services to help ensure that artificial intelligence 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. Our vendors may also incorporate generative artificial intelligence tools into their offerings without disclosing this use to us, and the providers of these generative artificial intelligence tools may not meet existing or rapidly evolving regulatory or industry standards with respect to privacy and data protection and may inhibit our or our vendors' ability to maintain an adequate level of service and experience. 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 generative artificial intelligence, 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 artificial intelligence, 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.

Risks Related to Our Indebtedness

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, 2024, we and our subsidiaries had total consolidated indebtedness of $1.7 billion. This includes $550.0 million of indebtedness outstanding under our unsecured 2.50% Convertible Senior Notes due 2027 (the "2027 Notes") and $747.5 million of indebtedness outstanding under our 2.25% Convertible Senior Notes due 2029 (the "2029 Notes"). On January 17, 2024, we incurred $450.0 million of gross initial principal indebtedness under our financing agreement by and among Blue Owl Capital Corporation as administrative agent, certain lenders, the Company as borrower, and certain of our subsidiaries as guarantors, which together with a first amendment dated February 12, 2024 and second amendment dated June 20, 2024, are referred to as the Amended Financing Agreement. The proceeds received under the Amended Financing Agreement fully repaid the indebtedness outstanding under the Amended Loan Agreement. 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.

We have incurred indebtedness under our convertible senior notes and are party to a financing agreement that contains operating and financial covenants that may restrict our business and financing activities.

In March 2020, we issued the 2027 Notes, pursuant to which we pay interest semiannually in arrears at a rate of 2.50% per year. The 2027 Notes will mature on March 15, 2027 unless earlier converted or repurchased, at which time we will settle any conversions of the 2027 Notes in cash, shares of our common stock or a combination thereof, at our election. In January and February 2021, we issued the 2029 Notes, pursuant to which we pay interest semiannually in arrears at a rate of 2.25% per year. The 2029 Notes will mature on February 1, 2029 unless earlier converted or repurchased, at which time we will settle any conversions of the 2029 Notes in cash, shares of our common stock or a combination thereof, at our election. Under certain circumstances, the holders of the 2027 Notes and the 2029 Notes (collectively, the "Notes"), may require us to repay all or a portion of the principal and interest outstanding under the Notes in cash prior to their respective maturity dates, which could have an adverse effect on our financial results.

In January 2024, we entered into the Financing Agreement, pursuant to which the lenders thereunder 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 of $450.0 million (the "Initial Term Loan") and (ii) subject to the satisfaction of certain terms and conditions set forth in the Financing Agreement, one or more incremental term loans in an aggregate principal amount not to exceed $300.0 million. The Initial Term Loan was funded on January 17, 2024. We are required to make principal payments of $22.5 million on the outstanding balance of the term loans commencing on June 30, 2027 in quarterly installments in amounts and subject to conditions as set forth in the Financing Agreement, including variable interest rates and additional quarterly installments of $10.0 million if our market capitalization is at any time after January 17, 2024 less than $1.5 billion. The stated maturity date of the term loans is January 17, 2029, with two springing earlier maturity dates at 91 days prior to the stated maturity dates of the 2027 Notes and the 2029 Notes, respectively, in each case to the extent there is an aggregate outstanding amount of such notes of more than $50 million on such dates. The Financing Agreement restricts our ability, among other things and subject to certain limited exceptions, to:

- sell, transfer or otherwise dispose of any of our business or property;
- make material changes to our business;
- enter into transactions resulting in significant changes to the voting control of our stock;
- make certain changes to our organizational structure;
- consolidate or merge with other entities or acquire other entities;
- incur additional indebtedness or create encumbrances on our assets;
- pay dividends, or make distributions on or repurchase our stock;
- enter into transactions with our affiliates;
- make payments in respect of subordinated indebtedness or royalty monetization transactions; or
- make certain investments.

As of December 31, 2024, we are required to maintain, under the Amended Financing Agreement, a minimum unrestricted qualified cash balance of $78.0 million, at all times, and to comply with various operating covenants and default clauses that may restrict our ability to finance our operations, engage in business activities or expand or fully pursue our business strategies. As security for the obligations under the Amended Financing Agreement, we and our subsidiaries that are party to the Amended Financing Agreement as guarantors are required to grant to the administrative agent, for the benefit of the lenders and secured parties, a continuing first priority security interest in substantially all of our assets and the assets of our subsidiaries that are party to the Amended Financing Agreement as guarantors (including all equity interests owned or hereafter acquired by us or such subsidiaries), subject to certain exceptions. A breach of any of these covenants or clauses could result in a default under the Amended Financing Agreement, which could cause all of the outstanding indebtedness under the facility to become immediately due and payable and cause us to incur additional fees related to an early repayment, or result in a material adverse effect on our business, financial condition and operating results.

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, unless we elect to satisfy our conversion obligation by delivering solely shares of our common stock (other than paying cash in lieu of delivering any fractional share), we would be required to settle a portion or all of our conversion obligation through the payment of cash, which could adversely affect our liquidity. In addition, even if holders do not elect to convert their Notes, we could be required under applicable accounting rules to reclassify all or a portion of the outstanding principal of the Notes as a current rather than long-term liability, which would result in a material reduction of our net working capital.

Risks Related to Our Need for Additional 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, 2024, we had working capital of $566.3 million, of which cash and cash equivalents amounted to $681.1 million and restricted cash amounted to $0.1 million. We expect that our cash and cash equivalents, and restricted cash and proceeds from Attruby product revenue will be sufficient to fund our operations through at least the next 12 months from the date of this report. However, our operating plan may change as a result of many factors currently unknown to us, 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 financing, 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 other product candidate, if approved;
- our ability to satisfy the conditions required by the funding of the investment amount under the Funding Agreement;
- the time and cost necessary to complete ongoing and planned clinical trials, including our ongoing Phase 3 clinical trials of low-dose infigratinib, and our ongoing Phase 3 clinical trial of 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.

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.

The Funding Agreement contains certain conditions to the Purchasers' funding obligations and various covenants and restrictions on our operations that, if violated, may adversely affect our financial condition and operating results. An increase of the royalty rate on the net sales of Attruby under the Funding Agreement could harm our financial condition and operating results.

In January 2024, we and our subsidiaries Eidos Therapeutics, Inc., 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, the "Purchasers"), and Alter Domus (US) LLC, as the collateral agent, to help support the commercial launch of Attruby. Under the Funding Agreement, the 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, subject to certain conditions relating to the FDA approval and other customary conditions.

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 Attruby, providing the 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. 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. Pursuant to the Funding Agreement, the Seller Parties have granted to the collateral agent, for the benefit of the Purchasers, a security interest in specific assets related to Attruby. If the Seller Parties are unable to comply with applicable obligations, the Purchasers may be entitled to take possession of such assets, which could have a material adverse effect on our business, financial condition and results of operations.

Under the Funding Agreement, following the Purchasers' payment of the Investment Amount to us, the 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 adjust to a maximum rate of 10% in 2027. Such increase(s) could result in additional payments by us to the Purchasers and may materially harm our liquidity and profitability or otherwise affect our financial condition and operating results. 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.

Following the FDA approval of Attruby on November 22, 2024, we received gross proceeds of $500.0 million under the Funding Agreement in December 2024. As of December 31, 2024, the Company had a balance of $479.1 million in deferred royalty obligation, net of debt discount and issuance cost accretion.

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 financing, 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 financing, 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.

Risks Related to Our Common Stock

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

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

- our failure to successfully commercialize Attruby and Beyonttra, or any other 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 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, 2024, our beneficial stockholders, directors, and executive officers beneficially own 47.7% 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 Beyonttra or any of our product candidates, if approved, and the timing and costs of our commercialization activities;
- the timing, results and cost of, and level of investment in, our clinical development activities for our current product candidates and any other product candidates we may identify and pursue, which may change from time to time;
- the cost of manufacturing Attruby and Beyonttra and our current product candidates and the related materials or other product candidates that we may identify, which may vary depending on the quantity of production and the terms of agreements with manufacturers;
- our ability to conduct our ongoing and planned clinical trials in accordance with our current plans and to obtain regulatory approval for our current product candidates or other product candidates that we may identify, and the timing and scope of any such approvals we may receive;
- the timing and success or failure of clinical trials for competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners;
- expenditures that we or will or may incur to acquire or develop additional product candidates and technologies;
- our ability to attract, hire and retain qualified personnel;
- the level of demand for Attruby and Beyonttra and our current product candidates or other product candidates that we may identify, should they receive approval, which may vary significantly;
- future accounting pronouncements or changes in our accounting policies;
- future tax regulation changes that impact effective tax rates;
- the success of our restructuring initiatives;
- the risk/benefit profile, cost and reimbursement policies with respect to Attruby and Beyonttra and our current product candidates or other product candidates that we may identify, if approved, and existing and potential future drugs that compete with our products and product candidates;

- changes in global economic and market conditions, including inflationary pressures, interest rate increases, supply chain shortages 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, the current and former U.S. presidential administrations and members of Congress have proposed, and future administrations may propose, various U.S. federal tax law changes, which, if enacted, may have an adverse effect on our business operations and financial performance. 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. In addition, pursuant to the Financing Agreement, we are not permitted to declare or pay any cash dividends or make cash distributions on any class of our capital stock or any other equity interest, except in limited circumstances. We currently intend to invest our future earnings, if any, to fund our growth. Therefore, you are not likely to receive any dividends on your common stock for the foreseeable future. Since we do not intend to pay dividends, your ability to receive a return on your investment will depend on any future appreciation in the market value of our common stock. There is no guarantee that our common stock will appreciate or even maintain the price at which our holders have purchased it.

We 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.

Environmental, social and governance matters may impact our business and reputation.

In addition to the changing rules and regulations related to environmental, social and governance (ESG) matters imposed by governmental and self-regulatory organizations, a variety of third-party organizations, institutional investors and customers evaluate the performance of companies on ESG topics, and the results of these assessments are widely publicized. These changing rules, regulations and stakeholder expectations have resulted in, and are likely to continue to result in, increased general and administrative expenses and increased management time and attention spent complying with or meeting such regulations and expectations. Reduced access to or increased cost of capital may occur as financial institutions and investors increase expectations related to ESG matters.

Developing and acting on initiatives within the scope of ESG, and collecting, measuring and reporting ESG-related information and metrics can be costly, difficult and time consuming and is subject to evolving reporting standards. We may also communicate certain initiatives and goals, regarding environmental matters, diversity, social investments and other ESG-related matters, in our SEC filings or in other public disclosures. These initiatives and goals within the scope of ESG could be difficult and expensive to implement, the technologies needed to implement them may not be cost effective and may not advance at a sufficient pace, and we could be criticized for the accuracy, adequacy or completeness of the disclosure. Furthermore, statements about our ESG-related initiatives and goals, and progress against those goals, may be based on standards for measuring progress that are still developing, internal controls and processes that continue to evolve and assumptions that are subject to change in the future. In addition, we could be criticized for the scope or nature of such initiatives or goals, or for any revisions to these goals. If our ESG-related data, processes and reporting are incomplete or inaccurate, or if we fail to achieve progress with respect to our goals, including our previously announced commitments to reduce greenhouse gas emissions, within the scope of ESG on a timely basis, or at all, our reputation, business, financial performance and growth could be adversely affected. In addition, in recent years "anti-ESG" sentiment has gained momentum across the U.S., with several states and Congress having proposed or enacted "anti-ESG" policies, legislation, or initiatives or issued related legal opinions, and the President having recently issued an executive order opposing diversity equity and inclusion ("DEI") initiatives in the private sector. Such anti-ESG and anti-DEI-related policies, legislation, initiatives, litigation, legal opinions, and scrutiny could result in the Company facing additional compliance obligations, becoming the subject of investigations and enforcement actions, or sustaining reputational harm.

General Risk Factors

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.

Significant political, trade, regulatory developments, and other circumstances beyond our control, 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, on February 1, 2025, the U.S. imposed a 25% tariff on imports from Canada and Mexico, which were subsequently suspended for a period of one month, and a 10% additional tariff on imports from China. Historically, tariffs have led to increased

trade and political tensions. In response to tariffs, other countries have implemented retaliatory tariffs on U.S. goods. 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.

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. Although to our knowledge we have not experienced any such material system failure or cybersecurity incident or breach to date, 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 on a monthly 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, 2024, the following are the material properties that we occupy:

Property Description	Location	Square Footage	Owned or Leased	Initial Lease Term End Date	Lease Extension Options
Office space and laboratory facility	Raleigh, NC	21,263	Leased	2026	Five-year option to extend
Office space and laboratory facility	Palo Alto, CA	10,391	Leased	2025	One-year option to extend
Office space	San Francisco, CA	52,604	Leased	2026	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 13, 2025, there were 46 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. In addition, pursuant to the Financing Agreement, we are not permitted to declare or pay any cash dividends or make cash distributions on any class of our capital stock or any other equity interest, except in limited circumstances.

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

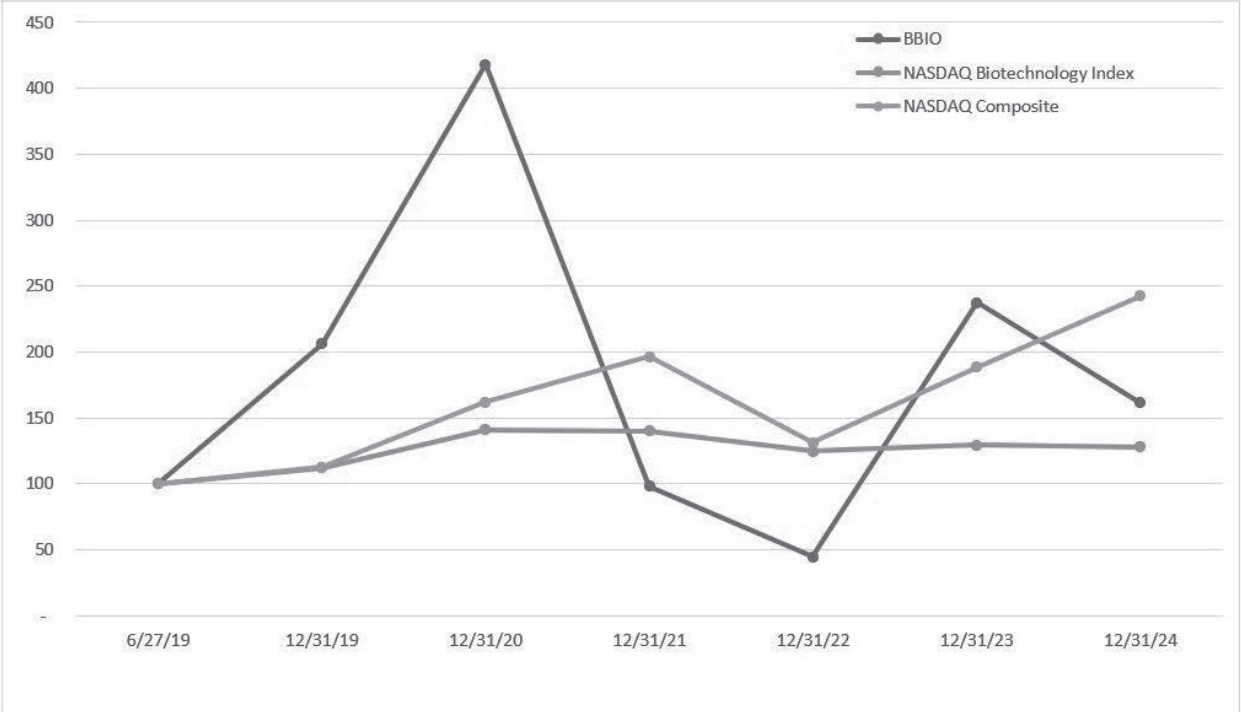
The graph set forth below compares the cumulative total stockholder return on our common stock for the period commencing on June 27, 2019, the date our common stock began trading on the Nasdaq, and ending on December 31, 2024, with the cumulative total return of the Nasdaq Composite Index and the Nasdaq Biotechnology Index over the same period. This graph assumes the investment of $100.00 on June 27, 2019 in each 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 invested on June 27, 2019 in shares of our common stock or index, including reinvestment of dividends.

Sales of Unregistered Securities

During the year ended December 31, 2024, we did not issue or sell any unregistered securities.

Issuer Purchases of Equity Securities

During the year ended December 31, 2024, we did not repurchase any Company equity securities.

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 of 1933, as amended (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). In some cases, you can identify these statements by forward-looking words such as "may," "will," "expect," "believe," "anticipate," "intend," "could," "should," "estimate," or "continue," and similar expressions or variations. Such forward-looking statements are subject to risks, uncertainties and other factors that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified below, and those discussed in the section titled "Risk Factors" included in this Annual Report on Form 10-K. The forward-looking statements in this Annual Report on Form 10-K represent our views as of the date of this Annual Report on Form 10-K. Except as may be required by law, we assume no obligation to update these forward-looking statements or the reasons that results could differ from these forward-looking statements. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Annual Report on Form 10-K.

Overview

BridgeBio Pharma, Inc. ("we" or the "Company") is a new type of biopharmaceutical company founded to discover, create, test and deliver transformative medicines to treat patients who suffer from genetic diseases. BridgeBio's pipeline of development programs ranges from early science to advanced clinical trials.

As described in Part I, Item 1. "Business" of this Annual Report on Form 10-K, we currently have one commercial product, Attruby™ that received FDA approval on November 22, 2024 and Beyonttra that received approval from the EC on February 10, 2025, and multiple product candidates in late-stage development. 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 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. On November 22, 2024 the Company received FDA approval of Attruby (acoramidis), and initiated the commercial launch of Attruby in the United States. However, we have not generated any significant revenue from product sales. To date, we have funded our operations with proceeds from the sale of our equity securities, issuance of convertible notes, debt borrowings, royalty financing, sale of certain assets and, to a lesser extent, upfront and milestone payments from licensing arrangements.

We have incurred significant operating losses since our inception. For the years ended December 31, 2024 and 2023, we incurred net losses of $543.3 million and $653.3 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 the development and eventual commercialization of our other 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.

GondolaBio was formed on June 5, 2024 and we were the sole member. On August 16, 2024, based on the recommendation of a special committee of independent and disinterested directors of BridgeBio, we entered into a

transaction agreement (the "Transaction Agreement") providing for the formation and funding by certain third party investors of GondolaBio, LLC, a Delaware limited liability company ("GondolaBio"), a legal joint venture entity for the purpose of researching, developing, manufacturing and commercializing pharmaceutical products, including certain assets contributed to GondolaBio by BridgeBio. The investors providing financing to GondolaBio consist of an investor syndicate, including Viking Global Investors LP, Patient Square Capital, Sequoia Capital, Frazier Life Sciences, Cormorant Asset Management, Aisling Capital and an entity owned by Neil Kumar, the Company's Chief Executive Officer. The investors have committed $300.0 million of tranched financing to GondolaBio, of which $60.0 million had been contributed during the period August 16, 2024 through December 31, 2024. We contributed certain assets and our 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. On August 16, 2024, in conjunction with the Transaction Agreement, GondolaBio's limited liability company agreement was amended and restated to reflect a change in its governance structure and composition of the board of managers, which was determined to be a VIE reconsideration event. Based on the VIE reconsideration assessment, GondolaBio was deemed a VIE. As a result of the change in governance structure and composition of the board of managers, we are no longer the primary beneficiary, as we no longer have the power over key decisions that significantly impact GondolaBio's economic performance. Accordingly, we deconsolidated GondolaBio, inclusive of Portal Therapeutics, Inc. and Sub21, Inc., on August 16, 2024. On August 16, 2024, we recognized an approximate $52.0 million net gain from deconsolidation of subsidiaries which is presented on the consolidated statements of operations for the year ended December 31, 2024. Upon the deconsolidation of GondolaBio on August 16, 2024, we accounted for our investment in GondolaBio, for which we had significant influence through our ownership interest, using the equity method of accounting. GondolaBio was also deemed a related party. For the period August 16, 2024 through December 31, 2024, we recognized a net loss from equity method investment of $8.5 million. As of December 31, 2024, the aggregate carrying amount of our equity method investment in GondolaBio is $41.5 million and is presented as part of "Investment in nonconsolidated entities" on our consolidated balance sheets.

On April 30, 2024, TheRas, Inc., doing business as BridgeBio Oncology Therapeutics (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. As part of the private equity financing transaction, BBOT's Certificate of Incorporation and Investors' Rights Agreement were amended and restated to reflect a change in 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, BBOT was deemed a VIE. As a result of the change in the governance structure and composition of the board of directors, we are no longer the primary beneficiary of BBOT, as we no longer have the power over key decisions that significantly impact BBOT's economic performance. Accordingly, we deconsolidated BBOT on April 30, 2024. On April 30, 2024, we recognized a $126.3 million gain from deconsolidation of subsidiaries which is presented on the consolidated statements of operations for the year ended December 31, 2024. Upon the deconsolidation of BBOT, BridgeBio accounted for its retained investments in BBOT, for which it has significant influence through its ownership interest, using the equity method of accounting. BBOT was also deemed a related party. 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, 2024, the aggregate carrying amount of our equity method investment in BBOT is $102.2 million and is presented as part of "Investment in nonconsolidated entities" on our consolidated balance sheets.

On March 1, 2024, certain subsidiaries of BridgeBio, including Eidos Therapeutics, Inc., 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 European Union 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, effective upon the date that certain antitrust clearances have been obtained, 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 and will be eligible to receive up to $150.0 million in regulatory and sales milestone payments through 2026 (of which $75.0 million is for a regulatory milestone dependent upon EC approval of acoramidis on or before December 31, 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. In June 2024, BridgeBio Europe B.V. ("BridgeBio B.V.") entered into the Bayer

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 the use in the commercialization in the Licensed Territory under the Bayer License Agreement. Under the Bayer Supply Agreement, Bayer shall pay to BridgeBio B.V. a commercial product per unit price equal to the applicable fully burdened manufacturing cost per unit of product, which shall include the cost of the API used to manufacture the product and the packaging price. As of December 31, 2024, there have been no commercial product supply sales to Bayer. The condition for the $75.0 million regulatory-based milestone payment was achieved upon the EC approval of Beyonttra on February 10, 2025. The Company anticipates receiving this milestone payment from Bayer in April 2025.

On February 7, 2024, our subsidiary, QED, and Kyowa Kirin Co., Ltd ("Kyowa Kirin" or "KKC") entered into a partnership wherein 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 ("KKC Agreement"). In exchange, QED received an upfront payment of $100.0 million and will be eligible to receive royalties up to the mid-twenties percent on sales of infigratinib in Japan, with the potential to receive up to $81.4 million in development and sales-based milestone payments.

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 ("Net Sales"), which under certain conditions may adjust to a maximum rate of 10% in 2027. 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, the Seller Parties 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 Attruby on November 22, 2024, and in accordance with the Funding Agreement (as described below), 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 *Liquidity and Capital Resources* section for additional details regarding this 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 the Company 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. Refer to *Liquidity and Capital Resources* section for additional details regarding this agreement.

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.

In January 2022, we committed to a restructuring initiative designed to drive operational changes in our business processes, efficiencies and cost savings to advance our corporate strategy and development programs. The restructuring initiative included, among other components, consolidation and rationalization of our facilities,

reprioritization of development programs and the reduction in our workforce. Upon entering into the Bayer License Agreement and termination of the Navire-BMS License Agreement in March 2024 (refer to Note 11 for details regarding these transactions) and our announced decision to cease pursuing development of BBP-631, the Company's investigational adeno-associated virus 5 gene therapy, for congenital adrenal hyperplasia ("CAH") in September 2024, we have committed to additional restructuring plans to reprioritize and advance our corporate strategy and development programs. We estimate our remaining restructuring charges, consisting primarily of winding down costs and exit and other related costs will be immaterial. 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, 2024 and 2023, our restructuring, impairment and related charges amounted to $15.6 million and $7.9 million, respectively, which consisted primarily of winding down costs, exit and other related costs, impairments and write-offs of long-lived assets, and severance and employee-related costs.

Basis of Presentation and Consolidation

Since our inception, we have created wholly-owned subsidiaries or made investments in certain controlled entities, including partially-owned subsidiaries for which we have majority voting interest under the VOE model or for which we are the primary beneficiary under the VIE model, which we refer to collectively as our consolidated entities. Ownership interests in consolidated entities that are held by entities other than us are reported as redeemable convertible noncontrolling interests and noncontrolling interests in our consolidated balance sheets. Losses attributed to redeemable convertible noncontrolling interests and noncontrolling interests are reported separately in our consolidated statements of operations.

Results of Operations

Comparison of the years ended December 31, 2024 and 2023

We have included our financial results for 2024 compared to 2023. Our financial results for 2023 compared to 2022 can be found in Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2023, filed with the U.S. Securities and Exchange Commission (the "SEC"), on February 22, 2024 and is incorporated herein by reference.

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

	Year Ended December 31,	
	2024	2023
	(in thousands)	
Revenue	$ 221,902	$ 9,303
Cost of revenue	3,878	2,446
Research and development	506,461	455,711
Selling, general and administrative	288,931	150,590
Restructuring, impairment and related charges	15,605	7,926
Loss from operations	(592,973)	(607,370)
Interest income	17,249	18,038
Interest expense	(99,290)	(81,289)
Gain on deconsolidation of subsidiaries	178,321	—
Loss on extinguishment of debt	(26,590)	—
Net loss from equity method investments	(31,183)	—
Other income (expense), net	12,272	17,370
Income tax expense	1,153	—
Net loss	(543,347)	(653,251)
Net loss attributable to redeemable convertible noncontrolling interests and noncontrolling interests	7,585	10,049
Net loss attributable to common stockholders of BridgeBio	(535,762)	(643,202)

	December 31, 2024	December 31, 2023
	(in thousands)	
Cash and cash equivalents	$ 681,101	$ 375,935
Restricted cash	126	16,653
Investments in equity securities	—	58,949

The results of operations for the years ended December 31, 2024 and 2023 are not necessarily indicative of the results to be expected for the year ending December 31, 2025 or for any other future annual or interim period.

Cash, Cash Equivalents, Restricted Cash and Investments in Equity Securities

As of December 31, 2024, we had cash and cash equivalents of $681.1 million and restricted cash of $0.1 million, compared to cash and cash equivalents of $375.9 million, restricted cash of $16.7 million and investment in equity securities of $58.9 million as of December 31, 2023.

Under the terms of the Amended Financing Agreement, the Company is required to deposit 75% of proceeds, net of certain permitted costs, received from certain asset sale transactions into an escrow account to be controlled by the Administrative Agent. During the three months ended June 30, 2024, we received $235.0 million in aggregate from Bayer and Kyowa Kirin, and deposited net proceeds of $159.3 million into the escrow accounts, which was classified as "Restricted cash" on the consolidated balance sheet. Furthermore, under the terms of Amended Financing Agreement, between June 20, 2024 and through the earlier of the FDA approval date or November 30, 2024, the Company was able to request a release of funds in an aggregate amount not to exceed 50% of the original net cash proceeds received from asset sale transactions. During the three months ended June 30, 2024, $20.0 million was released from the escrow accounts. Following the FDA approval of Attruby in November 2024 and receipt of consent from the lenders, the remaining $139.3 million was released from the escrow accounts and classified as cash on the consolidated balance sheet.

Restricted cash as of December 31, 2023 primarily represents funds in a controlled account that was established in connection with the Loan and Security Agreement ("Amended Loan Agreement") that is described in Note 9. The use of such non-interest-bearing cash was restricted per the terms of the underlying amended loan agreement and was to be used solely for certain research and development expenses directly attributable to the performance of obligations associated with the Navire-BMS License Agreement, which is further described in Note 11. Upon the termination of the Amended Loan Agreement and full repayment of the term loan in January 2024 (refer to Note 9 for details), the non-interest-bearing cash was no longer restricted.

Revenue

The following table summarizes our revenue for the following periods:

	Year Ended December 31,		Change
	2024	2023	
	(in thousands)		
Revenue	$ 221,902	$ 9,303	$ 212,599

Revenue increased by $212.6 million in 2024 in comparison to 2023. Revenue for 2024 primarily consisted of $207.7 million from the recognition of the upfront license fee and services revenue under the Bayer License Agreement and the KKC Agreement; net product revenue from the commercial sale of Attruby in the U.S. of $2.9 million; and $9.9 million attributable to the remaining services revenue in connection with the Navire-BMS License Agreement as a result of the termination of the agreement. Revenue for 2023 primarily consisted of the recognition of services revenue under the Navire-BMS License Agreement and license revenue for the shipment of clinical supplies to our partners pursuant to our executed supply agreements and services revenue.

The level of revenue, including license and service 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 product sales.

Operating Costs and Expenses

Research and Development Expenses

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

	Year Ended December 31,		
	2024	2023	Change
	(in thousands)		
Research and development	$ 506,461	$ 455,711	$ 50,750

Research and development expenses increased by $50.8 million in 2024 compared to 2023. This change was primarily due to an increase in personnel costs of $39.0 million and external costs of $23.6 million to support the advancement of research and development for our key programs, which was partially offset by a decrease in stock-based compensation of $11.8 million primarily due to a reversal of performance-based milestone award obligations that were no longer determined to be probable.

Research and development costs consist primarily of external costs, such as fees paid to consultants, contractors, contract manufacturing organizations ("CMOs"), and contract research organizations ("CROs"), purchase of active pharmaceutical ingredients ("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 research programs, which are presented in the following table in "Other research programs."

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

	Year Ended December 31,	
	2024	2023
	(in thousands)	
Acoramidis for ATTR-CM	$ 164,782	$ 101,041
Infigratinib for achondroplasia and hypochondroplasia	91,869	63,239
BBP-418 (ribitol) for LGMD2I/R9	40,220	33,903
Encaleret for ADH1	49,091	44,773
Other development programs	71,732	82,165
Other research programs	88,767	130,590
Total	$ 506,461	$ 455,711

Selling, General and Administrative Expenses

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

	Year Ended December 31,		
	2024	2023	Change
	(in thousands)		
Selling, general and administrative	$ 288,931	$ 150,590	$ 138,341

Selling, general and administrative expenses increased by $138.3 million in 2024 compared to 2023, mainly due to an increase in personnel related expense of $56.1 million and external costs of $55.2 million to support our commercialization readiness efforts, which included costs incurred for marketing, advertising and hiring of a sales force for the U.S.; nonrecurring deal-related expenses of $16.5 million; and an increase in stock-based compensation expense of $10.5 million.

Restructuring, Impairment and Related Charges

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

	Year Ended December 31,					
	2024		2023		Change	
			(in thousands)			
Restructuring, impairment and related charges	$	15,605	$	7,926	$	7,679

As discussed in Note 17 to our consolidated financial statements, in January 2022, we committed to a restructuring initiative designed to drive operational changes in our business processes, efficiencies and cost savings to advance our corporate strategy and development programs. The restructuring initiative included, among other components, consolidation and rationalization of our facilities, reprioritization of development programs and the reduction in our workforce. Upon entering into the Bayer License Agreement and termination of the Navire-BMS License Agreement in March 2024 (refer to Note 11 for details regarding these transactions) and our announced decision to cease pursuing development of BBP-631 for CAH in September 2024, we have committed to additional restructuring plans to reprioritize and advance our corporate strategy and development programs. We estimate our remaining restructuring charges, consisting primarily of winding down costs and exit and other related costs will be immaterial. 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:

	Year Ended December 31,					
	2024		2023		Change	
			(in thousands)			
Interest income	$	17,249	$	18,038	$	(789)

Interest income consists of interest income earned on our cash equivalents and marketable securities. The amount of interest income during 2024 as compared to 2023 was generally consistent. Generally, increases and decreases in interest income are attributable to changes in the interest-bearing average balances of our cash equivalents and marketable securities and fluctuations in interest rates.

Interest Expense

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

	Year Ended December 31,					
	2024		2023		Change	
			(in thousands)			
Interest expense	$	(99,290)	$	(81,289)	$	(18,001)

Interest expense consists primarily of interest expense incurred under our 2029 Notes issued in January 2021, our 2027 Notes issued in March 2020, our term loan under the Amended Financing Agreement, our term loan under the Amended Loan Agreement, and our deferred royalty obligation under the Funding Agreement.

On January 17, 2024, we paid our outstanding term loan principal balance under our Amended Loan Agreement with the proceeds from the Amended Financing Agreement plus additional cash from our operations. Under the Amended Financing Agreement, we were extended a senior secured credit facility of $450.0 million in an aggregate principal amount for the Initial Term Loan, which is subject to variable interest rates. As a result of the variable interest rates under our Amended Financing Agreement and Funding Agreement we expect our interest expense will continue to fluctuate in the future. Refer to the *Liquidity and Capital Resources* section below and Note 9 for details regarding the Term Loan and the Amended Financing Agreement.

Gain on Deconsolidation of Subsidiaries

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

	Year Ended December 31,		
	2024	2023	Change
		(in thousands)	
Gain on deconsolidation of subsidiaries	$ 178,321	$ —	$ 178,321

On August 16, 2024, we entered into the Transaction Agreement providing for the formation and funding by certain third party investors of GondolaBio. Under the Transaction Agreement, the investors contributed $60.0 million and we contributed certain assets and our equity in Portal Therapeutics, Inc. and Sub 21, Inc. to GondolaBio. As a result of the private equity financing transaction and contribution, we deconsolidated GondolaBio, inclusive of Portal Therapeutics, Inc. and Sub21, Inc., on August 16, 2024 and recognized a gain from deconsolidation of approximately $52.0 million during the year ended December 31, 2024. Refer to Note 6 for further details regarding the GondolaBio private equity financing transaction.

On April 30, 2024, BBOT, a majority-owned subsidiary of BridgeBio, completed a $200.0 million private equity financing with external investors. As a result of the private equity financing transaction, BridgeBio deconsolidated BBOT on April 30, 2024 and recognized a gain from deconsolidation of $126.3 million during the year ended December 31, 2024. Refer to Note 6 for further details regarding the BBOT private equity financing transaction.

Loss on Extinguishment of Debt

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

	Year Ended December 31,		
	2024	2023	Change
		(in thousands)	
Loss on extinguishment of debt	$ (26,590)	$ —	$ (26,590)

On January 17, 2024, upon receiving 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 in 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:

	Year Ended December 31,		
	2024	2023	Change
		(in thousands)	
Net loss from equity method investments	$ (31,183)	$ —	$ (31,183)

Upon the deconsolidation of GondolaBio on August 16, 2024 and BBOT on April 30, 2024, we accounted for our investments in GondolaBio and BBOT using the equity method of accounting. In 2024 we recorded net losses from equity method investments in GondolaBio and BBOT of $8.5 million and $22.7 million, respectively.

Other Income (Expense), net

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

	Year Ended December 31,		
	2024	2023	Change
		(in thousands)	
Other income (expense), net	$ 12,272	$ 17,370	$ (5,098)

Other income (expense), net in 2024 consists mainly of the net realized gain of $8.1 million from our investments in equity securities, and $3.4 million of other income recognized under the Transition Service Agreements with GondolaBio and BBOT. Other income (expense), net in 2023 consists mainly of net realized and unrealized gains from changes in the fair value of our equity security investments of $18.3 million, offset by a $1.2 million loss from the deconsolidation of PellePharm.

Income Taxes

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 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.

Beginning in 2022, the 2017 Tax Cuts and Jobs Act amended Section 174 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 United States). We realized a deferred tax asset for capitalized R&E expenditures for the year ended December 31, 2024 which is fully offset with a valuation allowance.

As of December 31, 2024, we had net operating losses of approximately $1.4 billion and $439.4 million for federal and state income tax purposes, respectively, available to reduce future taxable income, if any. The federal net operating losses generated prior to 2018 in the amount of $10.8 million will begin to expire in 2036 and losses generated after 2018 in the amount of $1.4 billion will carry over indefinitely and would 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 $404.5 million available to reduce future taxable income, if any, which will begin to expire in 2030. As of December 31, 2024, we had federal research and development and orphan drug credit carryforwards of $120.3 million, which will expire beginning in 2038 if not utilized. As of December 31, 2024, we had state research and development credit carryforwards of $29.1 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 consolidated entities' historical operating losses and forecast of future losses, we have provided a valuation allowance against the U.S. federal, state, and foreign deferred tax assets resulting from the tax loss and credits carried forward. The valuation allowance increased by $55.2 million and $138.2 million for the years ended December 31, 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 (the "Code"), and similar state provisions. The annual limitation may result in the expiration of net operating losses and credits before utilization. In the event that we have a change of ownership, utilization of the net operating loss and tax credit carryforwards may be restricted.

Net Loss Attributable to Redeemable Convertible Noncontrolling Interests and Noncontrolling Interests

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

	Year Ended December 31,		
	2024	2023	Change
		(in thousands)	
Net loss attributable to redeemable convertible noncontrolling interests and noncontrolling interests	$ 7,585	$ 10,049	$ (2,464)

Net loss attributable to redeemable convertible noncontrolling interests and noncontrolling interests in our consolidated statements of operations consists of the portion of the net loss of those consolidated entities that is not allocated to us. Changes in the amount of net loss attributable to noncontrolling interests are directly impacted by changes in the net loss of our consolidated entities and are the result of ownership percentage changes. Refer to Note 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 financing, sale of certain assets and, to a lesser extent, upfront and milestone payments received from licensing arrangements. As of December 31, 2024, we had cash and cash equivalents of $681.1 million. The funds that were held by our wholly-owned subsidiaries and controlled entities are available for specific entity usage, except in limited circumstances. As of December 31, 2024, we had outstanding debt of $1.7 billion and a deferred royalty obligation of $479.1 million, each were net of discount and issuance cost accretion.

Since our inception, we have incurred significant operating losses. For the years ended December 31, 2024 and 2023, we incurred net losses of $543.3 million and $653.3 million, respectively. We incurred net cash outflow from operations of $520.7 million, $527.7 million and $419.5 million for the same periods, respectively. We had an accumulated deficit as of December 31, 2024 of $3.1 billion. 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 have very limited experience with commercialization, and we may not be able to generate significant revenues from product sales, if any, of Attruby or any of our other product candidates, even if any of our other 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 product sales 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 clinical programs.

Our short-term and long-term liquidity requirements include contractual payments related to our 2029 Notes, 2027 Notes and term loan (refer to Note 9 to our consolidated financial statements, accounts payable, accrued liabilities), our deferred royalty obligation under the Funding Agreement (refer to Note 10 to our consolidated financial statements), as well as obligations under our real estate leases (refer to Note 14 to our consolidated financial statements) and the remaining liabilities under our restructuring initiative (refer to Note 17 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 (see 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 restricted cash will fund our operations for at least the next 12 months based on current operating plans and financial forecasts. If our current operating plans or financial forecasts change, as a result of general market and economic conditions, inflationary pressures, supply chain issues, our commercialization of Attruby, and timing of our commercialization of other products 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, supply chain issues, our commercialization of Attruby, and timing of our commercialization of other products 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, if circumstances warrant, we will make appropriate adjustments to our operating plan.

Sources of Liquidity

Receivables from licensing and collaboration agreements.

On March 1, 2024, certain subsidiaries of the Company, including Eidos Therapeutics, Inc., 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 European Union 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, effective upon the date that certain antitrust clearances have been obtained, 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 and will be eligible to receive up to $150.0 million in regulatory and sales milestone payments through 2026 (of which $75.0 million is for a regulatory milestone dependent upon European Commission approval of acoramidis on or before December 31, 2025). We are also eligible to receive additional payments up to $450.0 million in additional sales milestones along with quarterly royalty payments. 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 Beyonttra in the EU, subject to reduction under certain circumstances as provided in the Bayer License Agreement. The condition for the $75.0 million regulatory-based milestone payment was achieved upon the EC approval of Beyonttra on February 10, 2025. The Company anticipates receiving this milestone payment from Bayer in April 2025.

On February 7, 2024, our subsidiary, QED, and Kyowa Kirin Co., Ltd ("Kyowa Kirin" or "KKC") entered into a partnership wherein 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 ("KKC Agreement"). In exchange, QED received an upfront payment of $100.0 million and will be eligible to receive royalties up to the mid-twenties percent on sales of infigratinib in Japan, with the potential to receive up to $81.4 million in development and sales-based milestone payments.

In September 2019, Eidos Therapeutics, Inc. ("Eidos"), entered into an exclusive license agreement with Alexion Pharma International Operations Unlimited 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 is eligible to receive $30.0 million in regulatory milestone payments and royalties in the low-teens based on net sales of acoramidis in Japan.

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 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.

In May 2023, we filed a shelf registration statement on Form S-3ASR (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 the 2023 ATM Agreement, with Goldman Sachs & Co. LLC and SVB Securities LLC or 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 2023 ATM Agreement. 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. As of December 31, 2024, we were eligible to sell up to $345.3 million of our common stock pursuant to the ATM Agreement under the 2023 Shelf.

Debt

As of December 31, 2024 and 2023, we have borrowings under the 2029 Notes, the 2027 Notes and the Loan Agreement, which are discussed below.

2029 Notes

In January 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 in our consolidated financial statements for other details, including our future minimum payments under the 2029 Notes.

2027 Notes

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 "Indenture"), between BridgeBio and U.S. Bank National Association, as trustee (the "Trustee"), in a private offering to qualified institutional buyers (the "2020 Note Offering"), pursuant to Rule 144A under the Securities Act.

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 in connection with the 2020 Note Offering.

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 in our consolidated financial statements for other details, including our future minimum payments under the 2027 Notes.

Term Loan, net

On January 17, 2024, we entered into the Financing Agreement with certain of our subsidiaries party thereto as guarantors, the Lenders and the Administrative Agent, which was amended on February 12, 2024.

Pursuant to the terms and conditions of the Financing Agreement, the Lenders have agreed to extend a senior secured credit facility to the Company 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 and (ii) one or more Incremental Term Loans in an aggregate amount not to exceed $300.0 million, subject to the satisfaction of certain terms and conditions set forth in the Financing Agreement. The Initial Term Loan was funded on January 17, 2024. Incremental Term Loans are available at the Company's and the Lenders' mutual consent from time to time after January 17, 2024.

The obligations of the Company under the Financing Agreement are and will be guaranteed by certain of the Company's existing and future direct and indirect subsidiaries, subject to certain exceptions (such subsidiaries, collectively, the "Guarantors"). As security for the obligations of the Company and the Guarantors, each of the Company and the Guarantors are required to grant to the Administrative Agent, for the benefit of the Lenders and secured parties, a continuing first priority security interest in substantially all of the assets of the Company and the Guarantors (including all equity interests owned or hereafter acquired by the Company and the Guarantors), subject to certain customary exceptions.

Any outstanding principal on the Term Loans will initially bear interest at a rate per annum equal to (A) in the case of Term Loans bearing interest based on the base rate defined in the Financing Agreement (and which base rate will not be less than 2.00%), the sum of (i) the base rate plus (ii) 5.75% and (B) in the case of Term Loans bearing interest based on the three-month forward-looking term secured overnight financing rate administered by the Federal Reserve Bank of New York ("Term SOFR"), the sum of (i) three-month Term SOFR (subject to 1.00% per annum floor), plus (ii) 6.75%. Accrued interest is payable quarterly following the funding of the Initial Term Loan on the Closing Date, on any date of prepayment or repayment of the Term Loans and at maturity.

The Company may prepay the Term Loans at any time (in whole or in part) or be required to make mandatory prepayments upon the occurrence of certain customary prepayment events. The mandatory prepayment events include certain permitted asset sales transactions (which include certain sales, leases, assignments, conveyances, transfers, licenses or exchanges of property) that occur prior to the date the FDA approves a first NDA for acoramidis, which would require the Company to deposit 75% of net cash received from such transactions into an escrow account controlled by the Administrative Agent, and the Company may also be subject to a specified disposition fee per transaction for certain asset sale transactions. In certain instances and during certain time periods, prepayments will be subject to customary prepayment fees. The amount of any prepayment fee may vary, but the maximum amount that may be due with any such prepayment would be an amount equal to 3.00% of the Term Loans being prepaid at such time, plus a customary make whole amount.

We have entered into asset sales transactions that occurred during the three months ended March 31, 2024 for the exclusive license agreements with Bayer and Kyowa Kirin for which the Company is required to deposit 75% of the proceeds, net of certain permitted costs, upon receipt of the upfront payments from Bayer and Kyowa Kirin into the escrow accounts. During the three months ended June 30, 2024, we received $235.0 million in aggregate from Bayer and Kyowa Kirin and deposited net proceeds of $159.3 million into the escrow accounts. Refer to Note 11 for further details regarding the exclusive license agreements with Bayer and Kyowa Kirin.

The completion of the $200.0 million private equity financing with external investors of BBOT was considered an asset sale transaction that was subject to a disposition fee under the Financing Agreement. Accordingly, we paid a disposition fee of $1.1 million to the Administrative Agent in May 2024. Refer to Note 6 for further details regarding the BBOT private equity financing transaction.

The Financing Agreement contains affirmative covenants and negative covenants applicable to the Company and its subsidiaries that are customary for financings of this type. Such covenants, among other items, limit the Company's and its subsidiaries' ability to (i) incur additional permitted indebtedness, (ii) pay dividends or make certain distributions, (iii) dispose of its and their assets, grant liens and license or permit other encumbrances on its and their assets, (iv) fundamentally alter the nature of their businesses and (v) enter into certain transactions with affiliates. The Company and the Guarantors are also required to maintain a minimum unrestricted cash balance of $70.0 million at all times. The Company and its subsidiaries are permitted to license their intellectual property, dispose of other assets and enter into monetization and royalty transactions, in each case, subject to satisfaction of certain terms and conditions. The Financing Agreement also includes representations, warranties, indemnities and

events of default that are customary for financings of this type, including an event of default relating to a change of control of the Company. Upon the occurrence of an event of default, the Lenders may, among other things, accelerate the Company's obligations under the Financing Agreement.

On June 20, 2024, the Company and each of the guarantors entered into the Second Amendment to the Financing Agreement. Under the Amended Financing Agreement, between June 20, 2024 and through the earlier of the FDA approval date and November 30, 2024, the Company was able to request a release of funds in an aggregate amount not to exceed 50% of the original net cash proceeds received from asset sale transactions. In June 2024, $20.0 million was released from the escrow accounts and classified as cash on the consolidated balance sheet. Furthermore, under the Amended Financing Agreement, the minimum qualified cash balance was amended from $70.0 million to $70.0 million plus 40% of any cash released by the Company from the escrow accounts, at all times. As of December 31, 2024, the minimum unrestricted qualified cash balance was $78.0 million.

Royalty Obligation

Funding Agreement

On January 17, 2024, the Company and its subsidiaries Eidos Therapeutics, Inc., BridgeBio Europe B.V. and BridgeBio International GmbH (collectively, the "Seller Parties") entered into the Funding Agreement with the Purchasers, and Alter Domus (US) LLC, as the collateral agent.

Pursuant to the Funding Agreement, the Purchasers agreed to pay to the Company $500.0 million (net of certain transaction expenses) ("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, "Funding Date").

In return, the Company granted the Purchasers the right to receive Royalty Interest Payments equal to 5% of the Net Sales of acoramidis. Each Royalty Interest Payment will become payable to the Purchasers on a quarterly basis after the Funding Date. In addition, the Seller Parties granted the collateral agent, for the benefit of the Purchasers, a security interest in specific assets related to acoramidis.

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 the event that a change in control (as customarily defined in the Funding Agreement) occurs on or after the effective date of the Funding Agreement and prior to FDA approval of acoramidis, either party may terminate the Funding Agreement and the Seller Parties shall make a one-time payment of $25.0 million (in the aggregate) to the Purchasers. 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. The Funding Agreement will terminate upon customary events.

Following the FDA approval of Attruby 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 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.

Refer to Note 10 in our consolidated financial statements for other details.

Cash Flows

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

	Year Ended December 31,		
	2024	2023	Change
	(in thousands)		
Net cash used in operating activities	$ (520,726)	$ (527,720)	$ 6,994
Net cash provided by investing activities	60,781	54,033	6,748
Net cash provided by financing activities	748,457	451,535	296,922
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 288,512	$ (22,152)	$ 310,664

Net Cash Flows Used in Operating Activities

Net cash used in operating activities was $520.7 million in 2024, consisting primarily of our net loss of $543.3 million; adjusted for non-cash items totaling $9.4 million, which primarily includes a gain of $178.3 million from the deconsolidation of subsidiaries, a net gain of $8.1 million from investment in equity securities, and 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, $15.8 million in accretion of debt, $6.1 million in depreciation and amortization; and a $32.0 million net cash inflow related to changes in operating assets and liabilities. 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 Agreement, an increase of $17.0 million in accrued compensation and benefits, an increase of $8.7 million in accrued research and development liabilities, partially offset by a decrease in prepaid expenses and other current assets of $13.9 million, which are collectively primarily due to timing of payments.

Net cash used in operating activities was $527.7 million in 2023, consisting primarily of our net loss of $653.3 million; adjusted for non-cash items totaling $120.5 million, which primarily includes $108.7 million in stock-based compensation expense, $10.2 million in accrued payment-in-kind interest, $8.9 million in accretion of debt, $6.5 million in depreciation and amortization, and offset by a net gain of $18.3 million from investment in equity securities; with the remaining $5.1 million net cash inflow related to changes in operating assets and liabilities. The $5.1 million net cash inflow related to changes in operating assets and liabilities was attributed mainly to a decrease of $15.3 million from licensing and collaboration agreements receivables primarily due to collections, an increase of $7.8 million in accrued compensation and benefits due to timing of payments; partially offset by a decrease of $9.9 million in accrued research and development liabilities due to timing of payments, a decrease in deferred revenue of $5.4 million due to revenue recognized, and a decrease in operating lease liabilities of $4.8 million.

Net Cash Flows Provided by Investing Activities

Net cash provided by investing activities was $60.8 million in 2024, attributable primarily to $95.0 million in proceeds from the maturities of marketable securities, $63.2 million in proceeds from the sale of equity securities, $25.7 million in special cash dividends received from 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 to FMI for intangible assets.

Net cash provided by investing activities was $54.0 million in 2023, attributable primarily to $110.6 million in proceeds from the sale of equity securities and $82.6 million in maturities of marketable securities, partially offset by purchases of investments in equity securities of $107.5 million and purchases of marketable securities of $29.7 million.

Cash Flows Provided by Financing Activities

Net cash provided by financing activities was $748.5 million in 2024, consisting 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.

Net cash provided by financing activities was $451.5 million in 2023, consisting primarily of $240.8 million in net proceeds from the issuance of common stock through the Private Placement offering, $144.0 million in net proceeds from the issuance of common stock through the Follow-on offering, $65.0 million in net proceeds from the issuance of common stock through the ATM offering, and $6.0 million in net proceeds from stock option exercises, partially offset by $6.9 million of repurchases of shares to satisfy tax withholdings.

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 Arrangements

We enter into collaboration arrangements with partners, under which we may grant licenses to further develop, manufacture and commercialize our drug compounds and or/products. 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, *Revenue from Contracts with Customers*. However, if we conclude that our partner is not a customer for certain activities and associated payments, such as for certain collaborative research, development, manufacturing, and commercial activities, we record such payments as a reduction of research and development expense or 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.

License Fees: For arrangements that include a grant of a license to our intellectual property, we consider whether the license grant is distinct from the other performance obligations included in the arrangement. Generally, we would conclude that the license is distinct if the customer is able to benefit from the license with the resources available to it. For licenses that are distinct, we recognize revenues from nonrefundable, upfront 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 up-front license fees. We evaluate the measure of progress 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).

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.

Product Sales, Net: Revenue is recognized when our customers obtain control of the product and revenue is adjusted to reflect discounts, chargebacks, rebates, returns and other allowances associated with the respective sales.

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 in the consolidated balance sheets and within research and development expense in the consolidated statements of operations. These costs are a significant component of our research and development expenses.

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

- fees paid to CROs in connection with preclinical and toxicology studies and clinical 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 assets.

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

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

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 (i) cash, (ii) equity of BridgeBio, or (iii) 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 Obligation

We treat the debt obligation to the Purchasers as discussed further in Note 10 as a deferred royalty obligation, 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 global net sales over the life of the arrangement. In connection therewith, we periodically assess our expected global net sales using internal projections, impute interest on the carrying value of the deferred royalty obligation, and record interest expense using the imputed effective interest rate. To the extent our estimates of future revenues 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 obligation. The assumptions used in determining the expected repayment term of the deferred royalty obligation and amortization period of the 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 Pronouncements*" 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, 2024, we held cash, cash equivalents, and restricted cash of $681.2 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. 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 or cash equivalents have a significant risk of default or illiquidity.

As of December 31, 2024, our 2029 Notes and 2027 Notes had principal balances of $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. However, as of December 31, 2024, our term loan under the Amended Financing Agreement had a principal balance of $450.0 million, which bears variable interest rates that are subject to variability as a result of changes in interest rates. The effect of a hypothetical 10% increase in interest rates applicable to the Amended Financing Agreement would increase our interest expense on our term loan by $1.8 million for the year ended December 31, 2024.

We do not believe that inflation and changing prices had a significant impact on our business, financial conditions or results of operations for any of the periods presented herein. Significant adverse changes in inflation and prices in the future could result in material losses.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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, 2024 and 2023, 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, 2024, 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, 2024 and 2023, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2024, 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, 2024, 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 20, 2025, 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, 2024, 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 20, 2025
We have served as the Company's auditor since 2018.

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

	December 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 681,101	$ 375,935
Investments in equity securities	—	58,949
Accounts receivable	4,722	1,751
Restricted cash	126	16,653
Prepaid expenses and other current assets	34,743	24,305
Total current assets	720,692	477,593
Investment in nonconsolidated entities	143,747	—
Property and equipment, net	7,011	11,816
Operating lease right-of-use assets	5,767	8,027
Intangible assets, net	23,926	26,319
Other assets	18,195	22,625
Total assets	$ 919,338	$ 546,380
Liabilities, Redeemable Convertible Noncontrolling Interests and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 9,618	$ 10,655
Accrued compensation and benefits	58,329	57,370
Accrued research and development liabilities	34,272	29,765
Operating lease liabilities, current portion	4,506	4,128
Deferred revenue, current portion	14,604	6,096
Accrued professional and other accrued liabilities	33,071	35,830
Total current liabilities	154,400	143,844
2029 Notes, net	738,872	736,905
2027 Notes, net	545,173	543,379
Term loan, net	437,337	446,445
Deferred royalty obligation, net	479,091	—
Operating lease liabilities, net of current portion	4,696	8,981
Deferred revenue, net of current portion	17,095	3,727
Other long-term liabilities	286	5,634
Total liabilities	2,376,950	1,888,915
Commitments and contingencies (Note 8)		
Redeemable convertible noncontrolling interests	142	478
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; 196,236,234 shares issued and 190,044,473 shares outstanding as of December 31, 2024, 181,274,712 shares issued and 175,082,951 shares outstanding as of December 31, 2023	196	181
Treasury stock, at cost; 6,191,761 shares as of December 31, 2024 and December 31, 2023	(275,000)	(275,000)
Additional paid-in capital	1,903,155	1,481,032
Accumulated other comprehensive income	8	31
Accumulated deficit	(3,096,263)	(2,560,501)
Total BridgeBio stockholders' deficit	(1,467,904)	(1,354,257)
Noncontrolling interests	10,150	11,244
Total stockholders' deficit	(1,457,754)	(1,343,013)
Total liabilities, redeemable convertible noncontrolling interests and stockholders' deficit	$ 919,338	$ 546,380

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

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

	Year Ended December 31,		
	2024	**2023**	**2022**
Revenue, net	$ 221,902	$ 9,303	$ 77,648
Operating costs and expenses:			
Cost of revenue	3,878	2,446	3,434
Research and development	506,461	455,711	399,462
Selling, general and administrative	288,931	150,590	143,189
Restructuring, impairment and related charges	15,605	7,926	43,765
Total operating costs and expenses	814,875	616,673	589,850
Loss from operations	(592,973)	(607,370)	(512,202)
Other income (expense), net:			
Interest income	17,249	18,038	7,542
Interest expense, net	(99,290)	(81,289)	(80,438)
Gain on deconsolidation of subsidiaries	178,321	—	—
Loss on extinguishment of debt	(26,590)	—	—
Net loss from equity method investments	(31,183)	—	—
Gain from sale of priority review voucher, net	—	—	107,946
Other income (expense), net	12,272	17,370	(7,500)
Total other income (expense), net	50,779	(45,881)	27,550
Loss before income taxes	(542,194)	(653,251)	(484,652)
Income tax expense	1,153	—	—
Net loss	(543,347)	(653,251)	(484,652)
Net loss attributable to redeemable convertible noncontrolling interests and noncontrolling interests	7,585	10,049	3,469
Net loss attributable to common stockholders of BridgeBio	$ (535,762)	$ (643,202)	$ (481,183)
Net loss per share attributable to common stockholders of BridgeBio, basic and diluted	$ (2.88)	$ (3.95)	$ (3.26)
Weighted-average shares used in computing net loss per share attributable to common stockholders of BridgeBio, basic and diluted	186,075,873	162,791,511	147,473,076

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

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

	Year Ended December 31,		
	2024	**2023**	**2022**
Net loss	$ (543,347)	$ (653,251)	$ (484,652)
Other comprehensive loss:			
Unrealized gains (losses) on available-for-sale securities	(23)	359	(196)
Comprehensive loss	(543,370)	(652,892)	(484,848)
Comprehensive loss attributable to redeemable convertible noncontrolling interests and noncontrolling interests	7,585	10,049	3,469
Comprehensive loss attributable to common stockholders of BridgeBio	$ (535,785)	$ (642,843)	$ (481,379)

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

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

	Year Ended December 31, 2024										
	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, 2021 [2]	$ 1,423	147,343,323	$ 154	6,191,761	$ (275,000)	$ 841,530	$ (132)	$ (1,436,966)	$ (870,414)	$ 3,412	$ (867,002)
Issuance of shares under equity compensation plans	—	2,658,109	3	—	—	663	—	—	666	—	666
Issuance of common stock under ESPP	—	339,549	—	—	—	2,558	—	—	2,558	—	2,558
Repurchase of restricted stock unit (RSU) shares to satisfy tax withholding	—	(171,209)	—	—	—	(1,561)	—	—	(1,561)	—	(1,561)
Stock-based compensation	—	—	—	—	—	94,173	—	—	94,173	—	94,173
Issuance of common stock under public offerings, net	—	455,800	—	—	—	4,852	—	—	4,852	—	4,852
Issuance of noncontrolling interests	—	—	—	—	—	—	—	—	—	4,815	4,815
Transfers from (to) noncontrolling interests	2,399	—	—	—	—	(3,512)	—	—	(3,512)	1,113	(2,399)
Unrealized loss on available-for-sale securities	—	—	—	—	—	—	(196)	—	(196)	—	(196)
Net income (loss)	(5,411)	—	—	—	—	—	—	(481,183)	(481,183)	1,942	(479,241)
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 ESPP	—	339,979	—	—	—	3,398	—	—	3,398	—	3,398
Repurchase of 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 gain 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 losses 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)

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

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

	Year Ended December 31,		
	2024	**2023**	**2022**
Operating activities:			
Net loss	$ (543,347)	$ (653,251)	$ (484,652)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation	95,800	108,710	91,559
Loss on extinguishment of debt	26,590	—	—
Accretion of debt	15,763	8,907	8,570
Depreciation and amortization	6,075	6,494	6,771
Noncash lease expense	4,110	4,032	5,172
Accrual of payment-in-kind interest on term loan	—	10,207	13,562
Net loss from equity method investments	31,183	—	—
Loss (gain) on deconsolidation of subsidiaries	(178,321)	1,241	—
Loss (gain) from investment in equity securities, net	(8,136)	(18,314)	8,222
Fair value of shares issued under a license agreement	—	—	4,567
Loss on sale of certain assets	—	—	6,261
Impairment of long-lived assets	271	—	12,720
Gain from sale of priority review voucher, excluding transaction costs	—	—	(110,000)
Gain from recognition of receivable from licensing and collaboration agreement	—	—	(12,500)
Other noncash adjustments, net	(2,756)	(803)	2,175
Changes in operating assets and liabilities:			
Accounts receivable	(2,971)	15,328	15,169
Prepaid expenses and other current assets	(13,918)	(2,702)	7,671
Other assets	1,542	(1,546)	10,971
Accounts payable	1,512	2,780	(349)
Accrued compensation and benefits	16,986	7,802	(2,362)
Accrued research and development liabilities	8,729	(9,855)	(4,309)
Operating lease liabilities	(5,902)	(4,829)	(6,245)
Deferred revenue	21,875	(5,438)	15,262
Accrued professional and other liabilities	4,189	3,517	(7,729)
Net cash used in operating activities	(520,726)	(527,720)	(419,494)
Investing activities:			
Purchases of marketable securities	(93,811)	(29,726)	(137,493)
Maturities of marketable securities	95,000	82,550	479,688
Purchases of investments in equity securities	(20,271)	(107,538)	(55,562)
Proceeds from sales of investments in equity securities	63,229	110,556	52,835
Proceeds from special cash dividends received from investments in equity securities	25,682	—	—
Payment for an intangible asset	(7,975)	—	(1,500)
Proceeds from sale of priority review voucher	—	—	110,000
Proceeds from sale of certain assets	—	—	10,000
Purchases of property and equipment	(933)	(1,306)	(4,821)
Decrease in cash and cash equivalents resulting from deconsolidation of subsidiaries	(140)	(503)	—
Net cash provided by investing activities	60,781	54,033	453,147
Financing activities:			
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 Amended Financing Agreement	450,000	—	—
Issuance costs and discounts associated with term loan under Amended Financing Agreement	(15,986)	—	—
Repayment of term loans	(473,417)	—	(20,486)
Proceeds from issuance of common stock through public offerings, net	314,741	449,810	4,852
Proceeds from BridgeBio common stock issuances under ESPP	4,502	3,398	2,558
Proceeds from stock option exercises, net of repurchases	3,656	6,008	666
Transactions with noncontrolling interests	—	(801)	—
Repurchase of RSU shares to satisfy tax withholding	(7,526)	(6,880)	(1,561)
Other financing activities	—	—	837
Net cash provided by (used in) financing activities	748,457	451,535	(13,134)
Net increase (decrease) in cash, cash equivalents and restricted cash	288,512	(22,152)	20,519
Cash, cash equivalents and restricted cash at beginning of year	394,732	416,884	396,365
Cash, cash equivalents and restricted cash at end of year	$ 683,244	$ 394,732	$ 416,884

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

	Year Ended December 31,		
	2024	**2023**	**2022**
Supplemental Disclosure of Cash Flow Information:			
Cash paid for interest	$ 91,342	$ 61,108	$ 54,443
Supplemental Disclosures of Noncash Investing and Financing Information:			
Unpaid property and equipment	$ 279	$ 100	$ 47
Transfers to noncontrolling interests	$ (5,819)	$ (10,534)	$ (3,512)
Recognized intangible asset recorded in "Accrued research and development liabilities"	$ —	$ —	$ 11,000
Payment-in-kind interest added to principal of term loan	$ —	$ —	$ 1,763
Reconciliation of Cash, Cash Equivalents and Restricted Cash:			
Cash and cash equivalents	$ 681,101	$ 375,935	$ 376,689
Restricted cash	126	16,653	37,930
Restricted cash — Included in "Other assets"	2,017	2,144	2,265
Total cash, cash equivalents and restricted cash at end of years shown in the consolidated statements of cash flows	$ 683,244	$ 394,732	$ 416,884

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

1. Organization and Description of Business

BridgeBio Pharma, Inc. ("BridgeBio", the "Company", or "we"), is a new type of biopharmaceutical company founded to discover, create, test and deliver transformative medicines to treat patients who suffer from genetic diseases. BridgeBio's pipeline of development programs ranges from early science to advanced clinical trials. 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 FDA approval of Attruby™ (acoramidis) and began to generate product revenue from the commercialization of Attruby in the United States (the "U.S."). In addition, we have three product candidates (low-dose infigratinib for achondroplasia, encaleret for ADH1, and BBP-418 for LGMD2I/R9x) 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. During the year ended December 31, 2024, we divested and deconsolidated (i) Portal Therapeutics, Inc. and Sub21, Inc. as part of the GondolaBio, LLC transaction, and (ii) TheRas, Inc. Each of Portal Therapeutics, Inc., Sub21, Inc. and TheRas, Inc. was formerly a majority-owned subsidiary. Portal Therapeutics, Inc. and Sub21, Inc. were contributed to GondolaBio, LLC in the GondolaBio, LLC transaction. GondolaBio, LLC and TheRas, Inc. were funded through private equity financing transactions with certain third party investors during the year ended December 31, 2024. Refer to Note 2 and Note 6 for further details regarding the GondolaBio, LLC and TheRas, Inc. transactions.

We previously disclosed in the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2024, filed on November 12, 2024, conditions existed that raised substantial doubt about our ability to continue as a going concern. As of November 12, 2024, we anticipated receiving $500.0 million milestone payment under our Funding Agreement upon FDA approval of acoramidis, generating product revenue from the sale of acoramidis, and/or potentially needing to raise additional capital to fund our operations in order to mitigate those concerns, however, there was no assurance that management's plans would be successful. As a result, we disclosed there was substantial doubt about our ability to continue as a going concern in the condensed consolidated financial statements included in the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2024.

Following the FDA approval of Attruby on November 22, 2024, we received the $500.0 million gross milestone payment under our Funding Agreement and began generating product revenue from the sale of Attruby. As a result of these efforts and due to expected cash flows from operations over the next twelve months, the substantial doubt about the Company's ability to continue as a going concern was resolved as of the date of issuance of these consolidated financial statements.

2. Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

The consolidated financial statements include the accounts of BridgeBio Pharma, Inc., its wholly-owned subsidiaries and controlled entities, 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" in 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 recurring adjustments, necessary for a fair statement of our financial position, our results of operations and comprehensive loss, stockholders' deficit and our cash flows for the periods presented. The results of operations for the years ended December 31, 2024, 2023 and 2022 are not necessarily indicative of the results to be expected for the year ending December 31, 2025 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.

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 Accounting Standards Codification ("ASC") 323 Investments — Equity Method and Joint Ventures, where we may not be the primary beneficiary, but may still exercise significant influence over operating activities 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 ("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.

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, a Delaware limited liability company ("GondolaBio"), and as a result, Portal Therapeutics, Inc. and Sub21, Inc. were deconsolidated in conjunction with the GondolaBio transaction described below.

GondolaBio was formed on June 5, 2024 and the Company was the sole member. On August 16, 2024, the Company, on the recommendation of a special committee of independent and disinterested directors of the Company, entered into a transaction agreement (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 certain assets contributed to GondolaBio by the Company. The third party investors have committed $300.0 million of tranched financing to GondolaBio, of which $60.0 million had been contributed as of December 31, 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. On August 16, 2024, in conjunction with the Transaction Agreement, GondolaBio's limited liability company agreement was amended and restated to reflect a change in its governance structure and composition of the board of managers, which was determined to be a VIE reconsideration event. Based on the VIE reconsideration assessment, 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. Upon the deconsolidation of GondolaBio on August 16, 2024, BridgeBio accounted for its investment in GondolaBio, for which it has significant influence through its ownership interest, using the equity method of accounting.

Since inception through April 29, 2024, TheRas, Inc. ("TheRas") was a majority-owned consolidated subsidiary of the Company. On April 30, 2024, the Company completed a $200.0 million private equity financing with external investors of TheRas, to accelerate the development of its oncology portfolio. Upon completion of the private equity financing, Company ownership was reduced to 37.9% of TheRas' equity. As part of the private equity financing transaction, TheRas' Certificate of Incorporation and Investors' Rights Agreement were amended and restated to reflect a change in TheRas' governance structure and composition of the board of directors, which was determined to be a VIE reconsideration event. Based on the VIE reconsideration assessment, TheRas was deemed a VIE. As a result of the change in governance structure and composition of the board of directors, BridgeBio is no longer the primary beneficiary, as it no longer has the power over key decisions that significantly impact TheRas' economic performance. Accordingly, BridgeBio deconsolidated TheRas and accounted for BridgeBio's retained investment in TheRas, for which it has significant influence through its ownership interest, using the equity method of accounting as of April 30, 2024.

As of December 31, 2020, we had an equity method and equity security investments in PellePharm. The equity security investments in PellePharm were without a readily determinable fair value and were carried at cost less impairment plus or minus observable price changes. PellePharm became a consolidated VIE in April 2021 under ASC 810, *Consolidation*. On January 16, 2023, PellePharm's board of directors authorized the assignment of all PellePharm's assets to PellePharm ABC, LLC for liquidation and distribution under the General Assignment for the Benefit of Creditors ("ABC"). As part of the ABC proceedings, PellePharm's board of directors resigned effective March 6, 2023. The date the board of directors resigned was determined to be a VIE reconsideration event. Based on the changes to PellePharm's governance structure and composition of the board of directors as a result of the ABC, BridgeBio was no longer the primary beneficiary, as it no longer had the power over key decisions that

significantly impact PellePharm's economic performance. Accordingly, BridgeBio deconsolidated PellePharm effective during the three months ended March 31, 2023.

Refer to Note 6 for further discussion on the GondolaBio, TheRas and PellePharm investments. GondolaBio and TheRas are accounted for as equity method investments as of December 31, 2024. We did not have any equity method investments as of December 31, 2023.

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, accounts receivable, and restricted cash. Substantially all of our cash, cash equivalents, and restricted cash are held in financial institutions in the United States. Amounts on deposit may at times exceed federally insured limits. Although management currently believes that the financial institutions with whom it 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 in such accounts as of and for the years ended December 31, 2024 and 2023.

During the years ended December 31, 2024, 2023 and 2022, our revenues were generated primarily from license and collaboration agreements with strategic partners and from product sales to distributors. We are subject to credit risk from our accounts receivables. 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.

The following table summarizes customers that represent 10% or greater of our consolidated revenue, net:

	Year ended December 31,		
	2024	2023	2022
		(in thousands)	
Bayer Consumer Care AG ("Bayer")	59.3%	*	*
Kirin Co., Ltd ("Kyowa Kirin" or "KKC")	34.3%	*	*
Bristol-Myers Squibb Company ("BMS")	*	80.6%	98.2%
LianBio	*	14.5%	*

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

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 manufacturers to supply products for the commercial sale of Attruby 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, and in some cases a single source manufacturer, to supply us with our requirements for the active pharmaceutical ingredients and formulated drugs related to the commercial sale of Attruby and the research and development of our other clinical product candidates. The commercial sale of Attruby and our other clinical development product candidates could be adversely affected by a significant interruption in the supply of active pharmaceutical ingredients and formulated drugs.

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 period. Significant estimates and assumptions made in the accompanying consolidated financial statements include, but are not limited to:

- accruals for research and development activities, such as clinical, development, regulatory, and sales-based milestone payments in our in-licensing agreements and asset acquisitions,

- deferred royalty obligations, related embedded derivative liability and underlying assumptions,
- determining and allocating the transaction price to performance obligations for transactions accounted for under ASC 606, *Revenue from Contracts with Customers* ("ASC 606"),
- advertising expense,
- 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, 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 and Cash Equivalents

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, treasury bills and securities issued by the U.S. government or its agencies.

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

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

	December 31,		
	2024	2023	2022
		(in thousands)	
Cash and cash equivalents	$ 681,101	$ 375,935	$ 376,689
Restricted cash	126	16,653	37,930
Restricted cash, non-current — included in "Other assets"	2,017	2,144	2,265
Total cash, cash equivalents and restricted cash shown on the consolidated statements of cash flows	$ 683,244	$ 394,732	$ 416,884

Restricted Cash

Restricted cash primarily represents funds in a controlled account that was established in connection with the Company's Term Loans described in Note 9.

Under the terms of the Financing Agreement (as defined in Note 9), the Company is required to deposit 75% of proceeds, net of certain permitted costs, received from certain asset sale transactions into escrow accounts to be controlled by the Administrative Agent. During the three months ended June 30, 2024, we received $235.0 million in aggregate from Bayer Consumer Care AG and Kyowa Kirin Co., Ltd, and deposited net proceeds of $159.3 million into the escrow accounts, which was classified as "Restricted cash" on the consolidated balance sheet. Furthermore, under the terms of the Amended Financing Agreement (as defined in Note 9), between June 20, 2024 and through the earlier of the FDA approval date of a first NDA for acoramidis or November 30, 2024, the Company was able to request a release of funds in an aggregate amount not to exceed 50% of the original net cash proceeds received from asset sale transactions. During the three months ended June 30, 2024, $20.0 million was released from the escrow accounts. Following the FDA approval of Attruby and receipt of consent from the lenders, the remaining $139.3 million was released from the escrow accounts and classified as cash on the consolidated balance sheet. Refer to Note 9 and Note 11 for further details regarding the Financing Agreement and the exclusive license agreements with Bayer Consumer Care AG and Kyowa Kirin Co., Ltd.

As of December 31, 2023, the use of such non-interest-bearing cash was restricted per the terms of the underlying amended Loan and Security Agreement and was to be used solely for certain research and development expenses directly attributable to the performance of obligations associated with the Navire-BMS License Agreement, which is further described in Note 11. As of December 31, 2023, restricted cash related to this agreement was $16.5 million, which is presented as part of "Restricted cash" on the consolidated balance sheets. Upon the termination of the Loan and Security Agreement and full repayment of the term loan in January 2024 (refer to Note 9 for details) the non-interest-bearing cash was no longer restricted.

Additionally, under certain lease agreements and letters of credit, we have pledged cash and cash equivalents as collateral. As of December 31, 2024, restricted cash related to such agreements was $0.1 million and $2.0 million, which is presented as part of "Restricted cash" and "Other assets", respectively, on the consolidated balance sheets. As of December 31, 2023, restricted cash related to such agreements was $0.1 million and $2.1 million, which is presented as part of "Restricted cash" and "Other assets", respectively, on the consolidated balance sheets.

Investment in Equity Securities

We have investment in equity securities of public companies starting in 2021. We measure the fair value of our investment in equity securities at each reporting period in accordance with ASC 321, *Investments — Equity Securities*. Changes in fair value resulting from observable price changes are included in "Other income (expense), net" in 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. During the year ended December 31, 2024, we liquidated our investments in equity securities.

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 statement of operations in the period realized.

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

Furniture and office equipment	3 - 5 years
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 $3.7 million, $4.1 million and $4.1 million for the years ended December 31, 2024, 2023 and 2022, 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" in 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 "Accrued professional and other accrued liabilities" and "Other long-term liabilities", respectively, in our consolidated balance sheets. Assets under finance leases are depreciated in a manner similar to other property and equipment.

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.

Impairment of Long-Lived Assets

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

Accrued Professional and Other Accrued Liabilities

Accrued professional and other accrued liabilities presented on the consolidated balance sheets consisted of the following balances:

	December 31,	
	2024	2023
	(in thousands)	
Accrued professional services	$ 3,673	$ 7,412
Accrued interest	11,056	17,761
Milestone liability	1,595	6,000
Royalty obligation, current portion	144	—
Other accrued liabilities	16,603	4,657
Accrued professional and other accrued liabilities	$ 33,071	$ 35,830

Segments

We are a single operating and reportable segment, which is in the business of identifying and advancing transformative medicines to treat patients. We operate in one segment because our business offerings have similar economics and other characteristics, including the nature of products, 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, contract manufacturing organizations ("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.

The following table summarizes our segment information for significant operating expenses and includes a reconciliation to net loss:

	Year Ended December 31,		
	2024	2023	2022
	(in thousands)		
Revenue, net	$ 221,902	$ 9,303	$ 77,648
Operating costs and expenses:			
Cost of revenue	3,878	2,446	3,434
Research and development by significant program:			
Acoramidis for ATTR-CM	164,782	101,041	91,901
Infigratinib	91,869	63,239	32,387
BBP-418 (ribitol) for LGMD2I/R9	40,220	33,903	22,372
Encaleret for ADH1	49,091	44,773	27,485
Other development programs	71,732	82,165	124,501
Other research programs	88,767	130,590	100,816
Total segment research and development	506,461	455,711	399,462
Selling, general and administrative	288,931	150,590	143,189
Restructuring, impairment and related charges	15,605	7,926	43,765
Total operating costs and expenses	814,875	616,673	589,850
Loss from operations	(592,973)	(607,370)	(512,202)
Other income (expense), net:			
Interest income	17,249	18,038	7,542
Interest expense, net	(99,290)	(81,289)	(80,438)
Gain on deconsolidation of subsidiaries	178,321	—	—
Loss on extinguishment of debt	(26,590)	—	—
Net loss from equity method investments	(31,183)	—	—
Gain from sale of priority review voucher, net	—	—	107,946
Other income (expense), net	12,272	17,370	(7,500)
Total other income (expense), net	50,779	(45,881)	27,550
Loss before income taxes	(542,194)	(653,251)	(484,652)
Income tax expense	1,153	—	—
Net loss	(543,347)	(653,251)	(484,652)
Net loss attributable to redeemable convertible noncontrolling interests and noncontrolling interests	7,585	10,049	3,469
Segment net loss attributable to common stockholders of BridgeBio	$ (535,762)	$ (643,202)	$ (481,183)

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

Total revenues are attributed to regions based on the headquarters of the customer or partner.

	Year ended December 31,		
	2024	2023	2022
Europe, Middle East, and Africa (EMEA)	59.5%	*	*
Asia-Pacific (APAC)	34.5%	14.5%	*
North America	*	84.9%	98.9%

* Represents less than 10% in the applicable year

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, 2024 and 2023, our capitalized property and equipment located in the United States and Canada is approximately 51.6% and 44.7%, and 69.1% and 30.6%, respectively.

Capped Call Transactions

In January 2021 and March 2020, in connection with the issuance of the 2029 Notes and the 2027 Notes, respectively, (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 Notes and/or offset any cash payments BridgeBio is required to make in excess of the principal amount of converted 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 Obligation

We treat the debt obligation to the Purchasers as defined and discussed further in Note 10 as a deferred royalty obligation, 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 global net sales over the life of the arrangement. In connection therewith, we periodically assess our expected global net sales using internal projections, impute interest on the carrying value of the deferred royalty obligation, and record interest expense using the imputed effective interest rate. To the extent our estimates of future revenues 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 obligation. The assumptions used in determining the expected repayment term of the deferred royalty obligation and amortization period of the 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 FASB ASC Topic 815, *Derivatives and Hedging* and Topic 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. The change in fair value is recorded in the accompanying consolidated statements of operations and comprehensive loss as a component of interest expense. As of December 31, 2024, the Company has an embedded derivative with a fair value of $41.1 million 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 obligation.

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.

License Fees: For arrangements that include a grant of a license to our intellectual property, we consider whether the license grant is distinct from the other performance obligations included in the arrangement. Generally, we would conclude that the license is distinct if the customer is able to benefit from the license with the resources available to it. For licenses that are distinct, we recognize revenues from nonrefundable, upfront 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 up-front license fees. We evaluate the measure of progress 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).

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.

Product Revenue, Net: Revenue is recognized when our customers obtain control of the product and revenue is adjusted to reflect discounts, chargebacks, rebates, returns and other allowances associated with the respective sales.

Accounts Receivable

Accounts receivable includes receivables from our product sales to customers, and from our partners as a result of licensing and collaboration agreements. Receivables from licensing and collaboration agreements represent valid claims against our partners, including unbilled receivables and royalty payments due from third parties for licensing our technology. Unbilled receivables include balances due from our partners related to development services and transition-related receivables that are recognized upon incurrence of the costs 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, 2024 and 2023, respectively, are presented as "Accounts receivable" in 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, 2024 and 2023, we did not have an allowance for credit losses.

Cost of Revenue

Cost of revenue consists of manufacturing costs, transportation and freight, and indirect overhead costs (including salary related and stock-based compensation expenses) associated with the commercial manufacturing and distribution of Attruby, third-party royalties payable on our net product revenues. Cost of revenue also consists of amortization of intangible assets associated with the sale of our products, which are amortized over the life of the underlying intellectual property. Cost of revenue may also include period costs related to excess or obsolete inventory adjustment charges, abnormal costs, unabsorbed manufacturing and overhead costs, and manufacturing variances. Prior to regulatory approval of our product candidates, we recorded 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 revenue. Subsequent to the FDA approval of Attruby in November 2024, these related costs for Attruby were capitalized as inventory costs and recognized in our consolidated statements of operations as cost of revenue upon sale of our product.

Research and Development Expenses

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

Accrued Research and Development Liabilities

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

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

- fees paid to CROs in connection with preclinical and toxicology studies and clinical 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 assets.

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

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

Under our asset acquisitions, 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 and asset acquisitions. Such royalties are expensed in the period of sale of the product.

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, and depreciation and amortization expenses.

Advertising Expense

Advertising expenses include costs incurred to market the Company's branded products. 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 and 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 $21.5 million for the year ended December 31, 2024 and are included in "Selling, general, and administrative expenses" in the consolidated statement of operations. Advertising costs for the years ended December 31, 2023 and 2022 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, 2024 and 2023, respectively.

Sales of Nonfinancial Assets

We generally account for sales of nonfinancial assets that are outside the scope of our ordinary activities under ASC 610-20, *Other Income - Gains and Losses from the Derecognition of Nonfinancial Assets* ("ASC 610-20"). Pursuant to ASC 610-20, we apply the guidance in ASC 606 to determine if a contract exists, identify the distinct nonfinancial assets, and determine when control transfers and, therefore, when to derecognize the nonfinancial asset. Additionally, we apply the measurement principles of ASC 606 to determine the amount of consideration, if any, to include in the calculation of the gain or loss for the sale of the nonfinancial asset.

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 ("RSA"), and restricted stock units ("RSU awards") under our equity incentive plans, as well as shares issued under our Employee Stock Purchase Plan ("ESPP"), through which employees may purchase our common stock at a discount to the market price.

We use the Black-Scholes 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 non-employees based on the fair value of the awards. Compensation expense for purchases under the ESPP is

recognized based on the fair value of the award on the date of offering. Stock-based compensation is recognized as expense on a straight-line basis over the requisite service period, which is generally the vesting period.

The estimated fair value of 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.

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 generally recorded in research and development expense, and selling, general and administrative expense based on the function of the applicable employee and non-employee.

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.

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 restricted stock units and awards and performance-based milestone compensation awards, shares issuable under the employee stock purchase plan and assumed conversion of our 2029 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 Pronouncements

In October 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standard Update ("ASU") 2023-06, *Disclosure Improvements: Codification Amendments in Response to the SEC's Disclosure Updated and Simplification Initiative*, which amends the disclosure or presentation requirements related to various subtopics in the FASB Accounting Standards Codification. ASU 2023-06 was issued in response to the U.S. Securities and Exchange Commission's (the "SEC") August 2018 final rule that updated and simplified disclosure requirements and is intended to align U.S. GAAP requirements with those of the SEC and to facilitate the application of U.S. GAAP for all entities. For entities subject to the SEC's existing disclosure requirements and for entities required to file or furnish financial statements with or to the SEC in preparation for the sale of or for purposes of issuing securities that are not subject to contractual restrictions on transfer, the effective date for each

amendment will be the date on which the SEC removes that related disclosure from its rules. However, if by June 30, 2027, the SEC has not removed the related disclosure from its regulations, the amendments will be removed from the Codification and not become effective for any entity. There was no material impact from the adoption of this ASU on our consolidated financial statements and disclosures.

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*, which are intended to improve reportable segment disclosure requirements. ASU 2023-07 expands public entities' segment disclosures by requiring disclosure of significant segment expenses that are regularly provided to the chief operating decision maker and included within each reported measure of segment profit or loss, an amount and description of its composition for other segment items, and interim disclosures of a reportable segment's profit or loss and assets. The amendments are effective for fiscal years beginning after December 15, 2023, and for interim periods within fiscal years beginning after December 15, 2024. The amendments should be applied retrospectively to all prior periods presented in the financial statements. There was no material impact from the adoption of this ASU on our consolidated financial statements, however we included additional disclosures in our above-mentioned segment disclosure.

New Accounting Pronouncements Not Yet Adopted

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*, which expands disclosures in an entity's income tax rate reconciliation table and disclosures regarding cash taxes paid both in the U.S. and foreign jurisdictions. The update will be effective for annual periods beginning after December 15, 2024. We are currently evaluating the impact that this guidance will have on our consolidated financial statements and disclosures.

In November 2024, the FASB issued ASU 2024-03, *Income Statement Reporting (Topic 220)- Comprehensive Income- Expense Disaggregation Disclosures*, 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. Early adoption is permitted. We are currently evaluating the impact that this guidance will have on our consolidated financial statements and disclosures.

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. We are currently evaluating the impact that this guidance will have on our consolidated financial statements and disclosures.

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, 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 obligation, net")	$ 41,091	$ —	$ —	$ 41,091

	December 31, 2023			
	Total	Level 1	Level 2	Level 3
	(in thousands)			
Assets				
Cash equivalents:				
Money market funds	$ 13,530	$ 13,530	$ —	$ —
Treasury bills	256,067	—	256,067	—
Total cash equivalents	269,597	13,530	256,067	—
Investments in equity securities	58,949	58,949	—	—
LianBio warrant	1,554	1,554	—	—
Total financial assets	$ 330,100	$ 74,033	$ 256,067	$ —
Liability				
Embedded derivative (included in "Accrued professional and other accrued liabilities")	$ 1,665	$ —	$ —	$ 1,665

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.

Investment in Equity Securities

We have investment in equity securities of publicly held companies, which are actively traded with quoted prices that are readily available, and we do not have restrictions on our ability to sell these securities. Therefore, these are classified within Level 1. Our investments in equity securities, which only consisted of an investment in LianBio, had an aggregate fair value of nil as of December 31, 2024 (refer to Note 6). Our investments in equity securities had an aggregate fair value of $58.9 million as of December 31, 2023, which included an investment in LianBio with a fair value of $22.4 million.

Total realized and unrealized gains and losses associated with investment in equity securities for the periods presented consisted of the following:

	Year Ended December 31,		
	2024	2023	2022
	(in thousands)		
Net realized gains recognized on investments in equity securities sold	$ 8,136	$ 8,668	$ 3,731
Net unrealized gains (losses) recognized on investments in equity securities held as of the end of the period	—	9,646	(11,953)
Total net gains (losses) included in "Other income (expense), net"	$ 8,136	$ 18,314	$ (8,222)

LianBio Warrant

As of December 31, 2023 our subsidiary, QED Therapeutics, Inc. ("QED") held a warrant which entitles QED to purchase shares of LianBio (the "LianBio Warrant"), refer to Note 6. We had classified the LianBio Warrant, which pertained to an equity security of a publicly held company, within Level 1 as the fair value of this equity security was derived from observable inputs such as quoted prices in an active market. In February 2024, we fully exercised the LianBio Warrant and purchased 347,569 shares of LianBio common stock for an immaterial amount.

Notes

The fair value of our 2029 Notes and our 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. As of December 31, 2024, the estimated fair value of our 2029 Notes and 2027 Notes, which have

aggregate face values of $747.5 million and $550.0 million, respectively, were $640.7 million and $578.1 million, respectively, based on their market prices on the last trading day for the period. As of December 31, 2023, the estimated fair value of our 2029 Notes and 2027 Notes, which have aggregate face values of $747.5 million and $550.0 million, respectively, were $638.7 million and $695.8 million, respectively, based on their market prices on the last trading day for the period.

Term Loan

The fair value of our outstanding term loan as of December 31, 2024 and 2023 (refer to Note 9) is estimated using the net present value of the payments, discounted at an interest rate that is consistent with a market interest rate, which is a Level 2 input. The estimated fair value of our outstanding term loan (as defined in Note 9) as of December 31, 2024 was $461.8 million and under the Loan Agreement (as defined in Note 9) as of December 31, 2023 was $389.1 million, respectively.

Deferred royalty obligation and embedded derivative liability

The embedded derivative liability associated with our deferred royalty obligation, as 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 obligation 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 interest expense. 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 sales of Attruby, (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, net of the bifurcated embedded derivative liability had an estimated fair value of $446.0 million as of December 31, 2024. During the period from November 22, 2024 through December 31, 2024, we recognized $1.6 million as a reduction to interest expense as the change in fair value for the embedded derivative liability as of December 31, 2024.

4. Cash Equivalents

We invest in certain U.S. government money market funds, treasury bills and commercial paper classified as cash equivalents.

Cash equivalents consisted of the following:

	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

	December 31, 2023			
	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Estimated Fair Value
	(in thousands)			
Cash equivalents:				
Money market funds	$ 13,530	$ —	$ —	$ 13,530
Treasury bills	256,036	31	—	256,067
Total cash equivalents	$ 269,566	$ 31	$ —	$ 269,597

5. Noncontrolling Interests

As of December 31, 2024 and 2023, 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" in 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. For the years ended December 31, 2024, 2023 and 2022, such adjustments in the aggregate amounts of $(5.8) million, $(10.5) million and $(3.5) million, respectively, are recorded to "Additional paid-in capital". All such adjustments are disclosed within the "Transfers from (to) noncontrolling interests" line item in the consolidated statements of redeemable convertible noncontrolling interests and stockholders' equity (deficit).

6. Equity Method Investments and Other Equity Investments

GondolaBio

Since inception through August 16, 2024, Portal Therapeutics, Inc. and Sub21, Inc. were majority-owned consolidated subsidiaries of the Company. On August 16, 2024, the Company contributed its equity ownership in these entities to GondolaBio, LLC and as a result, Portal Therapeutics, Inc. and Sub21, Inc. were deconsolidated in conjunction with the GondolaBio transaction 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 have committed $300.0 million of tranched financing to GondolaBio, of which $60.0 million had been contributed as of December 31, 2024. The related party investors contributed cash in an aggregate of $42.5 million to GondolaBio as of December 31, 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.

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 gain from deconsolidation of approximately $52.0 million which is presented as part of "Other income (expense), net" on the consolidated statements of operations for the year ended December 31, 2024.

Upon the deconsolidation of GondolaBio, BridgeBio accounted for its investment in GondolaBio, for which it has significant influence through its ownership interest, using the equity method of accounting under *ASC 323 Investments — Equity Method and Joint Ventures*. 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 ("IPR&D asset"). The basis difference is amortized as a component of net loss from equity method investment over

the useful life of the IPR&D asset. The amortization of the IPR&D asset for the period from August 16, 2024 through December 31, 2024 was $0.4 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, 2024, the aggregate carrying amount of the Company's equity method investment in GondolaBio is $41.5 million and is presented as part of "Investment in nonconsolidated entities" on the consolidated balance sheets.

In addition, on August 16, 2024, the Company and GondolaBio entered into a 24-month transition service agreement (the "GondolaBio Transition Service Agreement") for the provision of certain transitionary consulting services to be provided by the Company and GondolaBio. In October 2024, the Company and GondolaBio entered into a one-year agreement for a partial sublease of a facility ("sublease agreement"). Under the GondolaBio Transition Service Agreement and sublease agreement, the Company recognized $1.3 million in other income and $0.8 million of pass-through costs and sublease income recorded as an offset against operating expenses for the year ended December 31, 2024. As of December 31, 2024, the Company recognized $3.2 million in "Prepaid expenses and other current assets" for transitionary consulting services provided by BridgeBio to GondolaBio and for sublease income. The Company also recognized $0.7 million in "Research and development" expenses during the year ended December 31, 2024. As of December 31, 2024, the Company also recognized $1.2 million in "Accrued professional and other liabilities" for transitionary consulting services provided by GondolaBio to BridgeBio.

TheRas

On April 30, 2024, TheRas, Inc., doing business as BridgeBio Oncology Therapeutics ("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 BBOT's equity was reduced to approximately 37.9%.

As part of the private equity financing transaction, 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, BBOT was deemed a VIE. As a result of the change in governance structure and composition of the board of directors, BridgeBio is no longer the primary beneficiary of BBOT, as it no longer has the power over key decisions that significantly impact BBOT's economic performance. Accordingly, BridgeBio deconsolidated BBOT on April 30, 2024. On April 30, 2024, we recognized a $126.3 million gain from deconsolidation of a subsidiary, which is presented on the consolidated statements of operations for the year ended December 31, 2024. The gain on deconsolidation represents the difference between BridgeBio's equity investment in BBOT, valued at $124.9 million upon deconsolidation and the carrying value of the net assets held by BBOT on April 30, 2024.

Upon the deconsolidation of BBOT, BridgeBio accounted for its retained investment in BBOT, for which it has significant influence through its ownership interest, using the equity method of accounting under *ASC 323 Investments — Equity Method and Joint Ventures*. BBOT was also deemed a related party. BridgeBio's equity investment in BBOT, valued at $124.9 million upon deconsolidation, was compared to BridgeBio's percentage of underlying equity in net assets of 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 BBOT (referred to as a "basis difference"). The basis difference was attributed to BBOT's in-process research and development ("IPR&D asset"), and is amortized as a component of net loss from equity method investment over the estimated useful life of the IPR&D asset. The amortization of the IPR&D asset for the period from May 1, 2024 through December 31, 2024 was $1.7 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, 2024, the aggregate carrying amount of our equity method investment in BBOT is $102.2 million and is presented as part of "Investment in nonconsolidated entities" on our consolidated balance sheets.

In addition, on April 30, 2024, the Company and BBOT entered into an 18-month transition service agreement (the "BBOT Transition Service Agreement") for the provision of certain transitionary consulting services to be provided by the Company and BBOT. Under the BBOT Transition Service Agreement, the Company recognized $2.1 million in other income and $0.7 million in pass-through costs recorded as an offset against operating expenses for the year ended December 31, 2024. As of December 31, 2024, the Company recognized $0.5 million in "Prepaid expenses and other current assets" for transitionary consulting services provided by BridgeBio to BBOT. The Company also recognized $0.8 million in "Research and development" expenses during the year ended December 31, 2024. As of December 31, 2024, the Company recognized $0.1 million in "Accrued research and development liabilities" for transitionary consulting services provided by BBOT to BridgeBio.

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 account for BBP LLC's equity interest in LianBio under ASC 321 Investments - Equity Securities as an investment in equity securities.

For the years ended December 31, 2024, 2023 and 2022, we recorded unrealized gains of nil, $14.2 million and an unrealized loss of $22.6 million, respectively, for the ongoing mark-to-market adjustments of our investment, refer to Note 3.

Pursuant to a License Agreement entered into in October 2019 between QED and LianBio (the "QED-LianBio License Agreement", refer to Note 11), 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. Changes in fair value of the warrants were not material for the years ended December 31, 2024, 2023 and 2022.

In October 2021, the warrants held by QED to purchase shares of one of the subsidiaries of LianBio were converted into 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." 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 depositary fees of $0.05 per share held and applicable taxes. On February 20, 2024, QED exercised the 347,569 shares of LianBio warrants it held for an immaterial amount. As of February 22, 2024, the Company held 5,350,361 shares of LianBio common stock. In March 2024, we received net proceeds of $25.7 million as special cash dividends and recognized net realized gains of $1.8 million from our investment in LianBio equity securities.

PellePharm

As of April 15, 2021, BridgeBio had been the primary beneficiary of PellePharm as it had power over key decisions that significantly impact PellePharm's economic performance. BridgeBio also had the obligation to absorb losses or the right to receive benefits from PellePharm that could potentially be significant to PellePharm through its common and preferred stock interest in PellePharm. Accordingly, BridgeBio had consolidated PellePharm during the period April 15, 2021 through December 31, 2022.

On January 16, 2023, PellePharm's board of directors authorized the assignment of all PellePharm's assets to PellePharm ABC, LLC for liquidation and distribution under the General Assignment for the Benefit of Creditors ("ABC").

As part of the ABC proceedings, PellePharm's board of directors resigned effective March 6, 2023. The date the board of directors resigned was determined to be a VIE reconsideration event. Based on the changes to PellePharm's governance structure and composition of the board of directors as a result of the ABC, BridgeBio was no longer the primary beneficiary, as it no longer had the power over key decisions that significantly impact PellePharm's economic performance. Accordingly, during the three months ended March 31, 2023, BridgeBio deconsolidated PellePharm and recognized a loss of $1.2 million which is presented as part of "Other expense, net" on the consolidated statements of operations.

7. Intangible Assets, net

The following table summarizes our recognized intangible assets for the years ended December 31, 2024 and 2023 as a result of the arrangements described in the following sections:

	December 31, 2024		December 31, 2023	
	Weighted-average Estimated Useful Lives	Amount	Weighted-average Estimated Useful Lives	Amount
		(in thousands)		(in thousands)
Gross amount	10.0 years	$ 32,500	11.0 years	$ 32,500
Less: accumulated amortization		(8,574)		(6,181)
Total		$ 23,926		$ 26,319

Amortization expense recorded as part of "Cost of revenue" for the years ended December 31, 2024, 2023 and 2022 was $2.4 million, $2.4 million and $2.4 million, respectively. Future amortization expense is $2.4 million for each of the years from 2025 to 2028 and $14.3 million thereafter.

Novartis License Agreement

In January 2018, QED entered into a License Agreement with Novartis International Pharmaceutical, Inc. or Novartis, pursuant to which QED acquired certain intellectual property rights, including patents and know-how, related to infigratinib for the treatment of patients with fibroblast-growth factor receptor ("FGFR") driven diseases. QED accounted for the transaction as an asset acquisition as substantially all of the estimated fair value of the gross assets acquired was concentrated in a single identified asset, in-process research and development ("IPR&D"), thus satisfying the requirements of the screen test in ASU 2017-01, *Business Combinations (Topic 805), Clarifying the Definition of a Business*. The assets acquired and liabilities assumed in the transaction were measured based on their fair values. The fair value of the IPR&D acquired was charged to research and development expense as it had no alternative future use at the time of the acquisition.

If certain substantial milestones are met, QED could be required to pay up to $60.0 million in regulatory milestone payments, $35.0 million in sales-based milestone payments, and pay royalties of up to low double-digit percentages on net sales. Following the FDA approval of TRUSELTIQ™ in May 2021, we paid a one-time regulatory milestone payment to Novartis of $20.0 million. We capitalized such payment as a finite-lived intangible asset and amortize the amount over its estimated useful life on a straight-line basis. All clinical investigations under the associated Investigational New Drug application ("IND") were discontinued as of March 2023 and a request to withdraw the NDA for TRUSELTIQ™ was submitted in May 2023, due to difficulty enrolling study patients for the required confirmatory trial. Accordingly, the FDA announced the withdrawal of the approval of TRUSELTIQ™ in May 2023. The intellectual property rights, patents and know-how related to infigratinib are being applied to other clinical investigations for FGFR-driven diseases.

Asset Purchase Agreement with Alexion

In June 2018, our subsidiary Origin Biosciences, Inc. ("Origin"), entered into an Asset Purchase Agreement with Alexion Pharma Holding Unlimited Company ("Alexion"), to acquire intellectual property rights, including patent rights, know-how, and contracts, related to the ALXN1101 molecule. Origin accounted for the transaction as an asset acquisition as substantially all of the estimated fair value of the gross assets acquired was concentrated in a single identified asset ("IPR&D"), thus satisfying the requirements of the screen test in ASU 2017-01. The assets acquired and liabilities assumed in the transaction were measured based on their fair values. The fair value of the IPR&D acquired was charged to research and development expense as it had no alternative future use at the time of the acquisition.

Pursuant to the Asset Purchase Agreement, Origin was required to pay $15.0 million upon the satisfaction of a certain condition, which was met in 2021. We capitalized the amount as a finite-lived intangible asset and amortize it over its estimated useful life on a straight-line basis. In addition, under the Asset Purchase Agreement, Origin

could be required to pay up to $17.0 million in sales-based milestone payments and royalties of up to low double-digit percentages on net sales.

In connection with the Asset Purchase Agreement entered between Origin and Sentynl Therapeutics, Inc. ("Sentynl"), in March 2022 (the "Origin-Sentynl APA", refer to Note 12), Sentynl assumed the obligation to pay sales-based milestone payments and royalties to Alexion that occur subsequent to the closing of the Origin-Sentynl APA when they become due. Origin will continue to be responsible for a regulatory-based milestone payment upon first pricing approval in a European Medicines Agency country of up to $1.0 million when it becomes due. As a result of the Origin-Sentynl APA, we also derecognized the associated intangible asset with a net book value of $13.5 million as this was part of the assets that were transferred to Sentynl.

Diagnostics Agreement with Foundation Medicine

In November 2018, QED and Foundation Medicine, Inc. ("FMI"), entered into a companion diagnostics agreement relating to QED's drug discovery and development initiatives. Pursuant to the agreement, QED could be required to pay $12.5 million in regulatory approval milestones over a period of four years subsequent to the FDA approval of a companion diagnostic for TRUSELTIQ™ in patients with cholangiocarcinoma. The FDA approved the companion diagnostic for TRUSELTIQ™ in May 2021, which resulted in the capitalization of $12.5 million as a finite-lived intangible asset to be amortized over its estimated useful life on a straight-line basis. While the FDA announced the withdrawal of the approval for TRUSELTIQ™ in May 2023, the FMI companion diagnostics agreement drug discovery and development initiatives are being applied to other clinical investigations. In March 2024, QED and FMI entered into a settlement agreement for QED to pay the remaining $9.6 million payable over 12 equal monthly installments of $0.8 million beginning in March 2024. As of December 31, 2024, the amount due to FMI is presented in our consolidated balance sheets in "Accrued professional and other accrued liabilities" for $1.6 million. As of December 31, 2023, the amount due to FMI is presented in our consolidated balance sheets in "Accrued professional and other accrued liabilities" for $6.0 million and "Other long-term liabilities" for $5.0 million.

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 16). 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 restricted stock awards ("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, 2024.

Settlement Type	Potential Fixed Monetary Amount	Accrued Amount [1]
	(in thousands)	
Cash	$ 906	$ 73
Stock [2]	16,850	2,057
Cash or stock at our sole discretion	53,432	3,609
Total	$ 71,188	$ 5,739

(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 16.

Other Research and Development and Commercial Agreements

We may also enter into contracts in the normal course of business with contract research organizations for services related to clinical trials, with contract manufacturing organizations for clinical supplies, and with other vendors for preclinical studies, supplies, and other services and products for commercial and operating purposes. These contracts generally provide for termination on notice with potential termination charges. As of December 31, 2024 and 2023, there were no material amounts accrued related to termination charges.

We have entered into a commercial supply agreement to purchase active pharmaceutical ingredient ("API"), bulk drug product and packaging, for which we have a minimum purchase commitment of $32.9 million as of December 31, 2024. In addition, we have entered into agreements to support our commercial launch of Attruby for which we have a minimum commitment in aggregate of $1.0 million as of December 31, 2024.

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 in 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. As of December 31, 2024 and 2023, we did not have any material indemnification claims that were probable or reasonably possible, and consequently have not accrued any material liabilities in the consolidated financial statements as a result of these provisions.

Contingencies

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

9. Debt

Notes

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 of 1933, as amended (the "Securities Act"). The 2029 Notes issued in the 2021 Note Offering include $67.5 million aggregate principal amount of 2029 Notes sold to the initial purchasers (the "2029 Notes Initial Purchasers"), pursuant to the exercise in part of the 2029 Notes Initial Purchasers' option to purchase $97.5 million principal amount of additional 2029 Notes. On January 28, 2021, the 2029 Notes Initial Purchasers exercised the remaining portion of their option to purchase $30.0 million principal amount of additional 2029 Notes. The sale of those additional 2029 Notes closed on February 2, 2021, which resulted in the total aggregate principal amount of $747.5 million.

The 2029 Notes are senior, unsecured obligations of BridgeBio and will accrue interest payable semiannually in arrears on February 1 and August 1 of each year, beginning on August 1, 2021, at a rate of 2.25% per year. The 2029 Notes will mature on February 1, 2029, unless earlier converted, redeemed or repurchased. The 2029 Notes are

convertible into cash, shares of BridgeBio's common stock, or a combination of cash and shares of BridgeBio's common stock, at our election.

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

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

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

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

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

The conversion rate is subject to adjustment in some events but will not be adjusted for any accrued and unpaid interest. In addition, following certain corporate events that occur prior to the maturity date or if we deliver a notice of redemption, we will, in certain circumstances, increase the conversion rate for a holder who elects to convert its 2029 Notes in connection with such a corporate event. The maximum 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 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 or approximately their eight-year term.

2027 Notes, net

On March 9, 2020, we issued an aggregate principal amount of $550.0 million of our 2.50% Convertible Senior Notes due 2027 (the "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 Indenture) per $1,000 principal amount of 2027 Notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price of BridgeBio's common stock and the conversion rate on each such trading day; or,
- Upon the occurrence of specified corporate events, as defined in the 2027 Notes Indenture.

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). Based on the closing price of our common stock on December 31, 2024, the if-converted value of the 2027 Notes did not exceed its principal amount.

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 accounting for the issuance of the 2027 Notes in 2020 under ASC 470-20, *Debt: Debt with Conversion and Other Options*, we separately accounted for the liability and equity components of the 2027 Notes by allocating the proceeds between the liability component and the embedded conversion options, or equity component, due to our ability to settle the 2027 Notes in cash, BridgeBio's common stock, or a combination of cash and BridgeBio's common stock at our option. Effective January 1, 2021, we early adopted ASU 2020-06, *Debt – Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity* ("ASU 2020-06"), and, as a result, we no longer separately account for the liability and equity components of the 2027 Notes, and, instead, account for our 2027 Notes wholly as debt.

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. We allocated these costs to the liability and equity components based on the allocation of the proceeds. The portion of these costs allocated to the equity component totaling approximately $4.1 million was recorded as a reduction to additional paid-in capital in 2020. The portion of these costs allocated to the liability component totaling approximately $8.9 million 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 or approximately their seven-year term.

Additional Information Related to the Notes

The outstanding Notes' balances consisted of the following:

	December 31, 2024		December 31, 2023	
	2029 Notes	2027 Notes	2029 Notes	2027 Notes
	(in thousands)		(in thousands)	
Principal	$ 747,500	$ 550,000	$ 747,500	$ 550,000
Unamortized debt discount and issuance costs	(8,628)	(4,827)	(10,595)	(6,621)
Net carrying amount	$ 738,872	$ 545,173	$ 736,905	$ 543,379

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

	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	$ 18,786	$ 15,544	$ 34,330
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	$ 18,736	$ 15,495	$ 34,231
Effective interest rate	2.6%	2.8%	

	Year Ended December 31, 2022		
	2029 Notes	2027 Notes	Total
		(in thousands)	
Contractual interest expense	$ 16,819	$ 13,750	$ 30,569
Amortization of debt discount and issuance costs	1,869	1,699	3,568
Total interest and amortization expense	$ 18,688	$ 15,449	$ 34,137
Effective interest rate	2.6%	2.8%	

As of December 31, 2024, interest payable on the 2029 and 2027 Notes amounted to $7.0 million and $4.0 million, respectively. As of December 31, 2023, interest payable on the 2029 and 2027 Notes amounted to $7.0 million and $4.0 million, respectively. Such amounts are included in "Accrued professional and other accrued liabilities" in our consolidated balance sheets.

Future minimum payments under the Notes as of December 31, 2024, are as follows:

	2029 Notes	2027 Notes	Total
		(in thousands)	
Year ending December 31:			
2025	16,819	13,750	30,569
2026	16,819	13,750	30,569
2027	16,819	556,875	573,694
2028	16,819	—	16,819
2029	755,909	—	755,909
Total future payments	823,185	584,375	1,407,560
Less amounts representing interest	(75,685)	(34,375)	(110,060)
Total principal amount	$ 747,500	$ 550,000	$ 1,297,500

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, *Derivatives and Hedging,* to be classified in stockholders' equity and are not subsequently remeasured as long as the conditions for equity classification continue to be met. We recorded a reduction to additional paid-in capital of approximately $61.3 million and $49.3 million for the years ended December 31, 2021 and 2020, respectively, 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 ("Nasdaq"), on January 25, 2021 and March 4, 2020, respectively. The shares repurchased were recorded as "Treasury stock".

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), the "Amended Loan Agreement"), by and among (i) U.S. Bank National Association, in its capacity as administrative agent (in such capacity, the "Administrative Agent") and collateral agent (in such capacity, the "Collateral Agent"), (ii) certain lenders (the "Lenders"), (iii) BridgeBio, as a borrower, and (iv) certain subsidiaries of BridgeBio, as guarantors (the "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"), as further described below. On January 17, 2024, the Company fully repaid the term loan under the Amended Loan Agreement, as further described below.

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, comprised 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, 2022, which was available at our election after the occurrence of certain milestone events relating to data from our clinical trials. The terms related to the Tranche 2 Advance were modified in the First Amendment and Second Amendment as further discussed below. 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 is $450.0 million before any mandatory prepayment.

As security for our obligations under the Loan Agreement, each of BridgeBio and the Guarantors granted the Collateral Agent, for the benefit of the Lenders, a continuing security interest in substantially all of the assets of BridgeBio and the Guarantors (including all equity interests owned or hereafter acquired by BridgeBio and the Guarantors), subject to certain customary exceptions. Upon exceeding certain investment and disposition thresholds, additional subsidiaries of BridgeBio will be required to join as guarantors.

Any outstanding principal on the Term Loan Advances will accrue interest at a fixed rate equal to 9.0% per annum. 3.0% of which can be a payment-in-kind ("PIK") until January 1, 2025. Interest payments are payable quarterly following the funding of a Term Loan Advance. We would be required to make principal payments on the outstanding balance of the Term Loan Advances commencing on January 2, 2025 (the "Term Loan Amortization Date") in nine quarterly installments, plus interest. If we have achieved certain milestone events relating to data from the clinical trial of acoramidis (the "Acoramidis Milestone") on or prior to January 1, 2025, then the Term Loan Amortization Date would be automatically extended to January 2, 2026. Any amounts outstanding under the Term Loan Advances are due and payable on November 17, 2026 (the "Maturity Date").

We may prepay the outstanding principal amount of the Term Loan Advances at any time (in whole, but not in part), plus accrued and unpaid interest and a prepayment premium ranging from 1.0% to 3.0% of the principal amount outstanding depending on the timing of payment (plus a customary make-whole amount if prepaid on or prior to November 17, 2022).

At the Lenders' election, we were also required to make mandatory prepayments upon the occurrence of certain prepayment events related to the repurchase or redemption of pledged collateral, entry into certain royalty transactions, disposition of other assets or subsidiaries, and entry into licensing and other monetization transactions (all such events are referred to as prepayment events), which could be 50.0% or 75.0% of net cash proceeds from such transaction depending on achievement of the Acoramidis Milestone.

Subject to the mandatory prepayment requirements for certain prepayment events, the Loan Agreement contains customary affirmative and limited negative covenants which, among other things, limit our ability to (i) incur additional indebtedness, (ii) pay dividends or make certain distributions, (iii) dispose of our assets, grant liens, license or encumber our assets or (iv) fundamentally alter the nature of our business. BridgeBio and the Guarantors have broad ability to license our intellectual property, dispose of other assets and enter into monetization and royalty transactions, subject in each case to the requirement to make a mandatory prepayment described above. The Loan Agreement provides that BridgeBio and the Guarantors may, subject to certain limitations, (x) repurchase BridgeBio's equity interest and the equity interest of any of its subsidiaries, (y) enter into any joint ventures or similar investments, and (z) make other investments and acquisitions. Subject to the mandatory prepayment requirement described above, portfolio companies owned by BridgeBio that are not parties to the Loan Agreement are, subject to certain exceptions, not subject to any covenants or limitations under the Loan Agreement.

The Loan Agreement also contains customary events of default, including among other things, our failure to make any principal or interest payments when due, the occurrence of certain bankruptcy or insolvency events or the breach of the covenants under the Loan Agreement. Upon the occurrence of an event of default, the Lenders may, among other things, accelerate our obligations under the Loan Agreement.

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 of debt issuance costs were incurred for professional services provided by KKR Capital Markets LLC. KKR Capital Markets LLC is an affiliate of KKR Genetic Disorder L.P., a related party being a principal stockholder of BridgeBio.

In May 2022, we entered into the First Amendment, which, among other things:

- permitted the sale of our priority review voucher ("PRV", refer to Note 12) and, generally, future dispositions of other PRVs;
- reduced the aggregate amount of the Tranche 2 Advance from $300.0 million to $100.0 million and modified certain conditions to the availability thereof, as mentioned above;
- amended the principal payments such that the entire outstanding principal balance of the Term Loan Advances is due and payable at the Maturity Date or upon early termination; and
- modified the terms and conditions governing when certain entities into which we have made investments will be required to become guarantors under the Amended Loan Agreement.

In June 2022, the receipt of an upfront payment under the license development and commercialization agreement that our subsidiary, Navire Pharma, Inc. ("Navire"), entered into with Bristol-Myers Squibb Company ("BMS"), which is further described in Note 11, triggered certain mandatory prepayment provisions of the Amended Loan Agreement. As a result, we paid $20.5 million to the Lenders in June 2022, of which $20.1 million and $0.4 million were applied to principal and exit fee, respectively.

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 and $15.3 million for the years ended December 31, 2023 and 2022, respectively.

In November 2022, we entered into the Second Amendment, which, among other things:

- acknowledged that our prior prepayment made with certain cash proceeds received in connection the receipt of an upfront payment under the Navire-BMS License Agreement, which is further described in

Note 11, satisfied the mandatory prepayment requirement under the Amended Loan Agreement, on the terms and conditions specified in the Amended Loan Agreement;

- permitted certain budgeted expenses to be excluded from the definition of cash proceeds subject to the Company's mandatory prepayment obligations, on the terms and conditions specified in the Amended Loan Agreement, refer to Note 2 under Restricted Cash section for further discussion.
- removed certain threshold amounts applicable to certain prepayment events; and
- terminated the Lenders' $100.0 million Tranche 2 Advance.

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

	December 31, 2023 (in thousands)
Principal value of term loan	$ 429,916
PIK added to principal	25,531
Debt discount, issuance costs and exit fee accretion	(9,002)
Term loan, net	$ 446,445

For the year ended December 31, 2024, we recognized interest expense related to the Loan Agreement of $3.0 million, of which $0.4 million, relates to amortization of debt discount and issuance costs. For the year ended December 31, 2023, we recognized interest expense related to the Loan Agreement of $46.3 million, of which $5.2 million, relates to amortization of debt discount and issuance costs. For the year ended December 31, 2022, we recognized interest expense related to the Loan Agreement of $46.1 million, of which $5.0 million, relates to amortization of debt discount and issuance costs. As of December 31, 2023, interest payable included in "Accrued professional and other accrued liabilities" in our consolidated balance sheets amounted to $6.7 million.

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 and cash on hand, and recognized a loss on extinguishment of debt of $26.6 million.

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").

Pursuant to the terms and conditions of the Financing Agreement, the Lenders have agreed to extend a senior secured credit facility to the Company 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 Financing Agreement. The Initial Term Loan was funded on January 17, 2024. Incremental Term Loans are available at the Company's and the Lenders' mutual consent from time to time after January 17, 2024.

The obligations of the Company under the Financing Agreement are and will be guaranteed by certain of the Company's existing and future direct and indirect subsidiaries, subject to certain exceptions (such subsidiaries, collectively, the "Guarantors"). As security for the obligations of the Company and the Guarantors, each of the Company and the Guarantors are required to grant to the Administrative Agent, for the benefit of the Lenders and secured parties, a continuing first priority security interest in substantially all of the assets of the Company and the Guarantors (including all equity interests owned or hereafter acquired by the Company and the Guarantors), subject to certain customary exceptions.

Any outstanding principal on the Term Loans will initially bear interest at a rate per annum equal to (A) in the case of Term Loans bearing interest based on the base rate defined in the Financing Agreement (and which base rate will not be less than 2.00%), the sum of (i) the base rate plus (ii) 5.75% and (B) in the case of Term Loans

bearing interest based on the three-month forward-looking term secured overnight financing rate administered by the Federal Reserve Bank of New York ("Term SOFR"), the sum of (i) three-month Term SOFR (subject to 1.00% per annum floor), plus (ii) 6.75%. Accrued interest is payable quarterly following the funding of the Initial Term Loan on the Closing Date, on any date of prepayment or repayment of the Term Loans and at maturity.

The Company will be required to make principal payments of $22.5 million on the outstanding balance of the Initial Term Loan commencing on June 30, 2027 in quarterly installments (the "Scheduled Amortization Payments"); provided that if the Company achieves a senior total net leverage ratio of less than or equal to 5.00:1.00, up to four (4) Scheduled Amortization Payments may be deferred for a period of one fiscal quarter each. Such Scheduled Amortization Payments would be reduced in connection with voluntary or mandatory prepayments, if any, of the Initial Term Loans. Incremental Term Loans, if any, will be payable in accordance with their respective amortization schedules. Additionally, if the Company's market capitalization is less than $1.5 billion at any time after January 17, 2024, the Company shall also be required to make additional quarterly principal payments of $10.0 million on the outstanding balance of the Initial Term Loan (the "Special Amortization Payments") commencing with the first quarterly installment payment date occurring thereafter. The outstanding balance of the Term Loans, if not repaid sooner, shall be due and payable in full on the maturity date thereof. The stated maturity date of the Term Loans is January 17, 2029, with two springing earlier maturity dates at 91 days prior to the stated maturity dates of the Company's outstanding convertible senior notes, in each case to the extent there is an aggregate outstanding amount of such notes of more than $50.0 million on such dates.

The Company may prepay the Term Loans at any time (in whole or in part) or be required to make mandatory prepayments upon the occurrence of certain customary prepayment events. The mandatory prepayment events include certain permitted asset sales transactions (which include certain sales, leases, assignments, conveyances, transfers, licenses or exchanges of property) that occur prior to the date the FDA approves a first NDA for acoramidis, which would require the Company to deposit 75% of net cash received from such transactions into an escrow account controlled by the Administrative Agent, and the Company may also be subject to a specified disposition fee per transaction for certain asset sale transactions. In certain instances and during certain time periods, prepayments will be subject to customary prepayment fees. The amount of any prepayment fee may vary, but the maximum amount that may be due with any such prepayment would be an amount equal to 3.00% of the Term Loans being prepaid at such time, plus a customary make whole amount.

We have entered into asset sales transactions that occurred during the three months ended March 31, 2024 for the exclusive license agreements with Bayer Consumer Care AG and Kyowa Kirin Co., Ltd, for which the Company is required to deposit 75% of the proceeds, net of certain permitted costs, upon receipt of the upfront payments from Bayer Consumer Care AG and Kyowa Kirin Co., Ltd, into the escrow accounts. During the three months ended June 30, 2024, we received $235.0 million in aggregate from Bayer Consumer Care AG and Kyowa Kirin Co., Ltd, and deposited net proceeds of $159.3 million into the escrow accounts. Refer to Note 11 for further details regarding the exclusive license agreements with Bayer Consumer Care AG and Kyowa Kirin Co., Ltd.

The completion of the $200.0 million private equity financing with external investors of BBOT was considered an asset sale transaction that was subject to a disposition fee under the Financing Agreement. Accordingly, we paid a disposition fee of $1.1 million to the Administrative Agent in May 2024. Refer to Note 6 for further details regarding the BBOT private equity financing transaction.

The Financing Agreement contains affirmative covenants and negative covenants applicable to the Company and its subsidiaries that are customary for financings of this type. Such covenants, among other items, limit the Company's and its subsidiaries' ability to (i) incur additional permitted indebtedness, (ii) pay dividends or make certain distributions, (iii) dispose of its and their assets, grant liens and license or permit other encumbrances on its and their assets, (iv) fundamentally alter the nature of their businesses and (v) enter into certain transactions with affiliates. The Company and the Guarantors are also required to maintain a minimum qualified cash balance of $70.0 million, at all times. The Company and its subsidiaries are permitted to license their intellectual property, dispose of other assets and enter into monetization and royalty transactions, in each case, subject to satisfaction of certain terms and conditions. The Financing Agreement also includes representations, warranties, indemnities and events of default that are customary for financings of this type, including an event of default relating to a change of control of the Company. Upon the occurrence of an event of default, the Lenders may, among other things, accelerate the Company's obligations under the Financing Agreement.

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"). Under the Amended Financing Agreement, between June 20, 2024 and through the earlier of the date the FDA approves a first NDA for acoramidis and November 30, 2024, the Company was able to request a release of funds in an aggregate amount not to exceed 50% of the original net cash proceeds received from asset sale transactions. In June 2024, $20.0 million was released from the escrow accounts and classified as cash on the consolidated balance sheet. Furthermore, under the Amended Financing Agreement, the minimum qualified cash balance was amended from $70.0 million to $70.0 million plus 40% of any cash released by the Company from the escrow accounts, at all times. As of December 31, 2024, the minimum unrestricted qualified cash balance was $78.0 million.

We received net proceeds from the Initial Term Loan of $434.0 million, after deducting debt discount and issuance costs of $16.0 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	$ 450,000
Debt discount, issuance costs and exit fee accretion	(12,663)
Term loan, net	$ 437,337

For the year ended December 31, 2024, we recognized interest expense related to the Amended Financing Agreement $54.8 million, of which $3.3 million, relates to amortization of debt discount and issuance costs. There was no interest payable under the Amended Financing Agreement as of December 31, 2024.

Future minimum payments under the Amended Financing Agreement as of December 31, 2024 are as follows:

	Amount (in thousands)
Year Ending December 31:	
2025	50,660
2026	50,660
2027	116,245
2028	129,155
2029	294,215
Total future payments	640,935
Less amounts representing interest	(190,935)
Total principal amount of term loan payments	$ 450,000

The amounts in the table above do not take into account any changes due to mandatory payments under the terms of the Amended Financing Agreement.

10. Funding Agreement

On January 17, 2024, the Company and its subsidiaries, Eidos Therapeutics, Inc., 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, the "Purchasers"), and Alter Domus (US) LLC, as the collateral agent.

Pursuant to the Funding Agreement, the Purchasers agreed to pay to the Company $500.0 million (net of certain transaction expenses) ("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, "Funding Date").

In return, the Company granted the Purchasers the right to receive payments (the "Royalty Interest Payments") equal to 5% of the global Net Sales of acoramidis ("Net Sales"). Each Royalty Interest Payment will become payable to the Purchasers on a quarterly basis after the Funding Date. In addition, the Seller Parties granted the collateral agent, for the benefit of the Purchasers, a security interest in specific assets related to acoramidis.

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 the event that a change in control (as customarily defined in the Funding Agreement) occurs on or after the effective date of the Funding Agreement and prior to FDA approval of acoramidis, either party may terminate the Funding Agreement and the Seller Parties shall make a one-time payment of $25.0 million (in the aggregate) to the Purchasers. 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. The Funding Agreement will 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 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 deferred royalty obligation 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 and the $25.0 million one-time payment, 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 2. The aggregate fair value of the embedded derivative liability was $41.1 million as of December 31, 2024. We will remeasure the embedded derivative to fair value each reporting period until the time the features lapse and/or termination of the deferred royalty obligation.

The carrying value balances of our royalty obligation under the Funding Agreement consisted of the following:

	December 31, 2024 (in thousands)
Carrying value of deferred royalty obligation (Principal)	$ 507,114
Fair value of embedded derivative	41,091
Debt discount and issuance costs accretion	(69,114)
Deferred royalty obligation, net	$ 479,091

The effective interest rate as of December 31, 2024 was 19.3%. For the year ended December 31, 2024, we recognized interest expense related to the Funding Agreement of $8.3 million, of which $1.0 million, relates to amortization of debt discount and issuance costs. As of December 31, 2024, we recognized royalty interest payable of $0.1 million in “Accrued professional and other accrued liabilities” in our consolidated balance sheets.

11. License and Collaboration Agreements

Bayer Exclusive License

On March 1, 2024, certain subsidiaries of the Company, including Eidos Therapeutics, Inc., 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

European Union 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, effective upon the date that certain antitrust clearances have been obtained, or 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 $75.0 million is for a regulatory milestone dependent upon European Commission approval of acoramidis on or before December 31, 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 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 comprised 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, 2024. 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. 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 $135.0 million based on the stand-alone selling prices ("SSP") of each of the performance obligations as follows:

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

The SSP for the license was determined using an approach that considered discounted, probability-weighted cash flows related to the license transferred. The SSP for the ongoing research and development services were based

on estimates of the associated effort and cost of these services, adjusted for a reasonable gross profit margin that would be expected to be realized under similar contracts.

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

- We recognize revenue related to the license at a point in time upon transfer of the rights and control of the license to Bayer. The transfer of the rights and control of the license occurred in March 2024, thus we recognized the full amount allocated to the license and related know-how during the three months ended March 31, 2024.
- We are recognizing 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 2028. We have recognized $1.0 million of revenue relating to this performance obligation during the year ended December 31, 2024.

As of December 31, 2024, there are no outstanding receivables from licensing and collaboration agreements relating to the Bayer License Agreement within our consolidated balance sheet. During the year ended December 31, 2024 we recognized revenue of $131.5 million under the Bayer License Agreement. 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 included in "Deferred revenue, net of current portion") related to our research and development services obligations.

In addition, under the terms of the Financing Agreement, the Bayer License Agreement represents an asset sale transaction that requires the Company to deposit 75% of proceeds, net of certain permitted costs, received from the transaction into an escrow account to be controlled by the Administrative Agent. In May 2024, we deposited $84.7 million into the escrow account from the receipt of the $135.0 million from Bayer, which was released and classified as cash upon the FDA approval of Attruby in November 2024. Refer to Note 9 for further details regarding the Financing Agreement.

In June 2024, BridgeBio Europe B.V. ("BridgeBio B.V.") entered into the Bayer 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 the use in the commercialization in the Licensed Territory under the Bayer License Agreement. Under the Bayer Supply Agreement, Bayer shall pay to BridgeBio B.V. a commercial product per unit price equal to the applicable fully burdened manufacturing cost per unit of product, which shall include the cost of the active pharmaceutical ingredient ("API") used to manufacture the product and the packaging price. As of December 31, 2024, there have been no commercial product supply sales to Bayer.

The condition for the $75.0 million regulatory-based milestone payment was achieved upon the EC approval of Beyonttra on February 10, 2025. The Company anticipates receiving this milestone payment from Bayer in April 2025.

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 partnership wherein 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 Agreement"). In exchange, QED received an upfront payment of $100.0 million in June 2024, and will be eligible to receive royalties up to the mid-twenties percent on sales of infigratinib in Japan, with the potential to receive up to $81.4 million in development and sales-based milestone payments.

Unless earlier terminated, the KKC 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 Agreement in the event of a material breach or insolvency of the other party. Additionally, Kyowa Kirin may terminate the KKC Agreement for convenience upon at least 180 days' prior written notice, and QED may terminate the KKC 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 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.

We determined the initial transaction price at inception of the KKC Agreement to be $100.0 million, which is comprised 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, 2024. 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 during the three months ended March 31, 2024.
- We are recognizing 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 2029. We have recognized $5.7 million of revenue relating to this performance obligation during the year ended December 31, 2024.

In May 2024, QED and KKC negotiated a letter of agreement to commence manufacturing while a clinical supply agreement was in negotiation. During this time, KKC agreed to reimburse QED the full cost incurred for manufacturing. For the year ended December 31, 2024, QED has been reimbursed $1.4 million in accordance with this letter of agreement, and such costs are included in revenue in our consolidated statement of operations.

Subsequently, on January 3, 2025, QED and KKC entered into a clinical supply agreement, for which QED will manufacture and supply to KKC the clinical quantities of the Licensed Product, for development, including any and all clinical and non-clinical studies necessary for the filing of a New Drug Application, in the Field in the Territory. KKC shall pay to QED a per unit price as defined in the clinical supply agreement.

As of December 31, 2024, the receivables from licensing and collaboration agreements relating to the KKC Agreement within our consolidated balance sheet were immaterial. During the year ended December 31, 2024, we recognized revenue of $76.2 million under the KKC Agreement. 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 included in "Deferred revenue, net of current portion") related to our research and development services obligation.

In addition, under the terms of the Financing Agreement, the KKC Agreement represents an asset sale transaction that requires the Company to deposit 75% of proceeds, net of certain permitted costs, received from the transaction into an escrow account to be controlled by the Administrative Agent. In June 2024, we deposited $74.6 million into the escrow account from the receipt of the $100.0 million from KKC, which was released and classified as cash upon the FDA approval of Attruby in November 2024. Refer to Note 9 for further details regarding the Financing Agreement.

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 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 ("PRC"), Macau, Hong Kong, Taiwan, Thailand, Singapore, and South Korea (collectively, the "Asia Region"). The development and commercialization of BBP-398 within the Asia Region is governed under the Navire-LianBio License Agreement (as discussed below). 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.

Under the terms of the Navire-BMS License Agreement, Navire was entitled to receive a non-refundable, upfront payment of $90.0 million, which Navire received in full in June 2022. Additionally, Navire was eligible to receive additional payments totaling up to approximately $815.0 million in the aggregate, subject to the achievement of development, regulatory and commercial milestones, as well as tiered royalties in the low-to-mid teens as a percentage of adjusted net sales by BMS of the licensed products sold worldwide, outside of the Asia Region. Based on the terms of the Navire-BMS License Agreement, Navire will continue to lead its ongoing Phase 1 monotherapy and combination therapy trials (collectively, the "Phase 1 Trials"), and BMS will lead and fund all other development and commercialization activities. Navire is fully funding the Phase 1 trials with the exception of the combination therapy governed under the 2021 Navire-BMS Agreement. In accordance with the 2021 Navire-BMS Agreement, both parties are sharing all research and development costs equally for this trial. We have recorded all research and development costs for the Phase 1 Trials, as well as the reimbursement for the costs associated with the trial governed by the 2021 Navire-BMS Agreement within "Research and development expenses" in our consolidated statement of operations.

In March 2024, we received written notice from BMS for the termination of the Navire-BMS License Agreement effective June 2024, and all rights and obligations thereunder. 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. As a result of the termination, Navire is no longer entitled to any future unearned development, regulatory or sales-based milestone and royalty payments. However, we may in the future be eligible to receive earned payments for any milestones already achieved prior to termination and for achieving any milestones while closing out the remaining services.

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

- an exclusive license to develop and commercialize BBP-398 and the related know-how; and

- research and development services to complete the Phase 1 Trials for BBP-398.

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 BMS without the research and development services. Similarly, those services provide a distinct benefit to BMS within the context of the contract, separate from the license, as the services could be provided by BMS or another third party without our assistance. We entered into a clinical supply agreement for supply of clinical quantities of the licensed product for the licensed territory with BMS in March 2023. Navire supplied insignificant amounts and $2.0 million of clinical supplies to BMS for the years ended December 31, 2024 and December 31, 2023, respectively.

We determined the initial transaction price at inception of the Navire-BMS License Agreement to be $90.0 million, which is comprised of the fixed and non-refundable upfront payment. No additional development, regulatory, 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, 2024. 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, BMS' 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 $90.0 million based on the SSP of each of the performance obligations as follows:

- $70.2 million for the upfront transfer of the license; and
- $19.8 million for research and development services to complete the Phase 1 Trials of BBP-398.

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 recognized revenue for each of the two performance obligations as follows:

- We recognized revenue related to the license at a point in time upon transfer of the rights and control of the license to BMS. The transfer of the rights and control of the license occurred in June 2022, thus we recognized the full amount allocated to the license and related know-how during the three months ended June 30, 2022.
- We were recognizing revenue related to the research and development services to complete the Phase 1 Trials for BBP-398 over time using an input method to measure progress by utilizing costs incurred to-date relative to total expected costs. As a result of the Navire-BMS License Agreement termination, the research and development services performance obligation is complete and there are no remaining performance obligations. As such, the remaining revenue allocated to this performance obligation was recognized during the three months ended March 31, 2024. Revenue recognized related to this performance obligation for the years ended December 31, 2024, 2023, and 2022 were $9.9 million, $5.4 million, and $4.5 million respectively.

For the years ended December 31, 2024, 2023, and 2022 we recognized $9.9 million, $7.4 million, and $74.7 million respectively of revenue from the Navire-BMS License Agreement. As of December 31, 2024, there were no remaining balances in deferred revenue within our consolidated balance sheets. Our consolidated balance sheet as of December 31, 2023 includes a deferred revenue balance of $9.9 million ($6.1 million presented as "Deferred revenue, current portion" and $3.8 million included in "Other long-term liabilities") related to our research and development services obligation.

License and Collaboration Agreement with Helsinn

On March 29, 2021, QED entered into a license and collaboration agreement with Helsinn Healthcare S.A. (“ HHC”) and Helsinn Therapeutics (U.S.), Inc. (“HTU”), and collectively with HHC, Helsinn, (the “QED-Helsinn License and Collaboration Agreement”), pursuant to which QED granted to HHC exclusive licenses to develop, manufacture and commercialize QED’s product candidate, infigratinib, in oncology and all other indications except achondroplasia or any other skeletal dysplasias, worldwide, except for the People’s Republic of China, Hong Kong and Macau (“Greater China”), and under which QED received a co-exclusive license to co-commercialize infigratinib in the United States in the licensed indications. The QED-Helsinn License and Collaboration Agreement became effective on April 16, 2021. Upon approval by the FDA in May 2021, QED and HTU co-commercialized infigratinib in the licensed indications in the United States and shared profits and losses on a 50:50 basis. Additionally, QED and Helsinn shared global, excluding Greater China, research and development costs for infigratinib in the licensed indications at a rate of 40% for QED and 60% for Helsinn.

On February 28, 2022, QED and Helsinn amended the QED-Helsinn License and Collaboration Agreement (the “Amended QED-Helsinn License and Collaboration Agreement”), effective on March 1, 2022. Under the terms of the Amended QED-Helsinn License and Collaboration Agreement, Helsinn had an exclusive license to commercialize infigratinib in the United States and was responsible for solely developing, manufacturing and commercializing infigratinib in oncology indications except for achondroplasia or any other skeletal dysplasias worldwide, outside of Greater China. QED retains all rights to develop, manufacture and commercialize infigratinib in skeletal dysplasia, including achondroplasia.

The Amended QED-Helsinn License and Collaboration Agreement also provided for a transitional period, which extended from the effective date through August 31, 2022, for which QED was contracted to assist in research and development and commercialization activities. The costs related to QED’s contracted activities incurred during the transitional period were fully reimbursable by Helsinn and were due to QED subsequent to the transitional period. Helsinn also agreed to reimburse QED’s obligation to FMI described in Note 7 as part of the Amended QED-Helsinn License and Collaboration Agreement. In recording this transaction, we recognized a corresponding gain as part of “Other income (expense), net” in our consolidated statement of operations for the year ended December 31, 2022.

Effective December 21, 2022, QED and Helsinn (the “Helsinn Parties”), entered into a Mutual Termination Agreement (“MTA”), which terminates the Amended QED-Helsinn License and Collaboration Agreement and all rights and obligations thereunder. The Helsinn Parties agreed to perform certain close-out services to enable QED to pursue the development, manufacture and commercialization of infigratinib as a potential treatment of non-oncology indications, such as in achondroplasia worldwide, excluding China, Hong Kong, and Macau. As a result of the termination, QED is no longer entitled to any future regulatory or sales-based milestone payments. QED was subject to royalties on net sales of TRUSELTIQ™ through March 31, 2023, at which date Helsinn no longer sold the licensed product. Helsinn permanently discontinued the distribution of TRUSELTIQ™ and the FDA announced the withdrawal of the NDA approval in May 2023, additionally, all clinical investigations under the associated IND are discontinued. Helsinn completed sales of the licensed product during the three months ended March 31, 2023, and the associated revenue recognized was immaterial. The Helsinn Parties developed a Close-Out Plan, as defined within the MTA. Activities within the Close-Out Plan are to be shared equally subsequent to the lower of the first $11.0 million of costs, or QED’s obligation to FMI, which are the responsibility of QED. QED reached the threshold of $11.0 million in January 2023. The activities within the Close-Out Plan were substantially completed in 2023.

Upon the effective date of the MTA, all outstanding obligations of $31.3 million ($18.8 million relating to contracted research and development and commercial activities and $12.5 million relating to the reimbursement of QED’s obligation to FMI) under the Amended QED-Helsinn License and Collaboration Agreement related to the contracted services during the transitional period became due, of which all payments have been paid in full. In March 2024, QED reduced its obligation in FMI to $9.6 million and therefore, pursuant to the MTA, QED’s responsibility for close-out activities was lowered to this amount and Helsinn’s reimbursement of QED’s obligation to FMI was reduced from $11.0 million to $9.6 million. For the year ended December 31, 2024, QED has incurred immaterial close-out costs, of which all were subject to 50% reimbursement from Helsinn. For the year ended December 31, 2023, QED incurred $7.2 million of close-out costs, of which $6.0 million were subject to 50% reimbursement from Helsinn. As of December 31, 2024 and December 31, 2023, the outstanding receivable due from Helsinn was nil and $0.6 million, respectively. The outstanding receivables were presented in “Accounts Receivable” within our consolidated balance sheets. All close-out costs incurred, including Helsinn’s

reimbursements, are recorded in "Restructuring, impairment and related charges" within our consolidated statement of operations (See Note 17).

The QED-Helsinn License and Collaboration Agreement, the Amended QED-Helsinn License Collaboration Agreement, and the MTA are considered to be within the scope of ASC 808 as the parties are active participants and are exposed to the significant risks and rewards of the collaborative activity. The QED-Helsinn License and Collaboration Agreement and the Amended QED-Helsinn License and Collaboration Agreement are also partially within the scope of ASC 606 for the units of account where Helsinn is identified as a customer. For the units of account in the collaboration arrangement that do not represent a vendor-customer relationship, including the performance of collaborative research and development and commercialization services, we determined that ASC 606 is not appropriate to apply by analogy and applied a reasonable and rational accounting policy election that faithfully depicts the transfer of services to the collaboration partner over the estimated performance period. Reimbursement payments from Helsinn associated with the collaborative research and development and commercialization services are recognized as the related expense is incurred and classified as an offset to the underlying expense and excluded from the transaction price.

We evaluated the terms of the QED-Helsinn License and Collaboration Agreement and identified Helsinn as a customer with the following two distinct performance obligations: (1) exclusive licenses to develop, manufacture, and commercialize the underlying product, and (2) transfer of inventory within the transitional supply period. The Amended QED-Helsinn License and Collaboration Agreement did not give rise to any additional performance obligations. All of the license revenue, $56.0 million, relating to these units of account accounted for under ASC 606 were recognized in the year ended December 31, 2021.

For the unit of account that is within the scope of ASC 808 relating to collaborative research and development services, pursuant to the QED-Helsinn License and Collaboration Agreement, the Amended QED-Helsinn License Collaboration Agreement, and the MTA, we have recognized an immaterial amount and $3.0 million of Helsinn's share of research and development expenses for the years ended December 31, 2024 and 2023, respectively, as a reduction to restructuring, impairment and related charges. We have recognized Helsinn's share of research and development expenses of $21.5 million for the year ended December 31, 2022 as a reduction of research and development expenses.

For the unit of account that is within the scope of ASC 808 relating to commercial activities, pursuant to the QED-Helsinn License and Collaboration Agreement, the Amended QED-Helsinn License Collaboration Agreement, and the MTA, we accounted for Helsinn's share of the co-commercialization activities as reduction to selling, general and administrative expenses. We did not incur any costs relating to commercialization activities subject to reimbursement from Helsinn for the years ended December 31, 2024 and 2023. We recognized Helsinn's share of the co-commercialization activities of $1.5 million for the year ended December 31, 2022.

License Agreements with LianBio

Navire

In August 2020, Navire entered into an exclusive license agreement with LianBio (the "Navire-LianBio License Agreement"). Pursuant to the Navire-LianBio License Agreement, Navire granted to LianBio an exclusive, sublicensable license under the licensed patent rights and know-how to develop, manufacture and commercialize SHP2 inhibitor BBP-398, or BBP-398, for tumors driven by RAS and receptor tyrosine kinase mutations. Under the terms of the Navire-LianBio License Agreement, LianBio will receive commercial rights in China and selected Asian markets and participate in clinical development activities for BBP-398. In December 2024, we received a notice of termination from LianBio, which terminated the Navire-LianBio License Agreement and all rights and obligations thereunder.

During the years ended December 31, 2024, 2023 and 2022, we recognized $0.3 million, $1.1 million and $0.5 million, respectively, of revenue relating to the Navire-LianBio License Agreement and recorded such amounts within "Revenue" in our consolidated statement of operations.

QED

In October 2019, QED entered into an exclusive license agreement with LianBio (the "QED-LianBio License Agreement"). Pursuant to the QED-LianBio License Agreement, QED granted to LianBio an exclusive, sublicensable license under the licensed patent rights and know-how to develop, manufacture and commercialize infigratinib for any and all human prophylactic and therapeutic uses in all cancer indications (including in combination with other therapies) in certain territories outside the United States. Under the QED-LianBio License Agreement, QED received a nonrefundable upfront payment of $10.0 million and is eligible to receive development and sales milestones payments of up to $132.5 million and tiered royalties on net sales ranging from the low to mid-teens. In addition, QED also received warrants which entitled QED to purchase 10% of the then-fully diluted shares of one of the subsidiaries of LianBio upon achievement of certain contingent development milestones (refer to Note 6). In December 2024, we received a notice of termination from LianBio, which terminated the QED-LianBio License Agreement and all rights and obligations thereunder.

During the years ended December 31, 2024, 2023 and 2022, we recognized insignificant amounts of revenue relating to the QED-LianBio License Agreement and recorded such amounts within "Revenue" on our consolidated statement of operations.

License Agreement with Alexion

In September 2019, Eidos Therapeutics, Inc. ("Eidos"), entered into an exclusive license agreement with Alexion Pharma International Operations Unlimited 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 is eligible to receive $30.0 million in regulatory milestone payments and 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 also entered into a stock purchase agreement with Alexion, under which Eidos sold to Alexion 556,173 shares of Eidos common stock at a price per share of $44.95, for an aggregate purchase price of approximately $25.0 million. The excess of the purchase price over the value of the Eidos shares, determined based on the closing price of a share of Eidos' common stock of $41.91 as reported on Nasdaq as of the date of execution, was $1.7 million and recognized in revenue as part of the upfront payment as discussed below.

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. Eidos recognized the $25.0 million upfront fee and $1.7 million premium paid for Eidos' stock for a total upfront payment of $26.7 million in license revenue upon the effective date of the license agreement in September 2019. Eidos determined that the license was a right to use its intellectual property and as of the effective date, it had provided all necessary information to Alexion to benefit from the license and the license term had begun. In addition, Eidos entered into a clinical supply agreement in July 2020. Eidos has supplied insignificant amounts to Alexion as part of the clinical supply agreement during the years ended December 31, 2024, 2023, and 2022, respectively, and has recorded such amounts as "Revenue" in our consolidated statement of operations.

Furthermore, in October 2024, Alexion initiated the ACT-EARLY clinical trial in Japan under the Eidos-Alexion License Agreement for an upfront payment received of $3.0 million, to be used by Eidos to cover any out-of-pocket costs and employee costs incurred by Eidos. However, there have been no clinical costs incurred as of December 31, 2024 and we have recorded $3.0 million in "Deferred revenue, current portion" in our consolidated balance sheets.

In November 2024, BridgeBio and Alexion entered into a commercial supply agreement for the manufacture and supply of the Licensed Product for commercial use in the Territory. BridgeBio entered into the agreement as BridgeBio is the entity responsible for the manufacture of the Licensed Product. Under the commercial supply agreement, Alexion shall pay to BridgeBio a commercial product per unit price equal to the applicable fully burdened manufacturing cost per unit of product. BridgeBio has supplied $0.6 million of commercial products to Alexion during the year ended December 31, 2024 which is recorded in "Revenue" in our statement of operations.

12. Sale of Nonfinancial Assets

Sale of Priority Review Voucher

In May 2022, we announced that we entered into a definitive agreement to sell our PRV for $110.0 million. We received the PRV in February 2021 under an FDA program intended to encourage the development of treatments for rare pediatric diseases. We were awarded the PRV when our subsidiary, Origin received approval of NULIBRY™. The PRV sale was subject to customary closing conditions and was completed in June 2022 following the expiration of applicable U.S. antitrust clearance requirements. We accounted for this transaction under ASC 610-20, *Gains and Losses from the Derecognition of Nonfinancial Assets*. We received the gross proceeds of $110.0 million during the year ended December 31, 2022 and recognized a gain of $107.9 million, net of transaction costs, for the year ended December 31, 2022.

Asset Purchase Agreement with Sentynl

On March 4, 2022, Origin and Sentynl entered into the Origin-Sentynl APA, pursuant to which Sentynl acquired global rights to NULIBRY, as well as certain specified assets of Origin, and will be responsible for the ongoing development and commercialization of NULIBRY in the United States and developing, manufacturing and commercializing fosdenopterin globally. The transaction closed on March 31, 2022 (the "Closing Date"). Under terms of the Origin-Sentynl APA, Origin received an upfront payment of $10.0 million upon the Closing Date and is eligible to receive sales milestone payments, as well as tiered royalties in the low single-digits as a percentage of adjusted net sales of products related to the acquired assets. Origin will continue to be responsible for the payment of up to $4.5 million in aggregate payments upon achievement of regulatory-based milestones, including the first pricing approval in an EMA country or EMA major market country, under the Asset Purchase Agreement with Alexion Pharma Holding Unlimited Company, and under a separate agreement with a third party. In October 2022, we paid $3.5 million of the regulatory-based milestone payment as the milestone criteria was met. As of December 31, 2024, Origin will continue to be responsible for a regulatory-based milestone payment upon first pricing approval in an EMA country of up to $1.0 million when it becomes due. The condition for this regulatory-based milestone payment was met in January 2025.

We accounted for this transaction under ASC 610-20. Upon the Closing Date, we recognized a loss on sale of $6.3 million within "Other income (expense), net" in our consolidated statement of operations for the year ended December 31, 2022. The loss on sale was determined as the difference in the aforementioned upfront payment and the carrying value of the assets purchased by Sentynl of approximately $16.3 million, which comprised mainly of intellectual property rights and related intangible assets and existing inventories as of the Closing Date.

Origin's sale of the assets covered in the Origin-Sentynl APA was not subject to the limitation on our ability to dispose of assets under the terms of the Loan Agreement (see Note 9).

13. In-licensing and Other Research and Development Agreements

Stanford License Agreement

In April 2016, Eidos entered into a license agreement with the Board of Trustees of the Leland Stanford Junior University Stanford University ("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. In March 2017, Eidos paid a license fee of $10,000, which was recorded as research and development expense during the year ended December 31, 2017, as the acquired assets did not have any alternative future use. Eidos may also be required to make future payments of up to approximately $1.0 million to Stanford University upon achievement of specific intellectual property, clinical and regulatory milestone events, and pay royalties of up to low single-digit percentages on future net sales, if any. In addition, Eidos is obligated to pay Stanford University a percentage of non-royalty revenue received by Eidos from its sublicensees, with the amount owed decreasing annually for three years based on when the applicable sublicense agreement is executed.

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, 2024, we incurred and paid $8.1 million of licensing fees due to Stanford University related to the Company entering into the Bayer License Agreement in March 2024, recognized a milestone payable of $0.5 million upon the receipt of the FDA approval for Attruby, and recognized an immaterial amount of royalty payable from the net sales of Attruby. For the years ended December 31, 2023 and 2022, the license fees incurred was not material.

Diagnostics Agreement with Foundation Medicine

As discussed in Note 7, QED and FMI entered into a diagnostics agreement relating to QED's drug discovery and development initiatives. In connection with this agreement, there were no research and development expenses incurred by QED for the years ended December 31, 2024 and 2023. In connection with this agreement, QED recognized research and development expenses of $2.6 million during the year ended December 31, 2022.

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 AAV9 investigational drug product intended for the treatment of children with Canavan Disease, under the age of five years. BBP-631 is an intravenous AAV5 investigational drug product intended for the treatment of adults and children with congenital adrenal hyperplasia. The Resilience DMSAs have ten-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.

For the years ended December 31, 2024 and 2023, $3.5 million and nil, respectively, in research and development expenses were incurred, which was net of $4.3 million and nil, respectively, in cost sharing credits received in connection with the Resilience Agreements.

In September 2024, we announced our decision to cease pursuing development of BBP-631, the Company's investigational adeno-associated virus 5 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. We do not expect there to be a material financial impact from the termination of these agreements.

Other License and Collaboration Agreements

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

14. 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" in 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.

The components of lease cost are as follows:

	Year Ended December 31,		
	2024	2023	2022
	(in thousands)		
Straight line operating lease costs	$ 4,110	$ 4,032	$ 5,172
Finance lease costs	395	420	443
Variable lease costs	6,305	6,844	6,142
Total lease cost	$ 10,810	$ 11,296	$ 11,757

Supplemental cash flow information related to leases are as follows:

	Year Ended December 31,		
	2024	2023	2022
	(in thousands)		
Cash paid for amounts included in the measurement of lease liabilities:			
Operating cash flows for operating leases	$ 5,902	$ 4,829	$ 6,245
Operating cash flows for finance lease	445	397	423
Operating lease right-of-use assets obtained in exchange for operating lease obligations	1,591	1,179	240

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

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

As of December 31, 2024, future minimum lease payments for our noncancelable operating leases are as follows. Future minimum lease payments under our finance lease are not material.

	Amount (in thousands)
Year ending December 31:	
2025	$ 4,926
2026	2,468
2027	436
2028	439
2029	471
Thereafter	1,362
Total future minimum lease payments	10,102
Imputed interest	(900)
Total	$ 9,202
Reported as of December 31, 2024	
Operating lease liabilities, current portion	$ 4,506
Operating lease liabilities, net of current portion	4,696
Total operating lease liabilities	$ 9,202

The impairment losses related to operating lease right-of-use assets for the years ended December 31, 2024, 2023, and 2022 were not material.

Manufacturing Agreement

In December 2019, we entered into a manufacturing agreement with a third party contract manufacturer to secure clinical and commercial scale manufacturing capacity for the manufacture of batches of active pharmaceutical ingredients for product candidates of certain subsidiaries of BridgeBio. Under the terms of the agreement, we were assigned a dedicated manufacturing suite for certain months in each calendar year for a one-time fee of $10.0 million, which would be applied to the buildout, commissioning, qualification, validation, equipping and exclusive use of the dedicated manufacturing suite.

We recorded a construction-in-progress asset of $10.0 million for the payments directly associated with the dedicated manufacturing suite as these payments are deemed to represent a non-lease component. In 2020, we entered into a supplemental agreement with the vendor for certain upgrades on the dedicated manufacturing suite and for additional equipment of approximately $0.2 million. As of December 31, 2021, the readiness determination phase of the dedicated manufacturing suite was expected to be completed in 2022.

In March 2022, we mutually agreed with the vendor to terminate the manufacturing agreement. The termination agreement was executed effective May 2022. In accordance with the termination agreement, we paid the $2.0 million remaining payable related to the dedicated manufacturing suite and a termination fee of $1.8 million. For the year ended December 31, 2022, we recorded an impairment loss of $10.2 million for the carrying value of the construction-in-progress asset that was no longer recoverable as our rights to the dedicated manufacturing suite ceased pursuant to the termination agreement. The aforementioned impairment loss and the termination fee are included as part of “Restructuring, impairment and related charges” in our consolidated statement of operations for the year ended December 31, 2022 (see Note 17).

15. Public Offerings

2020 Shelf Registration

In July 2020, we filed a shelf registration statement on Form S-3 (the "2020 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 simultaneously entered into an Open Market Sale Agreement[SM] with Jefferies LLC and SVB Leerink LLC (collectively, the "Sales Agents"), to provide for the offering, issuance and sale by us of up to an aggregate of $350.0 million of our common stock from time to time in "at-the-market" offerings under the 2020 Shelf and subject to the limitations thereof (the "2020 Sales Agreement"). We will pay to the applicable Sales Agents cash commissions of up to 3.0% of the gross proceeds of sales of common stock under the 2020 Sales Agreement. During the year ended December 31, 2022, the Company sold 455,800 shares through this offering at an average price of $10.90 per share, resulting in net proceeds of $4.9 million. We did not issue any shares or receive any proceeds from this offering during the year ended December 31, 2023. In May 2023, we terminated the Open Market Sale Agreement[SM].

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.

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. 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, 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. As of December 31, 2024, 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, 2023, 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.

16. Stock-Based Compensation

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

	Year Ended December 31, 2024		
	BridgeBio Equity Plan	Other Subsidiaries Equity Plan	Total
	(in thousands)		
Research and development	$ 49,807	$ 37	$ 49,844
Selling, general and administrative	63,862	—	63,862
Restructuring, impairment and related charges	160	—	160
Total stock-based compensation	$ 113,829	$ 37	$ 113,866

	Year Ended December 31, 2023		
	BridgeBio Equity Plan	Other Subsidiaries Equity Plan	Total
	(in thousands)		
Research and development	$ 61,433	$ 214	$ 61,647
Selling, general and administrative	53,288	81	53,369
Total stock-based compensation	$ 114,721	$ 295	$ 115,016

	Year Ended December 31, 2022		
	BridgeBio Equity Plan	Other Subsidiaries Equity Plan	Total
	(in thousands)		
Research and development	$ 37,700	$ 287	$ 37,987
Selling, general and administrative	54,669	—	54,669
Restructuring, impairment and related charges	1,172	—	1,172
Total stock-based compensation	$ 93,541	$ 287	$ 93,828

We have recorded $18.1 million, $6.3 million, and $2.2 million of stock-based compensation expense for the years ended December 31, 2024, 2023 and 2022, respectively, for performance-based milestone awards that were achieved during the period and were settled in cash.

Equity-Based Awards of BridgeBio

On June 22, 2019, we adopted the 2019 Stock Option and Incentive Plan (the "2019 Plan"), which became effective on June 25, 2019. The 2019 Plan provides for the grant of stock-based incentive awards, including common stock options and other stock-based awards. We were authorized to issue 11,500,000 shares of common stock for issuance of awards under the 2019 Plan, which may be allocated among stock options, awards of restricted common stock, restricted common units and other stock-based awards. On June 2, 2020, our stockholders approved an amendment and restatement of the 2019 Plan (the "A&R 2019 Plan"), to, among other things, increase the number of shares of common stock reserved for issuance thereunder by 2,500,000 shares. The A&R 2019 Plan was further amended on December 15, 2021 (the "2021 A&R Plan"). 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 numbers of shares authorized for issuance by 6,500,000 shares.

The 2021 A&R Plan, provides that the number of shares reserved and available for issuance will automatically increase each January 1, beginning on January 1, 2020 and ending on the date of the Company's annual stockholder's meeting in calendar year 2023 (which occurred on June 21, 2023), by 5% of the issued and outstanding number of shares of common stock on the immediately preceding December 31, or such lesser number of shares as determined by the Compensation Committee of the Board of Directors.

On November 13, 2019, we adopted the 2019 Inducement Equity Plan (the "2019 Inducement Plan"). The 2019 Inducement Plan provides for the grant of stock-based awards to induce highly qualified prospective officers and employees who are not currently employed by BridgeBio or its Subsidiaries to accept employment and to provide them with a proprietary interest in BridgeBio, including common stock options and other stock-based awards. We were authorized to issue 1,000,000 shares of common stock for inducement awards under the 2019 Inducement Plan, which may be allocated among stock options, awards of restricted common stock, restricted common units and other stock-based awards. In February 2023, the 2019 Inducement Plan was amended and restated to increase the total number of shares authorized for issuance from 1,000,000 shares to 2,000,000 shares. In December 2023, the 2019 Inducement Plan was further amended and restated to increase the number of shares authorized for issuance from 2,000,000 shares to 3,750,000 shares.

As of December 31, 2024, 8,796,454 and 1,094,152 shares were reserved for future issuances under the 2021 A&R Plan and 2019 Inducement Plan (the "A&R 2019 Inducement Plan"), respectively. Pursuant to the Merger Transactions, we also reserved 2,802,644 shares specifically 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 (Exchange Program)

On April 22, 2020, we completed our 2020 Stock and Equity Award Exchange Program (the "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 then 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, 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 then 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.

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 year 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" in 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.

For the year ended December 31, 2024, we recognized a net reversal of $6.7 million in stock-based compensation cost associated with performance-based milestone awards, which includes reversals totaling $8.9 million for obligations that were no longer determined to be probable. For the years ended December 31, 2023 and 2022, we recognized $3.4 million and $0.7 million, respectively, of stock-based compensation cost associated with performance-based milestone awards whereby the milestones were determined to be probable of achievement as of each of the reporting date. Refer to Note 8 for contingent compensation accrued associated with performance-based milestones that are determined to be probable as of December 31, 2024.

Performance-based Milestone Awards

Apart from the Exchange Program discussed above, 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 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. For the years ended December 31, 2024, 2023, and 2022, we recognized $9.1 million, $16.8 million, and $1.9 million, respectively, of stock-based compensation expense associated with performance-based milestone awards that were determined to be probable of achievement as of each reporting date. The $9.1 million in stock-based compensation associated with performance-based milestone awards recognized for the year ended December 31, 2024 includes reversals totaling $1.6 million as the obligation was no longer determined to be probable. Refer to Note 8 for contingent compensation accrued associated with performance-based milestones awards that are determined to be probable as of December 31, 2024.

Stock Option Grants of BridgeBio

The following table summarizes BridgeBio's stock option activity under the Plans for the year ended December 31, 2024:

	Options Outstanding		Weighted-Average Exercise Price per Option	Weighted-Average Remaining Contractual Life (years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2023		12,332,442			
Regular equity program	10,793,862		$ 25.69	7.1	$ 178,594
Eidos Awards Exchange	1,221,942		$ 14.60	4.7	$ 31,580
Exchange Program	316,638		$ 2.19	5.3	$ 12,105
Granted		401,924			
Regular equity program	401,924		$ 27.54		
Exercised		(227,567)			
Regular equity program	(20,579)		$ 21.45		
Eidos Awards Exchange	(203,900)		$ 15.76		
Exchange Program	(3,088)		$ 0.59		
Cancelled		(6,916)			
Regular equity program	(2,580)		$ 29.49		
Eidos Awards Exchange	(3,867)		$ 63.38		
Exchange Program	(469)		$ 0.48		
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
Exercisable as of December 31, 2024		10,269,962			
Regular equity program	8,945,126		$ 27.27	5.8	$ 56,480
Eidos Awards Exchange	1,014,175		$ 14.18	4.3	$ 13,734
Exchange Program	310,661		$ 2.20	4.3	$ 7,936

The options granted to employees and non-employees are exercisable at the price 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, 2024 was $21.28.

The aggregate intrinsic value of options outstanding and exercisable as of December 31, 2024, in the table above are calculated based on the difference between the exercise price and the current fair value of BridgeBio common stock. The total intrinsic value of options exercised during the year ended December 31, 2024 was $2.9 million.

For the years ended December 31, 2024, 2023, and 2022, we recognized stock-based compensation expense of $22.4 million, $28.5 million, $39.7 million, respectively, related to stock options under the Plans. As of December 31, 2024, there was $22.2 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 1.5 years.

Restricted Stock Units (RSUs) of BridgeBio

The following table summarizes BridgeBio's RSU activity under the Plans for the year ended December 31, 2024:

	Unvested Shares of RSUs Outstanding		Weighted-Average Grant Date Fair Value
Balance as of December 31, 2023	8,942,813	$	16.27
Granted	6,103,761	$	28.40
Vested	(3,809,372)	$	19.37
Cancelled	(964,404)	$	20.71
Balance as of December 31, 2024	10,272,798	$	21.91

The RSUs have a service condition and generally vest over a period of two to four years.

For the years ended December 31, 2024, 2023, and 2022, we recognized stock-based compensation expense of $78.3 million, $59.1 million, $43.1 million, respectively, related to shares of RSUs under the Plans. As of December 31, 2024, there was $208.5 million of total unrecognized compensation cost related to RSUs under the Plans that is expected to be recognized over a weighted-average period of 2.5 years.

Market-Based RSUs of BridgeBio

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 4.22% - 4.35%, 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, 2024, 375,000 market-based RSUs were outstanding with a weighted average grant date fair value of $28.73. For the years ended December 31, 2024 and 2023, we recognized $7.6 million and $0.7 million, respectively, of stock-based compensation expense related to market-based RSU awards. As of December 31, 2024, there was $2.5 million of total unrecognized compensation cost related to market-based RSUs under the Plans that is expected to be recognized over a weighted-average period of 0.6 years.

Restricted Stock Awards (RSAs) of BridgeBio

In 2019, all unvested outstanding management incentive units and common units of BBP LLC which existed prior to the reorganization and IPO were cancelled and converted into shares of BridgeBio's RSAs.

The following table summarizes our RSA activity under the Plans for the year ended December 31, 2024:

	Unvested Shares of RSAs Outstanding	Weighted-Average Grant Date Fair Value
Balance as of December 31, 2023	85,453	$ 7.27
Granted — Exchange Program	8,057	$ 38.74
Vested — Exchange Program	(8,057)	$ 38.74
Vested — Regular equity program	(85,453)	$ 7.27
Balance as of December 31, 2024	—	$ —

For the years ended December 31, 2024, 2023, and 2022, we recognized stock-based compensation expense related to RSAs under the Plans as follows:

	Year Ended December 31,		
	2024	2023	2022
	(in thousands)		
Exchange Program	$ 312	$ 4,056	$ 3,238
Other RSAs	621	4,033	5,326
Total stock-based compensation expense	$ 933	$ 8,089	$ 8,564

As of December 31, 2024, there was no unrecognized compensation cost related to RSAs under the Plans. The respective balance of unvested RSAs as of December 31, 2024 and 2023 is included as outstanding shares disclosed in the consolidated balance sheets as the shares were actually issued but are subject to forfeiture per the terms of the awards.

2019 Employee Stock Purchase Plan (ESPP) of BridgeBio

On June 22, 2019, we adopted the 2019 ESPP, 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 years ended December 31, 2024, 2023, and 2022 we recognized $2.5 million, $2.3 million, and $2.6 million respectively, of stock-based compensation expense related to our ESPP. As of December 31, 2024, 3,361,774 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 ESPP. We used the following weighted-average assumptions in the Black-Scholes calculations:

	Year Ended December 31,					
	2024		2023		2022	
	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	92.0% - 93.1%	52.0% - 122.1%	66.2% - 67.5%	86.1% - 122.1%	65.9 %	52.0% - 191.7%
Risk-free interest rate	3.8% - 4.3%	5.0% - 5.5%	3.9% - 4.1%	3.1% - 5.5%	3.2 %	0.1% - 3.1%
Dividend yield	—	—	—	—	—	—
Weighted-average fair value of stock-based awards granted	$ 21.28	$ 11.34	$ 8.48	$ 8.22	$ 5.24	$ 6.29

17. Restructuring, Impairment and Related Charges

In January 2022, we committed to a restructuring initiative designed to drive operational changes in our business processes, efficiencies and cost savings to advance our corporate strategy and development programs. The restructuring initiative included, among other components, consolidation and rationalization of our facilities, reprioritization of development programs and the reduction in our workforce.

Upon entering into the Bayer License Agreement and termination of the Navire-BMS License Agreement in March 2024 (refer to Note 11 for details regarding these transactions) and our announced decision to cease pursuing development of BBP-631 for CAH in September 2024, we have committed to additional restructuring plans to reprioritize and advance our corporate strategy and development programs. We estimate our remaining restructuring charges, consisting primarily of winding down costs and exit and other related costs will be immaterial. 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 in our consolidated statement of operations for the years ended December 31, 2024, 2023, and 2022 consisted of the following:

	Year Ended December 31,		
	2024	2023	2022
		(in thousands)	
Winding down, exit and other related costs	$ 10,255	$ 7,211	$ 20,739
Severance and employee-related costs	5,079	715	10,306
Long-lived assets impairments and write-offs	271	—	12,720
Total	$ 15,605	$ 7,926	$ 43,765

The following table summarizes the activity related to the restructuring liabilities associated with our restructuring initiatives for the years ended December 31, 2024, 2023, and 2022:

	Year Ended December 31,		
	2024	2023	2022
		(in thousands)	
Beginning balance	$ 55	$ 6,826	$ —
Reclassification of final payment obligation related to a manufacturing agreement that was recognized in the prior period (see Note 14)	—	—	2,185
Restructuring, impairment and related charges	15,605	7,926	43,765
Cash payments	(13,374)	(14,697)	(25,232)
Noncash activities	(438)	—	(13,892)
Ending balance	$ 1,848	$ 55	$ 6,826

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

	December 31, 2024	December 31, 2023
	(in thousands)	
Accounts payable	$ 330	$ 48
Accrued compensation and benefits	332	—
Accrued research and development liabilities	1,020	7
Accrued professional and other accrued liabilities	166	—
Total	$ 1,848	$ 55

18. Income Taxes

The following table presents the components of net loss before income taxes:

	Year Ended December 31,		
	2024	2023	2022
		(in thousands)	
Domestic	$ 207,795	$ 565,840	$ 485,079
Foreign	334,399	87,411	(427)
Total loss before income taxes	$ 542,194	$ 653,251	$ 484,652

The following table presents income tax expense for the years ended December 31, 2024, 2023, and 2022:

	Year Ended December 31,		
	2024	2023	2022
		(in thousands)	
Current:			
U.S. Federal	$ 811	$ —	$ —
State	—	—	—
Foreign	342	—	—
Total Current	1,153	—	—
Deferred	—	—	—
Total income tax expense	$ 1,153	$ —	$ —

The following table presents a reconciliation of the statutory federal rate and our effective tax rate:

	Year Ended December 31,		
	2024	2023	2022
Tax at statutory federal rate	21.0 %	21.0 %	21.0 %
Foreign impact on cross border transactions	(10.0)	—	—
Change in valuation allowance	(7.0)	(20.3)	(21.7)
Research and development credits	3.2	2.3	3.2
Stock-based compensation	1.3	0.6	(1.8)
Disallowed executive compensation	(1.2)	(0.8)	—
Deconsolidation of subsidiaries	(1.4)	(1.4)	—
Foreign rate differential	(5.6)	(1.2)	—
Other	(0.5)	(0.2)	(0.7)
Effective income tax rate	(0.2)%	— %	— %

Significant components of our deferred tax assets and liabilities are as follows:

	December 31,	
	2024	2023
	(in thousands)	
Deferred tax assets:		
Net operating loss carry-forwards	$ 379,019	$ 358,867
Amortization	10,188	10,024
Accruals and reserves	7,787	6,453
Deferred revenue	—	2,130
Stock-based compensation	21,109	21,340
Equity method investment	2,998	—
Tax credits	117,020	97,735
Operating lease liabilities	2,200	3,153
Deferred income from asset sale	2,242	2,333
Capitalized research and experimental expenditures	150,520	144,873
Deferred interest expense	30,747	26,596
Property and equipment	918	822
Unrealized gains and losses	3,336	—
Other	554	4,230
Gross deferred tax assets	728,638	678,556
Less valuation allowance	(727,326)	(672,084)
Deferred tax assets, net of valuation allowance	1,312	6,472
Deferred tax liabilities:		
Operating lease right-of-use assets	(1,312)	(1,784)
Unrealized gains and losses	—	(4,688)
Deferred tax liabilities	(1,312)	(6,472)
Net deferred tax assets (liabilities)	$ —	$ —

As of December 31, 2024, we have net operating loss carryforwards available to reduce future taxable income, if any, for federal and state income tax purposes of approximately $1.4 billion and $439.4 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 $1.4 billion will carry over indefinitely and would 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 $404.5 million available to reduce future taxable income, if any, which will begin to expire in 2030.

As of December 31, 2024, we had federal research and development and orphan drug credit carryforwards of $120.3 million, which will expire beginning in 2038 if not utilized. As of December 31, 2024, we have California and other state research and development tax credit carryforwards of $29.1 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.

Beginning in 2022, the 2017 Tax Cuts and Jobs Act amended Section 174 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 United States). The Company generates a deferred tax asset for capitalized R&E expenditures for the year ended December 31, 2024 which is fully offset with 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 loss and credits carried forward. The valuation allowance increased by $55.2 million, $138.2 million, and $110.0 million for the years ended December 31, 2024, 2023, and 2022, 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 had a change of ownership, utilization of the net operating loss and tax credit carryforwards may be restricted.

As of December 31, 2024, we had 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:

	December 31,	
	2024	2023
	(in thousands)	
Balance at the beginning of the year	$ 30,856	$ 27,013
Additions of prior year positions	99	10
Reductions of prior year positions	(520)	(2,504)
Additions based on tax positions related to current year	6,431	6,337
Balance at the end of the year	$ 36,866	$ 30,856

As of December 31, 2024 and 2023, we have not recorded interest and penalties associated with our unrecognized tax benefits. Our policy is to recognize interest and penalties related to income tax matters in income tax expense.

Our unrecognized gross tax benefits would not reduce the annual effective tax rate if recognized because we have recorded a valuation allowance on our deferred tax assets.

We file federal and various income tax returns. We currently have no federal, state, or foreign tax examinations in progress. All years are open for examination by federal, state, and foreign authorities.

19. 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, 2024, 2023 and 2022, diluted and basic net loss per share attributable to common stockholders of BridgeBio was identical since potential common shares were excluded from the calculation, as their effect was anti-dilutive.

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

	As of December 31,		
	2024	2023	2022
Unvested RSAs	—	85,453	652,058
Unvested RSUs	10,272,798	8,942,813	4,108,642
Unvested performance-based RSUs	3,326	3,326	7,875
Unvested market-based RSUs	375,000	375,000	—
Common stock options issued and outstanding	12,499,883	12,332,442	11,637,861
Estimated shares issuable under performance-based milestone compensation arrangements	2,558,295	4,865,250	19,201,212
Estimated shares issuable under the ESPP	122,268	75,889	217,660
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
	46,412,863	47,261,466	56,406,601

Our 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 16, 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.

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 Exchange Act of 1934, as amended, with the U.S. Securities and Exchange Commission (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, 2024 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 was no change in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the year ended December 31, 2024 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Management's Annual Report on Internal Control over Financial Reporting

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, 2024, 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, 2024.

Deloitte & Touche LLP, an independent registered public accounting firm, audited the effectiveness of our internal control over financial reporting as of December 31, 2024, 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, 2024, 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, 2024, 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, 2024, of the Company and our report dated February 20, 2025, 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 20, 2025

ITEM 9B. OTHER INFORMATION

Effective on February 19, 2025, our board of directors reassigned the Company's Principal Financial Officer and Principal Accounting Officer roles from Brian Stephenson, Ph.D., and appointed them to Thomas Trimarchi, Ph.D., and Maricel M. Apuli, respectively, in each case as contemplated by Rule 16a-1 of the Exchange Act.

Dr. Trimarchi, age 40, joined the Company in April 2018 as the Chief Product Officer. In July 2024, he was promoted as President and Chief Operating Officer of the Company. Dr. Trimarchi leads cross-functional activities at the Company to develop a centralized operation across the late-stage pipeline prioritizing efficiency, rigor, and scale. He is also a board member of ML Bio, an affiliate of the Company focused on developing BBP-418 for limb-girdle muscular dystrophy type 2I/R9 (LGMD2I/R9), since November 2021. Prior to joining the Company, Dr. Trimarchi worked in corporate strategy at Regeneron Pharmaceuticals, Inc. from 2017 to 2018. From 2015 to 2017, Dr. Trimarchi was an equity analyst in the Global Investment Research division at Goldman Sachs. Dr. Trimarchi received a B.S. in Biology from the University of Vermont and a Ph.D. from NYU Grossman School of Medicine.

Ms. Apuli, age 48, joined the Company in September 2021 as Vice President, Corporate Controller. In January 2023, she was promoted to Chief Accounting Officer of the Company. Ms. Apuli oversees the Company's accounting, financial reporting, tax and SOX compliance, and finance-related functions. Prior to joining the Company, Ms. Apuli was Vice President, Corporate Controller at Guardant Health, Inc. from December 2019 to September 2021. From 2018 to 2019, Ms. Apuli was Vice President of Finance, Controller at Arlo Technologies, Inc. From 2013 to 2018, Ms. Apuli was Director of Accounting at KLA Corporation. Earlier in her career, she served as a Senior Audit Manager at PricewaterhouseCoopers LLP (U.S.). Ms. Apuli received a B.S. in Accountancy from the University of Santo Tomas-Legazpi.

Except as described above, there are no understandings or arrangements between each of Dr. Trimarchi and Ms. Apuli and any other person pursuant to which he or she was appointed as Principal Financial Officer or Principal Accounting Officer of the Company, as applicable. Neither Dr. Trimarchi nor Ms. Apuli has material interest in any transaction or proposed transaction in which the Company is or is to be a party. Neither Dr. Trimarchi nor Ms. Apuli has a family relationship with any director or executive officer of the Company.

Rule 10b5-1 Trading Plans

***Note*:** The following table discloses any officer (as defined in Rule 16a-1(f) under the Exchange Act) or director who entered into, modified or terminated a Rule 10b5-1 trading arrangement or non-Rule 10b5-1 trading arrangement (as such terms are defined in Item 408 of Regulation S-K) during the three months ended December 31, 2024:

Name and Title	Type of Trading Arrangement	Action Taken (Date of Action)	Duration or End Date	Aggregate Number of Securities to Be Sold	Description of Trading Arrangement
Hannah A. Valantine (Director)	Trading plan intended to satisfy the affirmative defense conditions of Securities Exchange Act Rule 10b5-1(c)	Adoption (December 5, 2024)	End Date (December 31, 2025)	17,167	Sale
Andrea Ellis (Director)	Trading plan intended to satisfy the affirmative defense conditions of Securities Exchange Act Rule 10b5-1(c)	Adoption (December 30, 2024)	End Date (December 31, 2025)	57,167	Sale

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 2025 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2024.

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/static-files/e15fa82d-1c86-4951-96a1-0676f0a6bb3d. 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 2025 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2024, 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 2025 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2024.

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 2025 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2024.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this Item is incorporated by reference from our definitive proxy statement for our 2025 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2024.

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:

2. Financial Statement Schedules:

All schedules have been omitted because of the absence of conditions under which they are required or because the required information, where material, is shown in the financial statements, financial notes or supplementary financial information.

(b) Exhibits required by Item 601 of Regulation S-K:

The exhibits listed in the accompanying Exhibit Index are filed as part of, or incorporated by reference into, this Annual Report on Form 10-K.

ITEM 16. FORM 10-K SUMMARY

None.

Exhibits

Exhibit Number	Exhibit Title	Form	File No.	Exhibit	Filing Date
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	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, among the Registrant and certain of its shareholders, dated June 26, 2019.	S-1	333-231759	4.3	June 24, 2019
4.3	Description of Securities.	10-K	001-38959	4.3	February 25, 2022
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
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	Lease Agreement, between BridgeBio Pharma LLC and Michael J. Harbour, dated as of March 23, 2017.	S-1	333-231759	10.8	May 24, 2019
10.7†	Exclusive (Equity) Agreement, by and between Eidos Therapeutics, Inc. and the Board of Trustees of the Leland Stanford Junior University, effective as of April 10, 2016, as amended by Amendment No. 1 effective September 25, 2017.	S-1	333-231759	10.9	May 24, 2019
10.8†	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
10.9†	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
10.10†	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
10.11#	Offer Letter, between BridgeBio Services, Inc. and Neil Kumar, dated December 14, 2017.	S-1	333-231759	10.19	June 11, 2019
10.12#	Offer Letter, between BridgeBio Services, Inc. and Brian Stephenson, dated October 28, 2018.	S-1	333-231759	10.20	June 11, 2019
10.13#	Offer Letter, between BridgeBio Services, Inc. and Charles Homcy, dated February 20, 2019.	S-1	333-231759	10.22	June 11, 2019

10.14#	Offer Letter, between BridgeBio Services, Inc. and Richard Scheller, dated April 5, 2019.	S-1	333-231759	10.23	June 11, 2019
10.15#†	Consulting Agreement between Frank McCormick and the Registrant, effective as of January 1, 2021.	10-K	001-38959	10.16	February 23, 2023
10.16#†	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
10.17#†	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
10.18	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
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.	10-K	001-38959	10.30	February 25, 2022
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

	August 7, 2018, September 10, 2020 and March 30, 2022, respectively.				
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†	Financing Agreement, dated January 17, 2024, by and among the Registrant, certain subsidiaries of the Registrant, various Lenders party thereto, and Blue Owl Capital Corporation as Administrative Agent.	10-Q	001-38959	10.2	May 2, 2024
10.34†	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
10.35†	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
10.36†	Exclusive License Agreement, dated March 1, 2024, by and among Eidos Therapeutics, Inc., BridgeBio	10-Q	001-38959	10.5	May 2, 2024

	International GmbH, BridgeBio Europe B.V., and Bayer Consumer Care AG.				
10.37†	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
10.38#†	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
10.39†	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
10.40**	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
10.41**	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
10.42#†	Employment Agreement between BridgeBio Services, Inc. and Thomas Trimarchi, dated October 10, 2024.	—	—	—	Filed herewith
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 Firm.	—	—	—	Filed herewith

24	Power of Attorney (reference is made to signature page hereto).	—	—	—	Filed herewith
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	—	—	—	Filed herewith
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	—	—	—	Filed herewith
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.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

BridgeBio Pharma, Inc.

Date: February 20, 2025

By: /s/ Neil Kumar
Neil Kumar, Ph.D.
Chief Executive Officer, Director
(Principal Executive Officer)

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Neil Kumar, Thomas Trimarchi and Maricel M. Apuli, as their true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for such person and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to the Annual Report on Form 10-K, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he or she could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Neil Kumar Neil Kumar, Ph.D.	Chief Executive Officer, Director (Principal Executive Officer)	February 20, 2025
/s/ Thomas Trimarchi Thomas Trimarchi, Ph.D.	President, Chief Operating Officer (Principal Financial Officer	February 20, 2025
/s/ Maricel M. Apuli Maricel M. Apuli	Chief Accounting Officer (Principal Accounting Officer)	February 20, 2025
/s/ Eric Aguiar Eric Aguiar, M.D.	Director	February 20, 2025
/s/ Jennifer E. Cook Jennifer E. Cook	Director	February 20, 2025
/s/ Douglas A. Dachille Douglas A. Dachille	Director	February 20, 2025
/s/ Ronald J. Daniels Ronald J. Daniels	Director	February 20, 2025
/s/ Andrea J. Ellis Andrea J. Ellis	Director	February 20, 2025

/s/ Fred Hassan Fred Hassan	Director	February 20, 2025
/s/ Charles Homcy Charles Homcy, M.D.	Director	February 20, 2025
/s/ Andrew W. Lo Andrew W. Lo, Ph.D.	Director	February 20, 2025
/s/ Frank P. McCormick Frank P. McCormick, Ph.D.	Director	February 20, 2025
/s/ James C. Momtazee James C. Momtazee	Director	February 20, 2025
/s/ Ali J. Satvat Ali J. Satvat	Director	February 20, 2025
/s/ Randal W. Scott Randal W. Scott, Ph.D.	Director	February 20, 2025
/s/ Hannah A. Valantine Hannah A. Valantine, M.D.	Director	February 20, 2025