As confidentially submitted to the Securities and Exchange Commission on August 5, 2024.
This Amendment No. 2 to the draft registration statement has not been publicly filed with the Securities and Exchange Commission and all information herein remains strictly confidential.

Registration No. 333-

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

BIOAGE LABS, INC.
(Exact name of Registrant as specified in its charter)

Delaware	**2834**	**47-4721157**
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

1445A South 50th Street
Richmond, California 94804
(510) 806-1445
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Kristen Fortney, Ph.D.
Chief Executive Officer and President
1445A South 50th Street
Richmond, California, 94804
(510) 806-1445
(Name, Address, Including Zip Code, And Telephone Number, Including Area Code, Of Agent For Service)

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Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this registration statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box. ☐

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

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 7(a)(2)(B) of the Securities Act. ☐

Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

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The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities, and we are not soliciting offers to buy these securities in any jurisdiction where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED , 2024

Shares

BIOAGE

Common Stock

This is the initial public offering of shares of common stock of BioAge Labs, Inc.

We are offering shares of our common stock. Prior to this offering, there has been no public market for our common stock. It is currently estimated that the initial public offering price will be between $ and $ per share. We have applied to list our common stock on the Nasdaq Global Market under the symbol "BAGE," and this offering is contingent upon obtaining such approval.

We are an "emerging growth company" and a "smaller reporting company" as defined under the federal securities laws and, as such, have elected to comply with certain reduced reporting requirements in this prospectus and may elect to do so in future filings.

Investing in our common stock involves a high degree of risk. See the section titled "Risk Factors" beginning on page 16.

	Per Share	Total
Initial public offering price	$	$
Underwriting discounts and commissions(1)	$	$
Proceeds, before expenses, to us	$	$

(1) See the section titled "Underwriting" for additional disclosure regarding the estimated underwriting discounts and commissions and estimated offering expenses.

We have granted the underwriters an option for a period of 30 days to purchase up to additional shares of common stock at the initial public offering price, less the underwriting discounts and commissions.

The underwriters expect to deliver the shares against payment in New York, New York on , 2024.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

Goldman Sachs & Co. LLC **Morgan Stanley** **Jefferies** **Citigroup**

, 2024

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Neither we nor the underwriters have authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any free writing prospectuses prepared by or on behalf of us or to which we have referred you. We and the underwriters do not take responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the shares of common stock offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus or in any applicable free writing prospectus is current only as of its date, regardless of its time of delivery or the time of any sale of shares of our common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

For investors outside of the United States: Neither we nor any of the underwriters have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than the United States. Persons outside of the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of our common stock and the distribution of this prospectus outside of the United States.

Through and including , 2024 (the 25th day after the date of this prospectus), all dealers that buy, sell or trade shares of our common stock, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to the dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

PROSPECTUS SUMMARY

This summary highlights selected information contained elsewhere in this prospectus and does not contain all of the information that you should consider in making your investment decision. Before investing in our common stock, you should carefully read this entire prospectus, including our consolidated financial statements and the related notes thereto and the information set forth under the sections titled "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations," and "Business," in each case included in this prospectus. Some of the statements in this prospectus constitute forward-looking statements that involve risks and uncertainties. See the section titled "Special Note Regarding Forward-Looking Statements" for additional information. Unless the context otherwise requires, we use the terms "BioAge Labs, Inc.," "BioAge," the "Company," "we," "us" and "our" in this prospectus to refer to BioAge Labs, Inc.

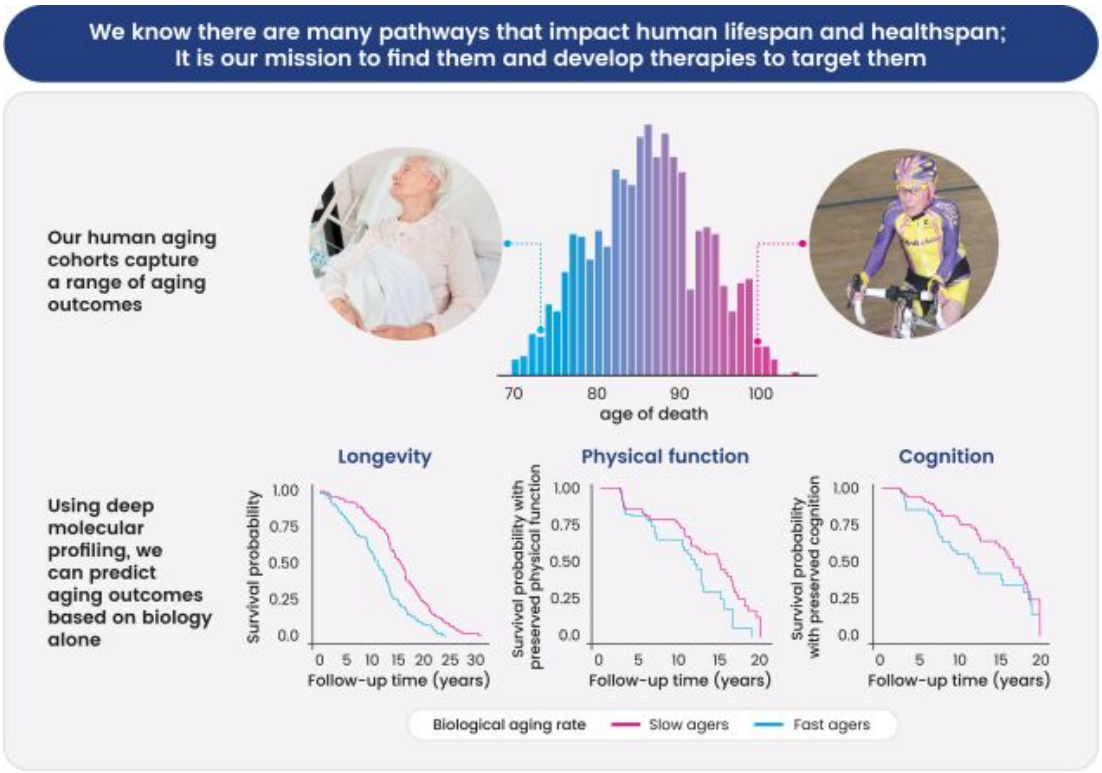
Overview

We are a clinical-stage biopharmaceutical company developing therapeutic product candidates for metabolic diseases, such as obesity, by targeting the biology of human aging. Our technology platform and differentiated human datasets enable us to identify promising targets based on insights into molecular changes that drive aging. Our primary focus is metabolic disease, one of the greatest global healthcare challenges. Azelaprag, our lead product candidate, is an orally available small molecule that has been well-tolerated in over 240 individuals across seven Phase 1 clinical trials. In preclinical obesity models, azelaprag demonstrated the ability to more than double the weight loss induced by a glucagon-like-peptide-1 receptor (GLP-1R) agonist while also restoring healthy body composition and improving muscle function. These preclinical results are supported by our Phase 1b clinical trial in older adults on bed rest where we observed decreased muscle atrophy, preservation of muscle quality and improved metabolism in subjects treated with azelaprag over a 10-day period. We plan to assess azelaprag's potential to drive significant improvements in weight loss when combined with a GLP-1R agonist in two Phase 2 clinical trials. While the results of these preclinical studies and early clinical trials have demonstrated the potential use of azelaprag for the treatment of metabolic disease, they may not be predictive of the results of later-stage clinical trials. The ongoing STRIDES clinical trial will assess azelaprag in combination with tirzepatide, marketed as Zepbound® by Eli Lilly and Company (Lilly), with topline results anticipated in . The second Phase 2 clinical trial will assess azelaprag in combination with semaglutide, marketed as Wegovy® by Novo Nordisk, with initiation expected in . We believe these trials will directly support our ultimate therapeutic goal of developing an all-oral combination product for obesity. We also intend to initiate an insulin sensitivity proof-of-concept trial of azelaprag monotherapy in to support potential indication expansion. We are also developing orally available small molecule brain-penetrant NLRP3 inhibitors for the treatment of diseases driven by neuroinflammation. We anticipate submitting an Investigational New Drug application (IND) for an NLRP3 inhibitor in and, if cleared, initiating a Phase 1 clinical trial in .

Our approach: Targeting human aging biology to treat chronic metabolic diseases

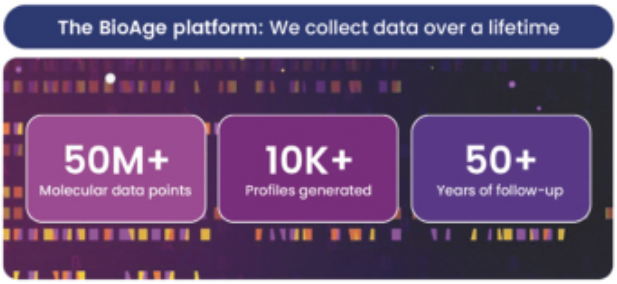
The burden of many serious and chronic diseases—including cardiovascular disease and diabetes—increases with age.

However, there is substantial natural variation in the human population, resulting in a broad range of aging trajectories and outcomes, with some people experiencing much longer lifespans as well as delayed disease onset. We created our company to identify biological pathways associated with longer, healthier human lifespans and to develop pharmaceutical products that can modulate these pathways with the intent to prevent and reverse specific diseases, focusing on metabolic diseases.



We capture a range of aging outcomes in our human aging cohorts, including functional and cognitive decline, disease incidence and mortality. In this example, deep, serial profiling of circulating proteins in these participants was used to understand the biology that drives these outcomes.

Our approach starts with human data. We examine the impact of the molecular changes that happen naturally as people age and study how these changes drive both functional decline (e.g., loss of muscle strength) and disease risk (e.g., obesity, insulin resistance, dyslipidemia, hypertension). To develop new insights into the biological drivers of aging, we have generated proprietary longitudinal human datasets based on exclusive access to a unique resource: serial biobanked human samples coupled with health records and functional measurements collected for up to 50 years, capturing individual aging trajectories measured over several decades. We analyze these samples using state-of-the-art molecular profiling technologies, measuring thousands of biologically relevant molecules, and then apply computational tools to the resulting data to extract potential drivers of a long and healthy lifespan.



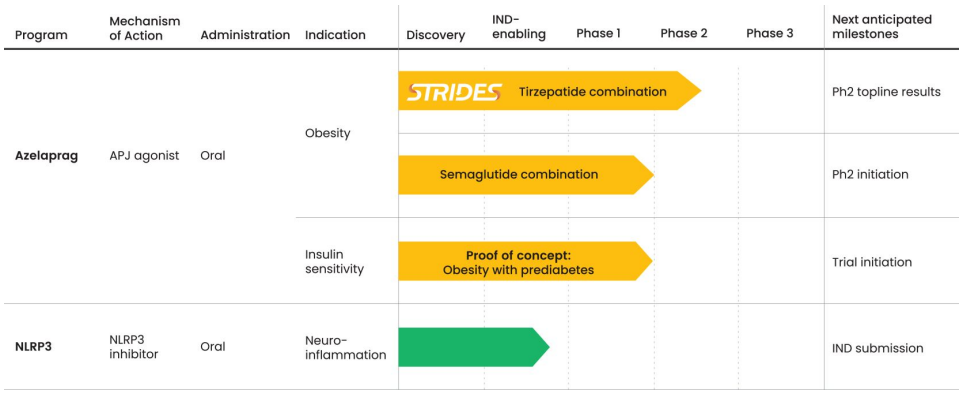
The BioAge platform encompasses over 50 million molecular data points spanning over 10 thousand individual participant profiles and over 50 years of follow-up.

We have selected chronic metabolic diseases as our primary focus within age related chronic diseases, given their high prevalence and resulting potential for impact on population health. Chronic metabolic diseases represent some of the largest addressable therapeutics markets. Through our approach, we expect to target outsized commercial opportunities, initially within the obesity and diabetes landscape. For instance, according to third-party estimates, the global market for GLP-1R agonists, including those used to treat diabetes, is expected to grow to $150 billion by 2031.

Our Pipeline

We are building a pipeline of platform-derived therapeutics targeting chronic metabolic disease. Our lead product candidate, azelaprag, is an orally available small molecule agonist of the apelin receptor (APJ) where activation has the potential to recapitulate many of the benefits of exercise. We are developing azelaprag for the treatment of obesity in combination with GLP-1R agonists with the goal of increasing overall weight loss, with the potential to also improve tolerability and body composition. We have initiated one Phase 2 clinical trial of azelaprag in combination with tirzepatide and plan to initiate a second Phase 2 clinical trial of azelaprag in combination with semaglutide in . We are also developing a series of oral small molecule inhibitors of NLRP3, a key driver of neuroinflammation, which is linked to many diseases including obesity. We anticipate submitting an IND for an NLRP3 inhibitor in and, if cleared, initiating a Phase 1 clinical trial in . From our platform, we have several additional targets with product candidates in discovery stages, and we are also continuously seeking to identify and develop further promising targets.

Our portfolio of product candidates is summarized in the figure below:



Our lead product candidate, azelaprag: an orally available, small molecule APJ agonist that has the potential to recapitulate the effects of exercise

Leveraging our platform, we found that apelin levels decrease with age and that higher levels of apelin are predictive of both improved physical function and increased longevity. Apelin is a type of signaling molecule released in response to exercise known as an exerkine, which, as shown in preclinical studies and clinical trials, has the potential to recapitulate many of the downstream benefits of exercise. Azelaprag is an orally available, small molecule agonist of APJ that we are developing for the treatment of obesity.

In December 2022, we announced results demonstrating statistically significant results on pharmacodynamic measures of maintenance of muscle size and quality in participants administered 240 mg of azelaprag as compared to placebo from our Phase 1b clinical trial in 21 healthy volunteers ≥65 years old over 10 days of bed rest, of which 10 received placebo. We also observed several metabolic benefits in subjects dosed with azelaprag, including significantly higher rates of muscle protein synthesis as well as preservation of predicted resting energy expenditure and cardiorespiratory fitness. Azelaprag was also observed to shift the levels of circulating proteins in a way that is highly overlapping with endurance exercise, further supporting that it may be able to mimic some global effects of exercise at the protein level.

Across seven Phase 1 clinical trials conducted between us and Amgen, azelaprag has been well-tolerated in over 240 individuals, with an adverse event rate similar to placebo.

We are advancing azelaprag as a treatment for obesity, where our key therapeutic goal is to achieve injectable-like overall weight loss in an all-oral combination with an incretin (a class of gut-derived metabolic hormones that includes GLP-1 and plays a role in increasing satiety, increasing insulin secretion and sensitivity, and delaying gastric emptying), with the potential to also improve tolerability and body composition.

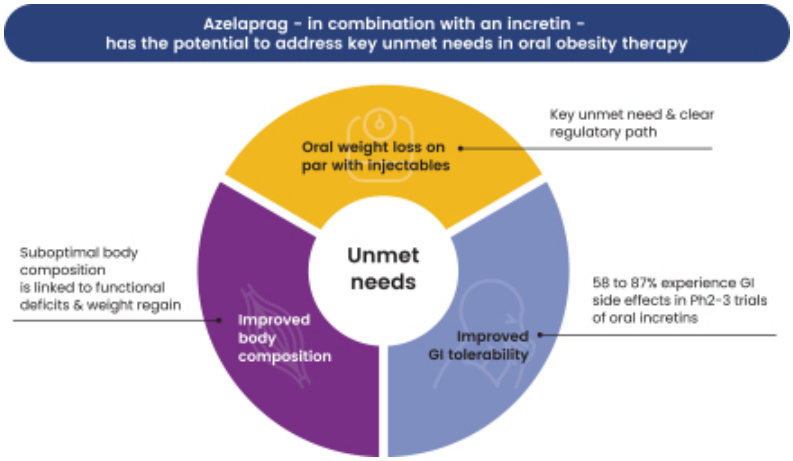
Similar to how exercise increases weight loss in obese patients on incretins, administration of azelaprag in combination with GLP-1R agonists resulted in potent synergistic increase in weight loss achieved in a preclinical model of diet-induced obesity. The addition of azelaprag was shown to approximately double total weight loss while restoring body composition and muscle function to that of lean controls, without any significant additional decrease in energy intake. The addition of azelaprag was also observed to significantly reduce non-fasting glucose levels. While the results of these preclinical studies and early clinical trials have demonstrated the potential use of azelaprag for the treatment of metabolic disease, they may not be predictive of the results in later-stage clinical trials.

The evolving obesity treatment landscape: we believe azelaprag addresses multiple key unmet needs

Obesity is associated with a range of adverse health outcomes such as insulin resistance, dyslipidemia and increased blood pressure that can be reduced or even completely resolved with weight loss, with outcomes largely proportional to the amount of weight lost. Until recently, pharmaceutical treatments for obesity had limited efficacy and furthermore were associated with side effects that led to poor tolerability. The development of a class of drugs known as incretins has dramatically changed the treatment landscape.

GLP-1R agonists are part of the incretin class, which mimics the effects of hormones released after eating and are used to treat metabolic diseases. Certain injectable GLP-1R agonists have recently been approved for the treatment of diabetes and obesity. However, there continues to be significant interest by pharmaceutical companies in oral obesity medications given strong patient preference and fewer supply chain challenges compared to injectables, including cold-chain requirements and high manufacturing costs.

Despite the recent approvals of such injectable GLP-1R agonists, there remain important unmet needs for people struggling with obesity, including improved oral efficacy, tolerability and body composition:



Key unmet needs for weight loss regimens include increased weight loss in an all-oral regimen, improved gastrointestinal (GI) tolerability and improved body composition.

- *Oral efficacy*: Overall weight loss with oral incretins has lagged injectables, potentially because the most advanced orals have a single target (GLP-1R) whereas some injectables have combined multiple mechanisms. For example, subjects in a clinical trial of oral semaglutide (50 mg), currently the most advanced oral drug in this class, achieved 15.1% weight loss at week 68, while subjects in a clinical trial of tirzepatide (15 mg), an FDA-approved dual GLP-1 / GIP agonist, which is currently the leading weight loss injectable, achieved 20.9% weight loss at week 72. Clinical trial results suggest efficacy of injectable incretins may increase further. For example, retatrutide, an investigational incretin that combines three different mechanisms, achieved 24.2% overall weight loss at week 48 in a Phase 2 clinical trial. Furthermore, oral doses that achieve more competitive efficacy have often been observed to come with the tradeoff of worsened tolerability.
- *Tolerability*: Current GLP-1R agonists are not well-tolerated by all patients. Across obesity trials of injectable semaglutide and tirzepatide, up to 44% of subjects experienced gastrointestinal side effects such as nausea, diarrhea, and vomiting, which contributed to a discontinuation rate of up to 17%. The incidence of gastrointestinal adverse events is even higher with other oral GLP-1R agonists in late-stage third-party clinical trials. Because these adverse effects appear to be dose-dependent, we

believe combination approaches with APJ agonists may provide an opportunity to achieve weight reduction goals using a lower and therefore potentially more tolerable dose of GLP-1R agonists.

- *Body composition*: The benefits of weight loss mediated by GLP-1R agonists can be compromised by suboptimal body composition—the balance of lean and fat mass. In older patients, up to half of the weight loss is comprised of lean body mass, which is primarily muscle. Suboptimal body composition has been linked to several adverse treatment outcomes including rebound weight gain and impaired physical function, especially in older patients.

We have initiated a Phase 2 clinical trial and are planning a second Phase 2 clinical trial of azelaprag in combination with injectable GLP-1R agonists, as these drugs are approved; however our ultimate objective is to develop an all-oral weight loss combination with an oral incretin. Dosing oral incretin drugs in combination with orally administered azelaprag could provide well-tolerated weight loss in line with that achieved by injectable agonists alone, as well as superior body composition.

Our azelaprag clinical development strategy

We are initiating two Phase 2 clinical trials of azelaprag in combination with GLP-1R agonists. The first of these trials, STRIDES, is an ongoing clinical trial of azelaprag in combination with tirzepatide in approximately 220 obese individuals aged 55 and over, an age group that represents 35-40% of the adult obese population in the U.S. We are initially focusing on these older patients because the muscle and metabolic benefits of azelaprag observed in our Phase 1b clinical trial were achieved in older patients. The goal of the STRIDES clinical trial is to establish proof of concept for enhanced weight loss. The primary endpoint of this trial will be weight loss at 24 weeks. In addition, biomarkers, changes in body composition and glucose control will be assessed as exploratory endpoints. We anticipate trial initiation in and topline results in .

We have a material transfer agreement with Lilly, under which Lilly has agreed to provide us with tirzepatide in connection with our STRIDES clinical trial of azelaprag in obesity. Lilly's Chorus clinical development organization is advising and assisting on all aspects of the Phase 2 STRIDES clinical trial design and execution, enabling us to benefit from Lilly's extensive clinical experience in this space, while retaining all rights to azelaprag.

The goals of our second Phase 2 clinical trial are to demonstrate:

- A GLP-1R-like agonist class effect.
- Efficacy in a wider population that includes younger patients.
- Overall weight loss achieved after 52 weeks of treatment.

To that end, we intend to combine azelaprag with semaglutide in our second Phase 2 clinical trial and enroll approximately 300 obese individuals ages 18 and older. Trial initiation is anticipated in . The primary endpoint of this Phase 2 clinical trial will be weight loss at 52 weeks, with similar exploratory endpoints to the tirzepatide combination trial.

While we are currently planning Phase 2 clinical trials with azelaprag in combination with injectable GLP-1R agonists, as these drugs are already approved, our ultimate objective is to develop an all-oral weight loss combination with an oral incretin.

In parallel, we intend to initiate an insulin sensitivity proof-of-concept trial of azelaprag monotherapy in to support potential indication expansion. The goal of this clinical trial is to assess the potential direct benefits of azelaprag, informing potential subsequent development for treatment of obesity with comorbid type 2 diabetes in combination with a GLP-1R agonist.

We are also developing orally available, brain-penetrant inhibitors of NLRP3, a key target for neuroinflammation

We are developing brain-penetrant, structurally novel small molecule inhibitors of NLRP3 that have a novel binding site. NLRP3 is a component of a multi-protein complex referred to as the inflammasome. NLRP3-driven neuroinflammation has been linked to both obesity and neurodegenerative diseases. We intend to submit an IND for an NLRP3 inhibitor to the FDA in and, if cleared, initiate a Phase 1 trial to evaluate safety, tolerability, pharmacokinetics and pharmacodynamics in healthy volunteers.

Our Team and Investors

We have assembled a leadership team of experts in aging biology and drug development. Our senior team consists of the following members:

- Kristen Fortney, Ph.D., our Chief Executive Officer and co-founder. Dr. Fortney has extensive experience in aging biology, genetics and bioinformatics and systems biology from her work at Stanford and the University of Toronto.
- Eric Morgen, M.D., our Chief Operating Officer and co-founder. Dr. Morgen was previously on the faculty at the University of Toronto, where his research focused on biomarker discovery and characterization in high-dimensional datasets from human cohorts.
- Dov Goldstein, M.D., our Chief Financial Officer. Dr. Goldstein previously served as Chief Financial Officer at Vicuron Pharmaceuticals, Inc. and Loxo Oncology Inc., as well as a Managing Partner at Aisling Capital. He was most recently the Chief Financial Officer and Chief Business Officer of Indapta Therapeutics, Inc.
- Paul Rubin, M.D., our Chief Medical Officer. Dr. Rubin has over 35 years of experience in the biotechnology industry and has led 12 compounds to U.S. approval, with five led from discovery through approval, including Lunesta® and Xopenex®. He most recently served as Executive Vice President Research and Development at miRagen Therapeutics, Inc., and was previously Chief Medical Officer at XOMA Corporation and Executive Vice President Research and Development at Sepracor, Inc.
- Ann Neale, our Chief Development Officer. Ms. Neale has over 30 years of experience in the biotechnology industry. She was most recently Senior Vice President of Development Operations at Principia BioPharma Inc. (acquired by Sanofi S.A.), where she led operations and resourcing strategy for multiple global early- and late-phase clinical programs.
- Peng Leong, Ph.D., our Chief Business Officer. Dr. Leong has extensive experience in the biotech industry, previously serving in healthcare investment banking at Piper Jaffray and as Head of General Medicine Business Development at Merck KgaA and Chief Business Officer at Kazia Therapeutics Limited.
- BJ Sullivan, Ph.D., our Chief Strategy Officer. Dr. Sullivan was previously in L.E.K. Consulting's life sciences practice, where he advised biopharma companies on growth strategy and M&A.
- George Hartman, Ph.D. leads our drug discovery efforts. Dr. Hartman is a co-founder of Novira Therapeutics, Inc. and previously served as executive director of medicinal chemistry at Merck & Co., Inc. where he and his group identified and brought 12 drug candidates into Phase 2 or Phase 3 clinical trials.

We are backed by a strong set of healthcare-specific investors, including our 5% or greater stockholders, a16z Bio + Health, Khosla Ventures, Sofinnova Investments, Longitude Capital, RA Capital, Cormorant Asset Management, Kaiser Permanente, and Horsley Bridge. Prospective investors should not rely on the investment decisions of our existing investors, as these investors may have different risk tolerances and strategies and have

purchased their shares in prior offerings at prices lower than the price offered to the public in this offering. In addition, some of these investors may not be subject to reporting requirements under Section 16 of the Securities Exchange Act of 1934, as amended (the Exchange Act), and, thus, prospective investors may not necessarily know the total amount of investment by each of the prior investors and if and when some of the prior investors decide to sell any of their shares.

Our Strategy

Our goal is to develop a focused portfolio of therapies for metabolic disease by targeting the biology of human aging.

Our strategy is to:

- Apply novel insights into aging biology to build a pipeline of therapeutics to transform the treatment of chronic metabolic diseases.
- Efficiently advance the clinical development of azelaprag as a novel exercise mimetic for the treatment of obesity.
- Establish azelaprag as a key component of all-oral obesity therapy.
- Maximize the potential of azelaprag in adjacent indications, including diabetes.
- Advance an NLRP3 inhibitor for the treatment of neuroinflammation.
- Selectively partner our product candidates to maximize patient impact and shareholder value.

Risks Associated with Our Business

Our business is subject to a number of risks and uncertainties, including those highlighted in the section titled “Risk Factors” immediately following this prospectus summary. These risks include, among others, the following:

- We are a clinical-stage biopharmaceutical company with a limited operating history, have not completed any clinical trials beyond Phase 1b and have no products approved for commercial sale, which may make it difficult for investors to evaluate our business, likelihood of success and viability.
- We have incurred significant operating losses since our inception and expect to incur significant losses for the foreseeable future. We are not currently profitable, and may never achieve or sustain profitability. If we are unable to achieve or sustain profitability, the market value of our common stock will likely decline.
- Even if this offering is successful, we will require substantial additional capital to finance our operations and achieve our goals. If we are unable to raise capital when needed or on terms acceptable to us, we may be forced to delay, reduce or eliminate our research or development programs, any future commercialization efforts or other operations.
- We are substantially dependent on the success of our lead product candidate, azelaprag, which is currently in clinical development, and for which we have not completed a Phase 2 efficacy trial, and any future product candidates we may develop. If we are unable to advance the development of, receive regulatory approval for and ultimately successfully commercialize azelaprag or any future product candidates we may develop, or experience significant delays in doing so, our business will be materially harmed.
- Drug development is a lengthy and expensive process, the outcome of clinical testing is inherently uncertain, and results of earlier studies and trials may not be predictive of future trial results. We may

incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of azelaprag and any future product candidates for many reasons, including a failure to replicate positive results from earlier preclinical studies or clinical trials in ongoing or future preclinical studies or clinical trials.

- We are developing our lead product candidate, azelaprag, and may develop future product candidates, in combination with other therapies, which would expose us to additional risks.
- We expect to expand our development, clinical and regulatory capabilities and operations as we grow, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.
- Our quarterly and annual operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.
- Negative results or publicity for one obesity drug could have a substantial impact on all drugs and product candidates for the treatment of obesity, including ours.
- We have identified material weaknesses in our internal control over financial reporting. If our remediation of the material weaknesses is not effective, or if we experience additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls in the future, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our common stock.
- We rely, and intend to continue to rely, on third parties to conduct our clinical trials and perform some of our research and preclinical studies. If these third parties do not satisfactorily carry out their contractual duties, fail to comply with applicable regulatory requirements or do not meet expected deadlines, our development programs may be delayed or subject to increased costs or we may be unable to obtain regulatory approval, each of which may have an adverse effect on our business, financial condition, results of operations and prospects.
- The manufacture of pharmaceutical products, including our product candidates, such as azelaprag, is complex. Our third-party manufacturers may encounter difficulties in production, which could delay or entirely halt their ability to supply our product candidates for clinical trials or, if approved, for commercial sale.

If we are unable to adequately address these and other risks we face, our business, results of operations, financial condition and prospects may be harmed.

Corporate and Other Information

We were incorporated under the laws of the State of Delaware on April 1, 2015, under the name BioAge Labs, Inc.

Our principal executive offices are located at 1445A South 50th Street, Richmond, California 94804, and our telephone number is (510) 906-1445. Our website address is https://bioagelabs.com. The information contained on, or that can be accessed through, our website is not part of, and is not incorporated by reference into, this prospectus. We have included our website in this prospectus solely as a textual reference. Investors should not rely on any such information in deciding whether to purchase our common stock.

The BioAge marks and logos, along with our other registered or common law trade names, trademarks or service marks, appearing in this prospectus are valuable company assets and are the exclusive property of

BioAge. Solely for convenience, the trademarks, service marks and trade names referred to in this prospectus appear without the ® and ™ symbols, but this should not be interpreted as a waiver of any rights, and we fully reserve the right to assert and protect our intellectual property rights concerning our marks in accordance with applicable laws.

All other service marks, trademarks and trade names appearing in this prospectus are the property of their respective owners. Our use of third-party trade names, trademarks or service marks in this prospectus does not imply any affiliation with, endorsement by, or sponsorship by us of those companies.

Implications of Being an Emerging Growth Company and a Smaller Reporting Company

As a company with less than $1.235 billion in revenue during our last fiscal year, we qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012 (JOBS Act). An emerging growth company may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies. These provisions include, but are not limited to:

- being permitted to present only two years of financial statements and only two years of reduced related "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure in this prospectus;
- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended (Sarbanes-Oxley Act), on the effectiveness of our internal controls over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, unless the Securities and Exchange Commission (SEC) determines the new rules are necessary for protecting the public;
- reduced disclosure obligations regarding executive compensation arrangements in our periodic reports, proxy statements and registration statements; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We will remain an emerging growth company until the earliest to occur of: (i) the last day of the fiscal year in which we have more than $1.235 billion in annual revenue; (ii) the date we qualify as a "large accelerated filer," with at least $700.0 million of equity securities held by non-affiliates; (iii) the date on which we have issued, in any three-year period, more than $1.0 billion in non-convertible debt securities; and (iv) the last day of the fiscal year ending after the fifth anniversary of the completion of this offering.

We have elected to take advantage of certain of the reduced disclosure obligations for emerging growth companies in the registration statement of which this prospectus is a part and may elect to take advantage of other reduced reporting requirements in future filings. As a result, the information that we provide to our stockholders may be different than you might receive from other public reporting companies in which you hold equity interests.

The JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards, until those standards apply to private companies. We have elected to use this extended transition period to enable us to comply with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended

transition period provided in the JOBS Act. As a result, our financial statements may not be comparable to companies that comply with such new or revised accounting standards. Until the date that we are no longer an emerging growth company or affirmatively and irrevocably opt out of the exemption provided by Section 7(a)(2)(B) of the Securities Act of 1933, as amended, (Securities Act), upon issuance of a new or revised accounting standard that applies to our financial statements and that has a different effective date for public and private companies, we will disclose the date on which adoption is required for non-emerging growth companies and the date on which we will adopt the recently issued accounting standard.

We are also a "smaller reporting company," meaning that the market value of our capital stock held by non-affiliates plus the proposed aggregate amount of gross proceeds to us as a result of this offering is less than $700.0 million and our annual revenue is less than $100.0 million during the most recently completed fiscal year. We may continue to be a smaller reporting company after this offering if either (i) the market value of our capital stock held by non-affiliates is less than $250.0 million or (ii) our annual revenue was less than $100.0 million during the most recently completed fiscal year and the market value of our capital stock held by non-affiliates is less than $700.0 million. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K, we are not required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

The Offering

Common stock offered by us	shares.
Option to purchase additional shares	We have granted the underwriters an option to purchase up to additional shares of common stock from us at any time within 30 days from the date of this prospectus.
Common stock to be outstanding immediately after this offering	shares (or shares, if the underwriters exercise their option to purchase additional shares in full).
Use of proceeds	We estimate that the net proceeds from this offering will be approximately $ million (or approximately $ million if the underwriters exercise their option to purchase additional shares in full), based upon the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. We currently intend to use the net proceeds from this offering, together with our existing cash and cash equivalents, to advance the continued development of azelaprag for the treatment of obesity in our ongoing STRIDES clinical trial in combination with tirzepatide, a Phase 2 clinical trial in combination with semaglutide, and the manufacture of drug products to support Phase 3 clinical trials sufficient for registration; the initiation of an insulin sensitivity proof-of-concept trial of azaelaprag monotherapy; to advance the clinical development of an NLRP3 inhibitor for the treatment of neuroinflammation through the submission of an IND for an NLRP3 inhibitor, and, if cleared, the initiation of a Phase 1 clinical trial, as well as for other research and development activities and potential expansion of our pipeline, as well as for working capital and other general corporate purposes. See the section titled “Use of Proceeds” for additional information.
Risk factors	Investing in our common stock involves a high degree of risk. You should read the section titled “Risk Factors” in this prospectus for a discussion of factors to consider carefully before deciding to invest in shares of our common stock.
Proposed Nasdaq trading symbol	“BAGE”

The number of shares of our common stock to be outstanding after this offering is based on shares of our common stock outstanding as of June 30, 2024, after giving effect to the automatic conversion of all shares of our outstanding redeemable convertible preferred stock as of June 30, 2024 into an aggregate of shares of our common stock in connection with the completion of this offering, and excludes:

- 20,183,532 shares of our common stock issuable upon the exercise of stock options outstanding as of June 30, 2024 under our 2015 Equity Incentive Plan, as amended (2015 Plan), with a weighted-average exercise price of $1.89 per share;
- shares of our common stock issuable upon the exercise of stock options granted after June 30, 2024, under our 2015 Plan, with a weighted-average exercise price of $ per share;
- 30,000 shares of common stock issuable upon exercise of a warrant outstanding as of June 30, 2024, with an exercise price of $0.72 per share;
- 111,436 shares of common stock issuable upon exercise of warrants outstanding as of June 30, 2024, with an exercise price of $2.30 per share;
- shares of our common stock reserved for future issuance under our 2024 Equity Incentive Plan (2024 Plan), which will become effective in connection with this offering (including shares reserved for issuance under our 2015 Plan which shares will be added to the 2024 Plan upon its effectiveness); and
- shares of our common stock to be reserved for future issuance under our 2024 Employee Stock Purchase Plan (ESPP), which will become effective in connection with this offering.

Our 2024 Plan and our ESPP provide for automatic annual increases in the number of shares of our common stock reserved thereunder. Such increases are not reflected in the numbers, above. For additional information regarding our 2015 Plan, 2024 Plan and ESPP, see the section titled “Executive Compensation—Equity Compensation Plans and Other Benefit Plans”.

Except as otherwise indicated, all information in this prospectus assumes or gives effect to the following:

- the automatic conversion of all shares of our convertible redeemable preferred stock outstanding as of June 30, 2024 into an aggregate of shares of our common stock in connection with the completion of this offering;
- a -for- reverse stock split of our common stock, which was effected on , 2024;
- the adoption, filing, and effectiveness of our restated certificate of incorporation and bylaws, each of which will occur immediately prior to the completion of this offering;
- no exercise of the outstanding options or warrants described above; and
- no exercise by the underwriters of their option to purchase additional shares of our common stock.

Summary Consolidated Financial Data

The following tables set forth our summary consolidated statements of operations and comprehensive loss and balance sheet data as of the dates indicated. The summary condensed consolidated statements of operations and comprehensive loss data for the years ended December 31, 2023 and 2022 are derived from our audited consolidated financial statements included elsewhere in this prospectus. The summary consolidated statements of operations and comprehensive loss data for the six months ended June 30, 2024 and 2023, and the summary consolidated balance sheet data as of June 30, 2024, are derived from our unaudited interim condensed consolidated financial statements included elsewhere in this prospectus. The unaudited interim condensed consolidated financial statements have been prepared on the same basis as our annual audited summary consolidated financial statements and, in the opinion of management, reflect all adjustments, which include only normal, recurring adjustments that are necessary to present fairly the unaudited interim condensed consolidated financial statements. The following summary consolidated financial data should be read in conjunction with the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and the related notes included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results that may be expected in any future period and results for the six months ended June 30, 2024 are not necessarily indicative of results to be expected for the full year ending December 31, 2024 or any other period. The summary consolidated financial data in this section are not intended to replace our consolidated financial statements and are qualified in their entirety by the consolidated financial statements and related notes included elsewhere in this prospectus.

	Year Ended December 31,		Six Months Ended June 30,	
	2023	2022	2024	2023
			(unaudited)	
	(in thousands, except share and per share amounts)			
Consolidated Statements of Operations and Comprehensive Loss Data:				
Operating expenses:				
Research and development	$ 33,886	$ 30,522	$ 19,792	$ 17,272
General and administrative	14,514	9,447	8,290	7,645
Total operating expenses	48,400	39,969	28,082	24,917
Loss from operations	(48,400)	(39,969)	(28,082)	(24,917)
Interest expense	(7,794)	(241)	(1,660)	(2,832)
Interest and other income	2,431	465	3,497	1,553
Gain (loss) from changes in fair value on derivative liability and warrants	(10,091)	23	(78)	(2,075)
Loss on extinguishment of convertible promissory notes	—	—	(250)	—
Total other income (expense)	(15,454)	247	1,509	(3,354)
Net loss	$ (63,854)	$ (39,722)	$ (26,573)	$ (28,271)
Net loss per share attributable to common stockholders, basic and diluted[1]	$ (8.55)	$ (5.32)	$ (3.52)	$ (3.79)
Weighted-average common shares outstanding, basic and diluted[1]	7,465,008	7,460,403	7,551,784	7,464,578
Comprehensive Loss				
Net Loss	(63,854)	(39,722)	(26,573)	(28,271)
Foreign translation adjustment	(3)	246	3	32
Total comprehensive loss	$ (63,857)	$ (39,476)	$ (26,570)	$ (28,239)

	Year Ended December 31,		Six Months Ended June 30,	
	2023	2022	2024	2023
			(unaudited)	
	(in thousands, except share and per share amounts)			
Unaudited pro forma net loss per share of common stock, basic and diluted[2]	$	$	$	$
Unaudited pro forma weighted-average shares outstanding, basic and diluted[2]				

(1) See Note 11 to our audited consolidated financial statements and unaudited condensed consolidated financial statements included elsewhere in this prospectus for further details on the calculation of historical net loss per share and the weighted-average number of shares of common stock used in the computation of the per share amounts.

(2) The unaudited pro forma basic and diluted net loss per share attributable to common stockholders for the year ended December 31, 2023 was computed using the weighted-average number of shares of common stock outstanding, including the pro forma effect of the automatic conversion of all outstanding shares of our redeemable convertible preferred stock into shares of our common stock on the later of January 1, 2023 or the date the shares were issued.

	As of June 30, 2024		
	Actual	Pro Forma[1]	Pro Forma As Adjusted[2]
		(unaudited)	
	(in thousands, except share and per share amounts)		
Consolidated Balance Sheet Data:			
Cash and cash equivalents	$ 159,085	$	$
Working capital[3]	150,671		
Total assets	164,402		
Total redeemable convertible preferred stock	342,831		
Total stockholders' (deficit) equity	(197,131)		

(1) Pro forma amounts give effect to (i) the automatic conversion of all outstanding shares of our redeemable convertible preferred stock as of June 30, 2024 into an aggregate of shares of our common stock and the related reclassification of the carrying value of the redeemable convertible preferred stock to permanent equity immediately prior to the completion of this offering and (ii) the issuance of shares of common stock pursuant to the net exercise of warrants to purchase shares of common stock immediately prior to the completion of this offering and the filing and effectiveness of our restated certificate of incorporation.

(2) Pro forma as adjusted amounts reflect pro forma adjustments described in footnote (1) above, as well as the sale of shares of our common stock in this offering, based upon the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. The pro forma as adjusted information is illustrative only and will change based on the actual initial public offering price and other terms of this offering determined at pricing. Each $1.00 increase or decrease in the assumed initial public offering price of $ per share would increase or decrease, as applicable, the pro forma as adjusted amount of each of our cash and cash equivalents, working capital, total assets and total stockholders' (deficit) equity by approximately $ million, assuming that the number of shares offered by us, as set forth on the cover of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions. Similarly, each increase or decrease of 1,000,000 in the number of shares offered by us in this offering would increase or decrease, as applicable, the pro forma as adjusted amount of each of our cash and cash equivalents, working capital, total assets and total stockholders' (deficit) equity by approximately $ million, assuming the assumed initial offering price remains the same and after deducting the estimated underwriting discounts and commissions.

(3) We define working capital as current assets less current liabilities. See our audited consolidated financial statements and unaudited condensed consolidated financial statements and the related notes included elsewhere in this prospectus for further details regarding our current assets and current liabilities.

RISK FACTORS

Investing in our common stock involves a high degree of risk. Before making your decision to invest in shares of our common stock, you should carefully consider the risks described below, together with the other information contained in this prospectus, including in the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and in our consolidated financial statements and the related notes included elsewhere in this prospectus. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are unaware of or that we deem immaterial may also become important factors that adversely affect our business. We cannot assure you that any of the events discussed below will not occur. These events could have a material and adverse impact on our business, financial condition, results of operations and prospects. If that were to happen, the trading price of our common stock could decline, and you could lose all or part of your investment.

Risks Related to Our Financial Position, Limited Operating History and Need for Additional Capital

We are a clinical-stage biopharmaceutical company with a limited operating history, have not completed any clinical trials beyond Phase 1b and have no products approved for commercial sale, which may make it difficult for investors to evaluate our business, likelihood of success and viability.

We are a clinical-stage biopharmaceutical company with a limited operating history on which to base your investment decision. Drug development is a highly speculative undertaking and involves a substantial degree of risk. It entails substantial upfront capital expenditures and significant risk that any product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval or become commercially viable. We commenced operations in 2015, have no products approved for commercial sale and have never generated any revenue. To date, we have devoted substantially all of our resources to identifying, acquiring and developing our product candidates and licensed technologies, building our pipeline, performing research, conducting preclinical studies and early-stage clinical trials, organizing and staffing our company, business planning, establishing and maintaining our intellectual property portfolio, establishing arrangements with third parties for the manufacture of our product candidates, raising capital and providing general and administrative support for these operations.

To date, we have funded our operations with proceeds from sales of our redeemable convertible preferred stock, convertible notes and proceeds from stock option exercises. From inception through June 30, 2024, we received an aggregate of $293.8 million in gross proceeds from sales of our redeemable convertible preferred stock, an aggregate of $26.4 million in gross proceeds from sales of our convertible notes, and $0.5 million in proceeds from stock option exercises.

We have not yet demonstrated an ability to successfully complete any clinical trials beyond our Phase 1 and Phase 1b clinical trials for azelaprag, obtain regulatory approvals, manufacture a commercial-scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. As a result, it may be more difficult for you to accurately predict our likelihood of success and viability than it could be if we had a longer operating history.

In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors and risks frequently experienced by clinical-stage biopharmaceutical companies. We also may need to transition from a company with a research and development focus to a company capable of supporting commercial activities. We have not yet demonstrated an ability to successfully overcome such risks and difficulties, or to make such a transition. If we do not adequately address these risks and difficulties or successfully make such a transition, our business will suffer.

We have incurred significant operating losses since our inception and expect to incur significant losses for the foreseeable future. We are not currently profitable, and may never achieve or sustain profitability. If we are unable to achieve or sustain profitability, the market value of our common stock will likely decline.

We have incurred significant operating losses since our inception and expect to incur significant losses for the foreseeable future. We do not have any products approved for sale and have not generated any product revenue since our inception. If our lead product candidate, azelaprag, nor any future product candidates are successfully developed, approved and commercialized, we may never generate significant revenue, if we generate any revenue at all. Our net losses were $63.9 million and $39.7 million for the years ended December 31, 2023 and 2022, respectively, and $26.6 million and $28.3 million for the six months ended June 30, 2024 and 2023, respectively. As of June 30, 2024, we had an accumulated deficit of $208.3 million. Substantially all of our losses have resulted from expenses incurred in connection with the development of, and in-licensing of intellectual property related to, azelaprag, the research and development of our NLRP3 program, our longitudinal human aging platform and from general and administrative costs associated with our operations. Azelaprag and any future product candidates will require substantial additional development time and resources before we would be able to apply for or receive regulatory approvals and begin generating revenue from product sales. We expect to continue to incur losses for the foreseeable future, and we anticipate these losses will increase substantially in connection with our additional ongoing and planned clinical trials for azelaprag including our ongoing STRIDES clinical trial for azelaprag in combination with tirzepatide and our planned Phase 2 clinical trial in combination with semaglutide, our planned initiation of an insulin sensitivity proof-of-concept trial of azelaprag monotherapy to support potential indication expansion; and our planned IND submission and Phase 1 clinical trial for an NLRP3 inhibitor for the treatment of neuroinflammation; and as we continue our development of, seek regulatory approval for and potentially commercialize azelaprag and any future product candidates we may develop and become a public company.

In addition, in May 2022, we entered into a loan and security agreement (the Loan Agreement) with SVB Innovative Credit Growth Fund IX, LP and Innovative Credit Growth Fund VIII-A, LP (collectively, the Lenders) pursuant to which we were able to borrow up to an aggregate of $25.0 million across two potential tranches until December 31, 2023 (the Term Loan). The Term Loan is secured by a lien covering substantially all of our assets, but not including our intellectual property or non-assignable licenses. In connection with the Term Loan, the Lenders were concurrently issued warrants to purchase 111,436 shares of our common stock at an exercise price of $2.30 per share, with a term of 10 years. The Loan Agreement required us to pay monthly interest payments until November 1, 2023, after which we commenced monthly principal payments. As of June 30, 2024 we had $11.0 million outstanding principal under the Term Loan. The Term Loan matures by April 1, 2026.

To become and remain profitable, we must succeed in developing, obtaining regulatory approvals for, and eventually commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing clinical trials of azelaprag and identifying, discovering, developing, in-licensing or acquiring any future product candidates, obtaining regulatory approval for azelaprag and any future product candidates, and manufacturing, marketing, and selling any products for which we may obtain regulatory approval. We are only in the preliminary stages of these activities. We may never succeed in these activities and, even if we do, may never generate revenue that is significant enough to achieve profitability. Because of the numerous risks and uncertainties associated with biopharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable may have an adverse effect on the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product candidates, achieve our strategic objectives or even continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

Even if this offering is successful, we will require substantial additional capital to finance our operations and achieve our goals. If we are unable to raise capital when needed or on terms acceptable to us, we may be forced to delay, reduce or eliminate our research or development programs, any future commercialization efforts or other operations.

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. Our operations have consumed substantial amounts of cash since inception, and we expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance azelaprag and any future product candidates through clinical development. We expect increased expenses as we continue our research and development, continue our clinical trials, initiate additional clinical trials, seek to expand our product pipeline and clinical applications, seek regulatory approval for our current and future product candidates and invest in our organization. In addition, if we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. Because the outcome of any preclinical study or clinical trial is highly uncertain, we cannot reasonably estimate the actual amount of capital necessary to successfully complete the development and commercialization of our product candidates. Furthermore, upon the closing of this offering, we expect to incur additional costs associated with operating as a public company that we did not incur as a private company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations.

We had $159.1 million in cash and cash equivalents as of June 30, 2024. Based on our current operating plan, we believe that the net proceeds from this offering, together with our existing cash and cash equivalents will be sufficient for us to fund our operations into . We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Changes beyond our control may occur that would cause us to use our available capital before that time, including changes in and progress of our drug development activities and changes in regulation. Our future capital requirements will be dependent on many factors, including:

- the progress, timing and results of preclinical studies and clinical trials for azelaprag or any future product candidates;
- the extent to which we develop, in-license or acquire any future product candidates or technologies;
- the number of future product candidates and additional indications for our current product candidates we may pursue, and the preclinical studies and clinical trials necessary to develop them;
- the costs, timing and outcome of seeking regulatory approvals of our current or future product candidates;
- the scope and costs of making arrangements with third-party manufacturers, or establishing manufacturing capabilities, for both clinical and commercial supplies of our current or future product candidates;
- the costs involved in growing our organization to the size needed to allow for the research, development and potential commercialization of our current or future product candidates;
- the costs associated with commercializing any approved product candidates, including establishing sales, marketing, market access and distribution capabilities;
- to the extent we pursue strategic collaborations, including collaborations to commercialize azelaprag or any of our future product candidates, our ability to establish and maintain collaborations on favorable terms, if at all, as well as the timing and amount of any milestone or royalty payments we are required to make or are eligible to receive under such collaborations or our current licenses;
- the costs associated with completing any post-marketing studies or trials required by the U.S. Food and Drug Administration (FDA) or other regulatory authorities;

- the revenue, if any, received from commercial sales of azelaprag or any of our future product candidates, if any are approved;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims that we may become subject to, including any litigation costs and the outcome of such litigation; and
- the costs associated with potential product liability claims, including the costs associated with obtaining insurance against such claims and with defending against such claims.

Even if this offering is successful, we will require additional capital to complete our planned clinical development programs for our current product candidates in order to seek regulatory approval, and we anticipate needing to raise additional capital to complete the development of, and eventually commercialize, our product candidates, if approved. Adequate additional financing may not be available to us on favorable terms, or at all. Our ability to raise additional funds will be dependent on financial, economic and market conditions, geopolitical issues and other factors, over which we may have limited or no control. 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. If adequate funds are not available on commercially acceptable terms when needed, we may be forced to delay, reduce or terminate the development or commercialization, if approved, of all or part of our research programs or product candidates or we may be unable to take advantage of future business opportunities. Furthermore, any additional capital-raising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our current and any future product candidates, if approved. Changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned.

We will be required to obtain further funding through public or private equity financings, debt financings, collaborative agreements, licensing arrangements or other sources of financing, which may dilute our stockholders or restrict our operating activities. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, each investor's ownership interests will be diluted, and the terms may include liquidation or other preferences that adversely affect each investor's rights as a stockholder. Debt financing or preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Such restrictions could adversely impact our ability to conduct our operations and execute our business plan. If we raise additional funds through upfront payments or milestone payments pursuant to strategic collaborations with third parties, we may have to relinquish valuable rights to our product candidates or grant licenses on terms that are not favorable to us.

Our failure to raise capital as and when needed or on acceptable terms could significantly harm our business, financial condition, results of operations and prospects and cause the price of our common stock to decline, and we may have to delay, reduce the scope of, suspend or eliminate one or more of our research or drug development programs, preclinical studies, clinical trials or future commercialization efforts.

Risk Related to Research, Discovery, Development, Regulatory Approval and Commercialization of our Product Candidates

We are substantially dependent on the success of our lead product candidate, azelaprag, which is currently in clinical development, and for which we have not completed a Phase 2 efficacy trial and any future product candidates we may develop. If we are unable to advance the development of, receive regulatory approval for and ultimately successfully commercialize azelaprag or any future product candidates we may develop, or experience significant delays in doing so, our business will be materially harmed.

Our future success is highly dependent on our ability to timely complete successful clinical trials, obtain regulatory approval for, and then successfully commercialize our lead product candidate azelaprag and any future product candidates, which may never occur. We are early in our development efforts with respect to azelaprag, for which we recently completed our Phase 1 and Phase 1b clinical trials. We are developing brain-penetrant structurally novel small molecule inhibitors of NLRP3 that have a novel binding site, which are in earlier stages of development. We currently have no products that are approved for sale in any jurisdiction. There can be no assurance that azelaprag or any future product candidates we develop will achieve success in its respective clinical trials or obtain regulatory approval. We may also become dependent on other product candidates that we may develop or acquire in the future. Given our early stage of development, it may be several years, if at all, before we have demonstrated the safety and efficacy of a product candidate sufficient to warrant approval for commercialization.

Our ability to generate product revenue, which we do not expect will occur for many years, if ever, will be heavily dependent on the successful development and eventual commercialization of azelaprag and any future product candidates. The success of azelaprag and any future product candidates will be dependent on several factors, including the following:

- successful and timely completion of preclinical studies and clinical trials demonstrating attractive, competitive target product profiles for our product candidates;
- clearance of INDs by the FDA or other similar clinical trial applications from other regulatory authorities for our future clinical trials for our pipeline product candidates;
- timely and successful enrollment of patients in, and completion of, clinical trials with favorable results;
- demonstration of safety, efficacy and acceptable risk-benefit profiles of our product candidates to the satisfaction of the FDA and other comparable foreign regulatory agencies;
- receipt of regulatory approvals from applicable regulatory authorities, if granted, including the completion of any required post-marketing studies or trials and available funding to perform any post-marketing commitments;
- raising additional funds necessary to complete clinical development of and commercialize our current or future product candidates;
- obtaining, protecting and enforcing our patent, trade secret and other intellectual property and regulatory exclusivity for our current and future product candidates;
- making arrangements with third-party manufacturers, or establishing manufacturing capabilities, for both clinical and commercial supplies of our current and future product candidates and ensuring a resilient, effective supply chain that produces supply that outpaces demand;
- developing and implementing marketing and reimbursement strategies, as well as adequate demand forecasts for supply and sales planning;
- establishing sales, marketing and distribution capabilities and launching commercial sales of our products, if and when approved, whether alone or in collaboration with others in a market where promotional sales approaches are rapidly moving to digital platforms;

- demonstration of product characteristics attractive to physicians, patients, advocates, payors and caregivers;
- acceptance of our products, if and when approved, by patients, the medical community and third-party payors underpinned by adequate health economic data and a meaningful value proposition;
- effectively competing with other therapies, including those that have not yet entered the market;
- obtaining and maintaining third-party payor coverage and adequate reimbursement in both public and private payor spaces, given the significant number of obese patients in the United States who my benefit from our product candidates;
- obtaining appropriate support from patient advocacy organizations;
- addressing any delays in our clinical trials resulting from any major natural disasters, health pandemics or significant political events; and
- maintaining a continued acceptable safety profile of the products following approval.

Many of these factors are beyond our control, and it is possible that none of our product candidates will ever obtain regulatory approval even if we expend substantial time and resources seeking such approval. If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, which would materially harm our business. For example, our business could be harmed if results of our ongoing or planned clinical trials of azelaprag show unexpected adverse events or a lack of efficacy in the indications we intend to treat or do not meet the clinical endpoints, or if we experience other regulatory or developmental issues.

Due to our limited resources and access to capital, we must, and have in the past decided to, prioritize development of certain product candidates over other potential product candidates. These decisions may prove to have been wrong and may adversely affect our ability to develop our own programs or our attractiveness as a commercial partner, and may ultimately have an impact on our commercial success.

Because we have limited resources and access to capital to fund our operations, we must decide which product candidates to pursue and the amount of resources to allocate to each. Our decisions concerning the allocation of research, collaboration, management and financial resources toward particular product candidates or therapeutic areas may not lead to the development of viable commercial products and may divert resources away from better opportunities. Similarly, any decisions to delay, terminate or collaborate with third parties in respect of certain product development programs may also prove not to be optimal and could cause us to miss valuable opportunities. If we make incorrect determinations regarding the market potential of our product candidates or misread trends in the biopharmaceutical industry, in particular for azelaprag, our business, financial condition and results of operations would be materially adversely affected.

Drug development is a lengthy and expensive process, the outcome of clinical testing is inherently uncertain, and results of earlier studies and trials may not be predictive of future trial results. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of azelaprag and any future product candidates for many reasons, including a failure to replicate positive results from earlier preclinical studies or clinical trials in ongoing or future preclinical studies or clinical trials.

Our lead product candidate, azelaprag, is in clinical development, and the risk of failure is high. It is impossible to predict when or if azelaprag or any future product candidates will prove effective and safe in humans or will receive regulatory approval. To obtain the requisite regulatory approvals to commercialize any product candidate, we must demonstrate through extensive preclinical studies and lengthy, complex and expensive clinical trials that our product candidates are safe and effective in humans. Clinical testing can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical

trial process. The results of preclinical studies and early clinical trials of azelaprag or any future product candidates, or a competitor's product candidate in the same class, may not be predictive of the results of later-stage clinical trials. For example, as is common in early-stage clinical trials, our Phase 1b bed rest atrophy clinical trial of azelaprag, conducted in a small number of healthy older individuals, evaluated a number of pharmacodynamic endpoints and biomarkers without correction for multiplicity. These results on measures of muscle size, quality and metabolism may not be replicated in later-stage clinical trials with different trial designs and patient populations. Interim, topline or preliminary results of a clinical trial are not necessarily indicative of final results. We may be unable to establish benefit on clinical endpoints that applicable regulatory authorities would consider clinically meaningful, and a clinical trial can fail at any stage of testing. Differences in trial design between early-stage clinical trials and later-stage clinical trials make it difficult to extrapolate the results of earlier clinical trials to later clinical trials. Moreover, clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in clinical trials have nonetheless failed to obtain regulatory approval of their products. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or to unfavorable safety profiles, notwithstanding promising results in earlier trials. There is typically a high rate of failure of product candidates proceeding through clinical trials, particularly in the earlier stages of development. Most product candidates that commence clinical trials are never approved as products, and there can be no assurance that any of our future clinical trials will ultimately be successful or support clinical development of azelaprag or any future product candidates.

We may experience delays in initiating or completing clinical trials. We also may experience numerous unforeseen events during, or as a result of, any future clinical trials that we could conduct that could delay or prevent our ability to receive regulatory approval or commercialize azelaprag or any future product candidates, including:

- regulators, institutional review boards (IRBs) or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site, or may halt or suspend an ongoing clinical trial;
- we may experience delays in reaching or fail to reach agreement on acceptable terms with prospective trial sites and prospective contract research organizations (CROs) the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical trial sites deviating from the trial protocol or dropping out of a trial;
- clinical trials of any product candidates may fail to show safety or efficacy, produce negative or inconclusive results and we may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials or we may decide to abandon product development programs;
- failure of our current or future product candidates in clinical trials to demonstrate important functional or patient-reported outcomes;
- the number of subjects required for clinical trials of any product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or subjects may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the trial, which may require that we add new clinical trial sites or investigators;
- we may elect, or regulators, IRBs, or ethics committees may require, that we or our investigators, suspend or terminate clinical research or trials for various reasons, including noncompliance with regulatory requirements or a finding that the participants in our trials are being exposed to unacceptable health risks;
- the cost of clinical trials of azelaprag or any future product candidates may be greater than we anticipate, and we may not have sufficient funds to complete such trials;

- the quality of azelaprag or any future product candidates or other materials necessary to conduct clinical trials of azelaprag or any future product candidates may be inadequate to initiate or complete a given clinical trial;
- our inability to manufacture sufficient quantities of azelaprag or any future product candidates for use in clinical trials;
- our inability to meet drug specifications suitable for use in clinical trials and commercial applications;
- reports from clinical testing of other therapies may raise safety or efficacy concerns about azelaprag or any future product candidates;
- the receipt of feedback from regulatory authorities that requires us to modify the design of our clinical trials;
- our failure to establish an appropriate safety profile for a product candidate based on clinical or preclinical data for such product candidate as well as data emerging from other molecules in the same class as azelaprag or any future product candidates; and
- the FDA or other regulatory authorities may require us to submit additional data such as long-term toxicology studies or impose other requirements before permitting us to initiate a clinical trial.

We could also encounter delays if a clinical trial is suspended or terminated by us, the IRBs of the institutions in which such trials are being conducted, or the FDA or other regulatory authorities, or if a clinical trial is recommended for suspension or termination by the Data Safety Monitoring Board for such trial. A suspension or termination may be imposed due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements, including the FDA's Good Clinical Practice (GCP) regulations, 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 or treatment, failure to establish or achieve clinically meaningful trial endpoints, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Clinical studies may also be delayed or terminated as a result of ambiguous or negative interim results. 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 azelaprag or any future product candidates. Further, the FDA or other regulatory authorities may disagree with our clinical trial design and our interpretation of data from clinical trials, or may change the requirements for approval even after they have reviewed and commented on the design for our clinical trials. For example, while the FDA has issued a draft guidance on developing products for weight management that describes appropriate efficacy endpoints for pivotal trials for product candidates for weight management, the guidance does not address endpoints related to change in body composition. While the FDA agreed with our primary endpoint of percent change in body weight for STRIDES, for change in body composition or muscle-related parameters we are currently examining or may examine in the future, we expect that we will have to demonstrate how any change in such parameters translates to clinical benefit.

We cannot predict with any certainty the schedule for commencement and completion of future clinical trials. Further, conducting clinical trials in foreign countries, as we have done and may do in the future for our product candidates, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks relevant to such foreign countries.

If we are required to conduct additional clinical trials or other testing of our current or future product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our current or future product candidates or other testing in a timely manner, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may incur unplanned costs, be

delayed in seeking and obtaining regulatory approval, if we receive such approval at all, receive more limited or restrictive regulatory approval, be subject to additional post-marketing testing requirements or have the drug removed from the market after obtaining regulatory approval.

Additionally, if the results of our clinical trials are inconclusive or if there are safety concerns or serious adverse events associated with our product candidates, we may:

- be delayed in obtaining regulatory approval, if at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired or may have restricted duration expectations or guidance;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to additional post-marketing testing requirements;
- be required to perform additional clinical trials to support approval or be subject to additional post-marketing testing requirements;
- have regulatory authorities withdraw, or suspend, their approval of the drug or impose restrictions on its distribution in the form of a Risk Evaluation and Mitigation Strategy (REMS);
- be subject to the addition of labeling statements, such as warnings or contraindications;
- be sued; or
- experience damage to our reputation.

Our drug development costs will also increase if we experience delays in testing or obtaining regulatory approvals. Also, delays in obtaining regulatory approval may increase commercialization costs if the competitive environment becomes more intense prior to market entry. We do not know whether any of our preclinical studies or clinical trials will begin as planned, need to be restructured or be completed on schedule, if at all.

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 other regulatory authorities. The FDA or other regulatory authorities 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 other regulatory authority, as the case may be, and may ultimately lead to the denial of regulatory approval of one or more of our product candidates.

In addition, many of the factors that cause, or lead to, termination or suspension of, or a delay in the commencement or completion of, clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. We may make formulation or manufacturing changes to our product candidates, in which case we may need to conduct additional preclinical studies to bridge our modified product candidates to earlier versions. If we experience delays in the commencement or completion of our clinical trials, or if we terminate a clinical trial prior to completion, the commercial prospects of our current or any future product candidates could be negatively impacted, and our ability to generate revenues from our current or future product candidates may be delayed or eliminated entirely.

We are developing our lead product candidate, azelaprag, and may develop future product candidates, in combination with other therapies, which would expose us to additional risks.

We are currently developing our lead product candidate, azelaprag, for use in combination with certain incretins for the treatment of obesity, and we may develop other product candidates for use in combination with

other therapies in the future. For example, our ongoing and planned Phase 2 trials of azelaprag are in combination with tirzepatide and semaglutide. The development of product candidates for use in combination with another product may present challenges that are not faced for single agent product candidates. Each of our Phase 2 trials of azelaprag in combination with tirzepatide and semaglutide, respectively, are designed to evaluate efficacy and it is possible that the results of these trials or future trials of azelaprag in combination with tirzepatide or semaglutide could show that azelaprag does not sufficiently contribute to the observed effects of individuals who participate in these trials. Even if any of our current or future product candidates were to receive regulatory approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA or other comparable foreign regulatory authorities could revoke approval of the therapy used in combination with any of our product candidates, or safety, efficacy, manufacturing or supply issues could arise with these existing therapies. In addition, it is possible that existing therapies with which our product candidates are approved for use could themselves fall out of favor or be relegated to later lines of treatment. This could result in the FDA or similar foreign regulatory authorities requiring us to conduct additional clinical trials, the need to identify other combination therapies for our product candidates or our own products being removed from the market or being less successful commercially.

If the FDA or other comparable foreign regulatory authorities do not approve or withdraw their approval of these other therapies, or if safety, efficacy, commercial adoption, manufacturing or supply issues arise with the therapies we choose to evaluate in combination with any of our current or future product candidates, we may be unable to obtain approval of or successfully market any one or all of the current or future product candidates we develop. Additionally, if the third-party providers of therapies or therapies in development used in combination with our current or future product candidates are unable to produce sufficient quantities for clinical trials or for commercialization of our current or future product candidates, such as in connection with our material transfer agreement with Eli Lilly (Lilly) for certain amounts of tirzepatide to be used in connection with our planned clinical trials of azelaprag, or if the cost of combination therapies are prohibitive, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and prospects.

Preliminary, topline or interim data from our clinical trials that we announce or publish from time to time may change as more patient data become available and/or are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary, topline or interim data from our clinical trials, such as preliminary, topline or interim or data analysis from our ongoing and planned Phase 2 clinical trials of azelaprag. These data and related findings and conclusions may only reflect certain endpoints rather than all endpoints and are subject to change. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the preliminary or topline results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated.

Preliminary or topline data also remain subject to review and verification procedures that may result in the final data being materially different from the preliminary or topline data we previously published. As a result, preliminary and topline data should be viewed with caution until the final data are available. In addition, we may report preliminary data or interim analyses of the clinical trials we may conduct and complete, which are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse changes between preliminary or interim data and final data could significantly harm our business and prospects. Further, additional disclosure of preliminary or interim data by us, including, for example, preliminary or interim data that becomes available to us from our ongoing and planned Phase 2 clinical trials of azelaprag or by our competitors in the future could result in volatility in the price of our common stock.

Further, the information we choose to publicly disclose regarding a particular study or clinical trial is typically selected from a more extensive amount of available information. You or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product, product candidate or our business. If the preliminary, topline or interim data that we report differ from later, final or actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, financial condition, results of operations and prospects.

We may not be successful in applying our longitudinal human aging platform to identify additional targets with therapeutic and commercial potential or in the discovery and development of commercially viable product candidates for us or our collaborators.

We use our longitudinal human aging platform to identify and prioritize potential drug targets, to assess the likelihood that we can develop a product candidate that interacts with the target to elicit the desired therapeutic effect, and to transition these insights efficiently into well supported therapeutic candidates. While we believe our platform will increase the likelihood of producing additional product candidates that provide meaningful clinical benefit, past success in identifying potential product candidates does not assure future success for our internal drug discovery programs. Our longitudinal human aging platform is novel, and we may not succeed in applying our platform to identify additional drug targets or transition these targets into promising future product candidates. We similarly cannot provide any assurance that, even if we do successfully identify additional targets, we will be able to successfully develop future product candidates and advance any such future product candidates into and through clinical development. Therefore, we are unable to predict the time and cost associated with the identification and development of any future product candidate or whether the application of our platform will result in the identification, development and ultimately regulatory approval of any future product candidates.

Efforts through our platform to identify, discover, acquire or in-license, and ultimately develop, product candidates require substantial technical, financial and human resources, whether or not any such future product candidates are ultimately identified. Our efforts may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development or regulatory approval for many reasons, including the following:

- the methodology used may not be successful in identifying any future potential product candidates;
- competitors may develop alternatives that render any product candidates we develop obsolete;
- any product candidates we develop may nevertheless be covered by third parties' patents or other exclusive rights;
- a product candidate may be shown, in subsequent preclinical or clinical investigations, to have harmful side effects or characteristics that indicate it is unlikely to be effective, or otherwise would not meet applicable regulatory criteria;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- a product candidate may not be accepted as safe and effective by physicians, patients, the medical community or third-party payors.

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

Our future growth may be dependent, in part, on our ability to develop and commercialize azelaprag, if approved, and any future product candidates in foreign markets for which we may rely on collaboration with

third parties. We are not permitted to market or promote azelaprag or any future product candidates before we receive regulatory approval from the applicable regulatory authority in that foreign market and may never receive such regulatory approval for azelaprag or any future product candidates. To obtain separate regulatory approval in many other countries, we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution of azelaprag or any future product candidates, and we cannot predict success in these jurisdictions. If we fail to comply with the regulatory requirements in international markets and receive applicable regulatory approvals, our target market will be reduced and our ability to realize the full market potential of azelaprag or any future product candidates will be harmed, and our business will be adversely affected. We may not obtain foreign regulatory approvals on a timely basis, if at all. Our failure to obtain approval of any of azelaprag or any future product candidates by regulatory authorities in another country may significantly diminish the commercial prospects of that product candidate and our business, financial condition, results of operations and prospects could be materially and adversely affected. Moreover, even if we obtain approval of azelaprag or any future product candidates and ultimately commercialize azelaprag or any future product candidates in foreign markets, we would be subject to the risks and uncertainties, including the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements and reduced protection of intellectual property rights in some foreign countries.

We may experience difficulty enrolling or keeping patients in our clinical trials, which could delay or prevent us from proceeding with, or otherwise adversely affect, clinical trials of our product candidates.

Our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition could reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, it is possible that we will be required to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which could negatively impact the number of patients who are available for our clinical trials in such clinical trial site.

Delays related to patient enrollment and difficulties related to patient retention may result in increased costs or may affect the timing or outcome of our future clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates. Further, if patients drop out of our clinical trials, miss scheduled doses or follow-up visits, or otherwise fail to follow clinical trial protocols, the integrity of data from our clinical trials may be compromised or not accepted by the FDA or other regulatory authorities, which would represent a significant setback for the applicable program.

Our current or future product candidates may not achieve adequate market acceptance among physicians, patients or their families, healthcare payors and others in the medical community necessary for commercial success.

Even if our current or future product candidates receive regulatory approval, they may not gain adequate market acceptance among physicians, patients or their families, third-party payors and others in the medical community. The degree of market acceptance of any of our approved product candidates will be dependent on a number of factors, including:

- the efficacy, durability and safety profile as demonstrated in clinical trials compared to alternative treatments, in addition to patient-reported outcomes;
- the timing of market introduction of the product candidate, as well as competitive products;
- the clinical indications for which a product candidate is approved;
- restrictions on the use of product candidates in the labeling approved by regulatory authorities, such as boxed warnings or contraindications in labeling, or a REMS, if any, which may not be required of alternative treatments and competitor products;

- the potential and perceived advantages of our current or future product candidates over alternative treatments;
- the cost of treatment in relation to alternative treatments and the cost/benefit ratios of each;
- the availability of coverage and adequate reimbursement by third-party payors, including government authorities, given the significant number of obese patients in the United States, and timing of relevant formulary decision-making resulting in this coverage and reimbursement;
- the availability of an approved product for use as a combination therapy;
- relative convenience and ease of administration in relation to competition;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the effectiveness of sales, marketing efforts and market access;
- publicity relating to our product candidates or those of our competitors; and
- the approval of new therapies for the same indications.

If any of our current or future product candidates are approved but do not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors and patients, we may not generate or derive sufficient revenue from that product candidate and our financial results would be negatively impacted.

We have never commercialized a product candidate as a company before and currently lack the comprehensive, fully staffed expertise, personnel and resources to successfully commercialize any products on our own or together with suitable collaborators. If, in the future, we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market any product we may develop, we may not be successful in commercializing those products if they are approved.

We do not have a sales or marketing infrastructure and have no experience in the sales, marketing or distribution of any current or future product candidates. To achieve commercial success for any approved product, we must either develop a sales and marketing organization or outsource these functions to third parties. In the future and if any of our product candidates are approved, we may choose to build a focused sales, marketing and commercial support infrastructure to sell, or participate in sales activities with collaborators for some of our current or future product candidates.

There are risks involved with both establishing our own commercial capabilities and entering into arrangements with third parties to perform these services. For example, factors that may inhibit our efforts to commercialize any approved product candidates include:

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

- unforeseen costs and expenses associated with creating an independent commercialization organization.

If the commercial launch of a product candidate, if approved, 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 our commercialization personnel.

If we enter into arrangements with third parties to perform sales, marketing, commercial support and distribution services, our sales revenue or the profitability of sales revenue may be lower than if we were to do so ourselves. In addition, we may not be successful in entering into arrangements with third parties to commercialize our product candidates or may be unable to do so on terms that are favorable to us. 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 product candidates effectively. If we do not establish commercialization capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates, if approved.

Risks Related to Our Business and Operations

Our future performance is dependent on our ability to retain key employees and to attract, retain and motivate qualified personnel and manage our human capital.

Our ability to compete in the highly competitive biotechnology and biopharmaceutical industries is largely dependent on our ability to attract, motivate and retain highly qualified managerial, clinical, scientific and medical personnel. We are highly dependent on the scientific and management expertise of Dr. Fortney, our Chief Executive Officer, the other members of our management team and other key employees and advisors. We currently do not maintain “key person” life insurance on these individuals or any of our employees. This lack of insurance means that we may not have adequate compensation for the loss of the services of any such individuals. The loss of one or more members of our management team or other key employees or advisors could delay our research and development programs and have a material and adverse effect on our business, financial condition, results of operations and prospects. We are dependent on the continued service of our technical personnel, because of the highly technical nature of drug development and the specific knowledge related to azelaprag or any future product candidates and technologies, and the specialized nature of the regulatory approval process. Because our management team and key employees are not obligated to provide us with continued service, they could terminate their employment with us at any time without penalty.

In addition, job candidates and existing employees often consider the value of the stock awards they receive in connection with their employment. If the perceived benefits of our stock awards decline, either because we are a public company or for other reasons, it may harm our ability to recruit and retain highly skilled employees. Our employees may be more likely to leave us if the shares they own have significantly appreciated in value relative to the original purchase prices of the shares, or if the exercise prices of the options that they hold are significantly below the market price of our common stock, particularly after the expiration of the lock-up agreements described herein.

We are currently a remote-based company, with a majority of our employees working remotely, and we primarily conduct our in-person operations at our research facility in Richmond, California. This region is headquarters to many other biopharmaceutical companies and academic and research institutions. Competition for skilled personnel in our market, and nationally, is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all. We also face competition for personnel from other companies, universities, public and private research institutions, government entities and other organizations. Our industry has experienced a high rate of turnover of management personnel in recent years. Our future performance will be dependent in large part on our continued ability to attract and retain highly qualified scientific, technical and

management personnel, as well as personnel with expertise in clinical testing, manufacturing, governmental regulation and commercialization. If we are unable to continue to attract and retain high-quality personnel, the rate and success at which we can discover and develop product candidates will be limited, which could have a material and adverse effect on our business, financial condition, results of operations and prospects.

Our quarterly and annual operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.

We expect our operating results to be subject to quarterly fluctuations. Our net loss and other operating results will be affected by numerous factors, including:

- variations in the level of expense related to the ongoing development of azelaprag or any future development programs;
- results of preclinical studies and clinical trials, or the addition or termination of future clinical trials or funding support by us, or existing or future collaborators or licensing partners;
- our ability to enroll patients in clinical trials and the timing of enrollment;
- the need to conduct unanticipated clinical trials or trials that are larger or more complex than anticipated;
- our execution of any additional collaboration, licensing or similar arrangements, and the timing of payments we may make or receive under existing or future arrangements or the termination or modification of any such existing or future arrangements;
- any intellectual property infringement lawsuit or opposition, interference or cancellation proceeding in which we may become involved;
- additions and departures of key personnel;
- strategic decisions by us or our competitors, such as acquisitions, divestitures, spin-offs, joint ventures, strategic investments or changes in business strategy;
- regulatory developments affecting azelaprag or any future product candidates or those of our competitors;
- potential unforeseen business disruptions that increase our costs or expenses;
- effects of global macroeconomic events, such as inflation, geopolitical conflicts, pandemics, natural disasters and supply chain issues, on our business and operations; and
- changes in general market and economic conditions.

If our quarterly or annual operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly or annual fluctuations in our operating results may, in turn, cause the price of our common stock to fluctuate substantially. We believe that quarterly or annual comparisons of our financial results are not necessarily meaningful and should not be relied on as an indication of our future performance.

We expect to expand our development, clinical and regulatory capabilities and operations as we grow, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We expect to increase the number of our employees and the scope of our operations, particularly in the areas of clinical development, clinical operations, manufacturing, late-stage regulatory affairs, finance, accounting, business operations, public company compliance, communications and other corporate development functions, and, if azelaprag or any future product candidates receive regulatory approval, sales, marketing and distribution capabilities. If we acquire additional product candidates or enter into future collaborations, we may have to

further expand our employee base beyond our current projections, which may include further preclinical research and development or later-stage regulatory operations. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth and with developing sales, marketing and distribution infrastructure, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources.

If we are not able to effectively manage growth and expand our operations, we may not be able to successfully implement the tasks necessary to further develop and commercialize, if approved, azelaprag or any future product candidates and, accordingly, we may not achieve our research, development and commercialization goals.

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do, if at all.

The development and commercialization of new drug products is highly competitive, and specifically the development and commercialization of therapeutics for the treatment of obesity is particularly competitive. Our current and any future product candidates, if approved, will face significant competition, including from well-established, currently marketed therapies or recommended standards of care, and our failure to demonstrate a meaningful improvement to the existing standards of care may prevent us from achieving significant market penetration. Many of our competitors have significantly greater resources and experience than we do, and we may not be able to successfully compete. We face substantial competition from multiple sources, including large and specialty biopharmaceutical and biotechnology companies, academic research institutions and governmental agencies and public and private research institutions.

Our lead product candidate, azelaprag, initially under development as a combination therapy for the treatment of obesity, if approved, would face competition from other approved treatments, some of which have already achieved commercial success. To compete successfully, we will need to differentiate our combination therapy, if approved, from currently marketed drugs as well as those that may be approved in the future, meaning that we will have to demonstrate that the relative cost, method of administration, safety, tolerability or efficacy of our combination therapy provides a better alternative or complement to existing and new therapies. Our commercial opportunity and likelihood of success will be reduced or eliminated if our azelaprag combination therapy is not ultimately demonstrated to be safer, more effective, more conveniently administered, or less expensive than the current standards of care. Furthermore, even if an azelaprag combination therapy is able to achieve these attributes, acceptance of such combination therapy may be inhibited by the reluctance of physicians to switch from existing therapies, or if physicians choose to reserve our azelaprag combination therapy for use in limited circumstances.

Many of our competitors have significantly greater financial, technical, manufacturing, marketing, sales and supply resources or experience than we have. If we obtain regulatory approval for any product candidate, we will face competition based on many different factors, including the safety and effectiveness of our current or any future product candidates, the ease with which our current or any future product candidates can be administered and the extent to which participants accept relatively new routes of administration, the timing and scope of regulatory approvals for these product candidates, the availability and cost of manufacturing, marketing and sales capabilities, price, reimbursement coverage and patent position. Competing products could present superior treatment alternatives, including by being more effective, safer, less expensive or marketed and sold more effectively than any products we may develop. Competitive products may make any products we develop obsolete or noncompetitive before we recover the expense of developing and commercializing our current or any future product candidates. Such competitors could also recruit our employees, which could negatively impact our level of expertise and our ability to execute our business plan. Mergers and acquisitions in the biopharmaceutical

and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified management and other personnel and establishing clinical trial sites and participants registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

The estimates of market opportunity and forecasts of market growth included in this prospectus may prove to be smaller than we believe, and even if the markets in which we compete achieve the forecasted growth, our business may not grow at similar rates, or at all.

We intend to initially focus our product candidate development on treatments for metabolic diseases, such as obesity. Our projections of addressable patient populations within any particular disease state that may benefit from treatment with our product candidates are based on our estimates. Market opportunity estimates and growth forecasts included in this prospectus are subject to significant uncertainty and are based on assumptions and estimates. These estimates, which have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations and market research, may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases. Similarly, the percent of the population with obesity and metabolic diseases could be lower than we anticipate. In both instances, the pool of potential patients that azelaprag could address could be substantially smaller than we anticipate. Additionally, the potentially addressable patient population for our product candidates may not ultimately be amenable to treatment with our product candidates. Our market opportunity may also be limited by future competitor treatments that enter the market. If any of our estimates prove to be inaccurate, the market opportunity for any product candidate that we or our strategic partners develop could be significantly diminished and have an adverse material impact on our business.

Negative results or publicity for one obesity drug could have a substantial impact on all drugs and product candidates for the treatment of obesity, including ours.

Our business can be affected by adverse publicity or negative public perception about us, our competitors, our product candidates or products, if approved, or our industry or competitors generally. Adverse publicity may include publicity about metabolic disease treatments or GLP-1R agonists generally, the efficacy, safety and quality of azelaprag, as well as of the broader category of obesity products, including any products that azelaprag are intended to be used in combination with, and regulatory investigations, regardless of whether these investigations involve us or the business practices or products of our competitors or our customers. Any adverse publicity or negative public perception could have a material adverse effect on our business, financial condition and results of operations. Further, any adverse effects in our clinical trials, even if not ultimately attributable to our product candidates, and the resulting publicity could result in withdrawal of clinical trial participants, and a decrease in demand for any such product candidates. Our business, financial condition and results of operations could be adversely affected if any of our product candidates or products, if approved, or any similar products distributed by other companies are alleged to be or are proved to be harmful to consumers or to have unanticipated and unwanted health consequences.

Our business entails a significant risk of product liability, and our ability to obtain sufficient insurance coverage could have a material and adverse effect on our business, financial condition, results of operations and prospects. If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit, delay or cease commercialization of our products.

When we conduct clinical trials of our current and any future product candidates, we may be exposed to significant product liability risks inherent in the development, testing, manufacturing and marketing of therapeutic treatments. Product liability claims could delay or prevent completion of our development programs. If we succeed in marketing products, if approved, such claims could result in an FDA investigation of the safety

and effectiveness of our products, our manufacturing processes and facilities or our marketing programs and potentially a recall of our products or more serious enforcement action, limitations on the approved indications for which they may be used or suspension or withdrawal of approvals. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit, delay or cease the commercialization of our products. Regardless of the merits or eventual outcome, liability claims may also result in decreased demand for our products, termination of clinical trial sites or entire trial programs, withdrawal of clinical trial participants, injury to our reputation and significant negative media attention, significant costs to defend the related litigation, a diversion of management's time and our resources from our business operations, substantial monetary awards to trial participants or patients, loss of revenue, the inability to commercialize any products that we may develop and a decline in our stock price.

We currently maintain approximately $19.0 million in general liability insurance and product liability insurance in the aggregate. We may, however, need to obtain higher levels of insurance coverage for later stages of clinical development or marketing any of our product candidates. Any insurance we have or may obtain may not provide sufficient coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to obtain sufficient insurance at a reasonable cost to protect us against losses caused by product liability claims that could have a material and adverse effect on our business, financial condition, results of operations and prospects. Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of our product candidates. Although we will maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies will also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

Our employees, independent contractors, consultants and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading, and we may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

We are exposed to the risk of employee fraud or other illegal activity by our employees, independent contractors, consultants and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to comply with FDA regulations, provide true, complete and accurate information to the FDA or other regulatory authorities, comply with manufacturing standards we may establish, comply with healthcare fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. If we obtain FDA approval of any of our current or future product candidates and begin commercializing those products in the United States, our potential exposure under these laws will increase significantly, and our costs associated with compliance with these laws will likely increase. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. It is not always possible to identify and deter employee misconduct, 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 comply with such laws or 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 material and adverse effect on our business, financial condition, results of operations and prospects, including the imposition of significant

civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, the curtailment or restructuring of our operations, loss of eligibility to obtain approvals from the FDA or other regulatory authorities exclusion from participation in government contracting, healthcare reimbursement or other government programs, including Medicare and Medicaid, integrity oversight and reporting obligations, or reputational harm.

We have received confidential and proprietary information from third parties. In addition, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies. Although we try to ensure that individuals working for or collaborating with us 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 confidential information proprietary to these third parties or our employees' former employers, or that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement. We may be subject to claims that patents and applications we have filed to protect inventions of our employees, consultants, advisors or other third parties, even those related to one or more of our product candidates, are rightfully owned by their former or concurrent employer. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees. If our defenses to these claims fail, in addition to requiring us to pay monetary damages, a court could prohibit us from using technologies or features that are essential to our product candidates, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. Moreover, any such litigation or the threat thereof may adversely affect our reputation, our ability to form strategic alliances or sublicense our rights to collaborators, engage with scientific advisors or hire employees or consultants, each of which would have an adverse effect on our business, results of operations and financial condition. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

We may engage in strategic transactions that could increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities, subject us to other risks, adversely affect our liquidity, increase our expenses and present significant distractions to our management.

From time to time, we may consider strategic transactions, such as acquisitions of companies, asset purchases and out-licensing or in-licensing of intellectual property, products or technologies. Additional potential transactions that we may consider include a variety of business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. We may not be able to find suitable partners or acquisition candidates, and we may not be able to complete such transactions on favorable terms, if at all. Any future transactions could increase our near and long-term expenditures, result in potentially dilutive issuances of our equity securities, including our common stock, or the incurrence of debt, contingent liabilities, amortization expenses or acquired in-process research and development expenses, any of which could affect our financial condition, liquidity and results of operations. Future acquisitions may also require us to obtain additional financing, which may not be available on favorable terms or at all. These transactions may never be successful and may require significant time and attention of our management. In addition, the integration of any business that we may acquire in the future may disrupt our existing business and may be a complex, risky and costly endeavor for which we may never realize the full benefits. Furthermore, we may experience losses related to investments in other companies, including as a result of failure to realize expected benefits or the materialization of unexpected liabilities or risks, which could have a material negative effect on our results of operations and financial condition. Accordingly, although there can be no assurance that we will undertake or successfully complete any additional transactions of the nature described above, any additional transactions that we do complete could have a material adverse effect on our business, results of operations, financial condition and prospects.

In May 2022, we entered into the Loan Agreement and the Term Loan we entered into in connection with the Loan Agreement restricts our ability to pursue certain mergers, acquisitions or consolidations that we may believe to be in our best interest.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

We have incurred substantial losses during our history and do not expect to become profitable in the near future, and we may never achieve profitability. Under current law unused U.S. federal net operating losses generated in tax years beginning after December 31, 2017, will not expire and may be carried forward indefinitely but the deductibility of such federal net operating losses for any year is limited to no more than 80% of current year taxable income (without regard to certain deductions). In addition, both our current and our future net operating losses and other tax attributes may be subject to limitation under Sections 382 and 383 of the U.S. Internal Revenue Code of 1986, as amended (the Code), if we undergo, or have undergone, an "ownership change," generally defined as a greater than 50 percentage point change (by value) in our equity ownership by certain stockholders or groups of stockholders over a three-year period. It is possible that we have undergone one or more "ownership changes" in the past. We may also undergo ownership changes in the future as a result of the offering or other shifts in the ownership of our capital stock, some of which may be outside of our control, which may further limit our ability to use our pre-change net operating loss carryforwards and other pre-change tax attributes (such as research tax credits) to offset our post-change income or taxes. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. In addition, at the state level, there may be periods during which the use of net operating losses is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, even if we attain profitability, we may be unable to use all or a material portion of our net operating losses and other tax attributes, which could adversely affect our future cash flows.

Changes in tax laws or regulations that are applied adversely to us may have a material adverse effect on our business, cash flows, financial condition or results of operations.

New income, sales, use or other tax laws, statutes, rules or regulations could be enacted at any time, which could adversely affect our business operations and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, future changes in corporate tax rates, the realization of net deferred tax assets relating to our operations, the taxation of foreign earnings, and the deductibility of expenses could have a material impact on the value of our deferred tax assets, could result in significant one-time charges, and could increase our future U.S. tax expense. In addition, for tax years beginning after December 31, 2021, current law requires taxpayers to capitalize and amortize certain research and development expenditures over five years if incurred in the United States and fifteen years if incurred in foreign jurisdictions, rather than deducting them concurrently. Although there have been legislative proposals to repeal or defer the capitalization requirement to later years, there can be no assurance that the provision will be repealed or otherwise modified.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

Upon the completion of this offering, we will become subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement causing us to fail to make any related party transaction disclosures. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected. In

addition, we do not have a formal risk management program for identifying and addressing risks to our business in other areas.

We have identified material weaknesses in our internal control over financial reporting. If our remediation of the material weaknesses is not effective, or if we experience additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls in the future, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our common stock

We have identified material weaknesses in our internal control over financial reporting. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. In preparing the financial statements as of and for the years ended December 31, 2023 and 2022, management determined it had not maintained appropriately designed entity-level controls impacting the control environment, risk assessment procedures and monitoring activities to prevent or detect material misstatements to our consolidated financial statements, which constituted material weaknesses. Specifically, the control deficiencies related to (i) insufficient identification and assessment of risks impacting the design, implementation and operating effectiveness of internal controls over financial reporting and (ii) insufficient evaluation and determination as to whether components of internal control were present and functioning based upon evidence maintained for activity level controls, including management review controls, across substantially all of our financial statement areas. Management also determined that it did not maintain effective information technology controls in the areas of user access, change management and segregation of duties, within the systems supporting our accounting and reporting processes.

To remediate these material weaknesses, we are in the process of implementing measures designed to improve our internal control over financial reporting. We have hired additional accounting personnel with technical accounting and financial reporting experience and have implemented improved process level and management review controls. We are currently collaborating with our internal audit consultants to enable the implementation of appropriate internal controls over financial reporting. We will also review and improve the design of our general information technology controls including managing user access, change management, and segregation of duties within the systems supporting our accounting and reporting processes.

We cannot assure you that the measures we have taken to date, and are continuing to implement, will be sufficient to remediate the material weaknesses we have identified or avoid potential future material weaknesses. If the steps we take do not correct the material weaknesses in a timely manner, we will be unable to conclude that we maintain effective internal control over financial reporting. Accordingly, there could continue to be a reasonable possibility that a material misstatement of our financial statements would not be prevented or detected on a timely basis.

If we fail to remediate our existing material weaknesses or identify new material weaknesses in our internal controls over financial reporting, if we are unable to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, if we are unable to conclude that our internal controls over financial reporting are effective, or if our independent registered public accounting firm is unable to express an opinion as to the effectiveness of our internal controls over financial reporting when we are no longer an emerging growth company, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could be negatively affected. As a result of such failures, we could also become subject to investigations by the stock exchange on which our securities are listed, the SEC or other regulatory authorities, and become subject to litigation from investors and stockholders, which could harm our reputation and financial condition or divert financial and management resources from our regular business activities.

We and the third parties with whom we work are, or may in the future be, subject to stringent and changing data privacy and security obligations.

In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, "process") certain personal information and other sensitive information, including our proprietary and confidential business data, trade secrets, employee data, intellectual property, data we collect about trial participants in connection with clinical trials, and other sensitive data. The global data protection landscape is rapidly evolving and we are or may become subject to numerous data privacy and security obligations, such as various state, federal and foreign laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements and other obligations that govern the processing of personal, sensitive or confidential information by us and on our behalf, and we may be subject to new or additional data protection laws and regulations and face increased scrutiny from regulators as our business grows. The legislative and regulatory landscape for data privacy and security continues to evolve in jurisdictions worldwide, and there has been an increasing focus on these issues with the potential to affect our business.

Various federal, state, local and foreign legislative and regulatory bodies, or self-regulatory organizations, may expand current laws, rules or regulations, enact new laws, rules or regulations or issue revised rules or guidance regarding data privacy and security that could result in fines or injunctions. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards, or perception of their requirements may have on our business. This evolution may create uncertainty in our business, affect our ability to operate in certain jurisdictions or to process personal information, necessitate the acceptance of more onerous obligations in our contracts, result in liability or impose additional costs on us. The cost of compliance with these laws, regulations and standards is high and is likely to increase in the future. Any failure or perceived failure by us to comply with federal, state or foreign laws or regulations, our internal policies and procedures or our contracts governing our processing of personal, sensitive or confidential information could result in negative publicity, government investigations and enforcement actions, claims by third parties and damage to our reputation, any of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including comprehensive consumer privacy laws, sector-specific privacy laws, consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), data breach notification laws, laws regarding on-line marketing, and other similar laws (e.g., wiretapping laws). For example, the Health Insurance Portability and Accountability Act of 1996, as amended by as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH) (collectively HIPAA), include a privacy rule and security rule that impose among other things, certain requirements relating to the privacy, security, transmission, and breach of individually identifiable health information. 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. Depending on the facts and circumstances, we could be subject to significant penalties if we violate HIPAA.

Certain states have also adopted comparable privacy and security laws and regulations, which govern the privacy, processing and protection of health-related and other personal information. Such laws and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us and our future customers and strategic partners.

Over a dozen states have also passed comprehensive consumer privacy laws, and similar laws are being considered in several other states, as well as at the federal and local levels, some of which we may become subject to. For example, the California Consumer Privacy Act of 2018 (as amended by the California Privacy Rights Act of 2020) (CCPA) imposes obligations on businesses that meet certain thresholds that process the personal information of California residents (including employees based in California). These obligations

include, but are not limited to, providing specific disclosures in privacy notices and affording California residents certain rights related to their personal information. The CCPA also provides for fines of up to $7,500 per intentional violation and allows private litigants affected by certain data breaches to recover significant statutory damages. The 2020 amendments to the CCPA also created the California Privacy Protection Agency, a new enforcement agency whose sole responsibility is to enforce the CCPA and is empowered to create new CCPA regulations. In addition to government activity, privacy advocacy groups and technology and other industries are considering various new, additional or different self-regulatory standards that may place additional burdens on us. In addition to government activity, privacy advocacy groups and technology and other industries continue to consider new or revised self-regulatory standards that may place additional burdens on us.

Outside the United States, the European Union's General Data Protection Regulation (EU GDPR) and the United Kingdom's GDPR (UK GDPR) impose strict requirements for processing the personal data of individuals. Among other requirements, the GDPR and UK GDPR (and certain other foreign jurisdictions) regulate the cross-border transfer of personal data, which could make it more difficult for us to transfer information across jurisdictions (such as transferring or receiving personal data that originates in the European Union (EU), or the United Kingdom to countries such as the United States which are not considered by the EU or United Kingdom to provide adequate protection of personal data). In October 2022, the EU-U.S. Data Privacy Framework was implemented, and the European Commission adopted an adequacy decision on July 10, 2023 that set conditions for personal data transfers from the EU to certified companies in the United States without additional safeguards in place. While we strive to adhere to all requirements to transfer information across jurisdictions using safeguards endorsed by government guidance (such as using the Standard Contractual Clauses approved by the European Commission), we must still adapt to changing guidance and will follow any anticipated litigation closely. As the regulatory guidance and enforcement landscape in relation to data transfers continue to develop, we could suffer additional costs, complaints and/or regulatory investigations or fines; we may have to stop using certain tools and vendors and make other operational changes; and/or it could adversely affect our business, financial condition, results of operations and prospects.

Any such changes in the law related to the use of personal information or data could compromise our ability to pursue our growth strategy effectively or even prevent us from providing certain products in jurisdictions in which we currently operate or may operate in the future. Complying with these numerous, complex and often changing regulations is expensive and difficult, and failure to comply with any data privacy or security laws, whether by us, one of our third-party Contract Development and Manufacturing Organizations (CDMOs), partners or another third party, could adversely affect our business, financial condition, results of operations and prospects and result in expenses which include, but are not limited to: investigation costs, material fines and penalties, compensatory, special, punitive and statutory damages, litigation, consent orders regarding our privacy and security practices, requirements that we provide notices, credit monitoring services and/or credit restoration services or other relevant services to impacted individuals, adverse actions against our licenses to do business, reputational damage and injunctive relief.

In addition to data privacy and security laws, we are also bound by contractual obligations related to data privacy and security. We may be contractually required to indemnify and hold harmless third parties from the costs or consequences of non-compliance with any laws, rules and regulations or other legal obligations relating to privacy or any inadvertent or unauthorized use or disclosure of data that we store or handle as part of operating our business. Any of these events could adversely affect our reputation, business, or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including clinical trials); inability to process personal information or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations.

We cannot assure you that our CROs, CDMOs or other third-party service providers with access to our or our suppliers', manufacturers', clinical trial participants' and employees' sensitive information for which we are responsible will not breach contractual obligations imposed by us, or that they will not experience data security

incidents, which could have a corresponding effect on our business, including putting us in breach of our obligations under privacy laws and regulations and/or which could in turn adversely affect our business, financial condition, results of operations and prospects. Our contractual measures and our own privacy and security-related safeguards cannot completely protect us from the risks associated with the third-party processing of such information. Any of the foregoing could adversely affect our business, financial condition, results of operations and prospects.

We also publicly post our privacy policies and practices concerning our collection, use, disclosure and other processing of the personal information provided to us. Although we endeavor to comply with our public statements and documentation, we may at times fail to do so or be perceived to have failed to do so. Our publication of our privacy policies and other statements we publish that provide promises and assurances about privacy and security can subject us to potential state and federal action if they are found to be deceptive, unfair or misrepresentative of our actual practices. Any actual or perceived failure by us to comply with federal, state or foreign laws, rules or regulations, industry standards, contractual or other legal obligations, or any actual, perceived or suspected cybersecurity incident, whether or not resulting in unauthorized access to, or acquisition, release or transfer of personal information or other data, may result in enforcement actions and prosecutions, private litigation, significant fines, penalties and censure, claims for damages by customers and other affected individuals, regulatory inquiries and investigations or adverse publicity and could cause our customers to lose trust in us, any of which could adversely affect our business, financial condition, results of operations and prospects.

We are dependent on the efficient and uninterrupted operation of our information technology systems, and those systems, or those of our third-party service providers, may be impacted by security incidents, cyberattacks, loss of data and other disruptions, which could adversely impact our business.

We are increasingly dependent on information technology systems and infrastructure to operate our business. In the ordinary course of business, we collect, store, generate, transfer, and transmit (collectively "process") confidential information (such as intellectual property, proprietary business data and patient data). It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such information. We also outsource elements of our information technology systems and operations to third parties (such as vendors, contractors and consultants), and as a result we rely on and take steps designed to manage a number of third-parties who have access to and process our confidential information.

While we take steps designed to detect, mitigate, and remediate vulnerabilities in our information systems, we may not detect or be able to remediate all such vulnerabilities. Further, we may experience delays in developing and deploying remedial measures and patches designed to address identified vulnerabilities, if at all. Despite the implementation of these security measures, our information technology systems and those of our third-party vendors and other contractors and consultants have been in the past and may be in the future potentially vulnerable to service interruptions, system malfunction, accidents by our employees or third-party service providers, natural disasters, terrorism, war, global pandemics, and telecommunication and electrical failures. We may also experience security incidents from inadvertent or intentional actions by our employees, third-party vendors, contractors, consultants, business partners and/or other third parties, including theft, fraud or unauthorized access to or use of our information technology systems, or attack or damage from hacking, cyberattacks or supply chain attacks by malicious third parties and sophisticated nation-state and nation-state-supported actors, which may compromise our system infrastructure, or that of our third-party vendors and other contractors and consultants, impede our ability to conduct business, delay our financial reporting or lead to data leakage. Any of the above concerns could apply to our third-party suppliers and vendors as well.

The risk of a security incident or disruption, particularly through cyberattacks or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity, and sophistication of attempted attacks and intrusions from around the world have increased. We may not be able to anticipate all types of security threats, nor implement preventive measures effective against all such security

threats. Any breach, loss or compromise of confidential proprietary, or personal information may also subject us to liability, government enforcement actions (for example, investigations, fines, penalties, audits, and inspections), additional reporting requirements and/or oversight, restrictions on processing sensitive information (including personal data), litigation (including class claims), indemnification obligations, negative publicity, reputational harm, monetary fund diversions, diversion of management attention, interruptions in our operations (including availability of data), financial loss and other similar harms. If the information technology systems of our third-party vendors and other contractors and consultants become subject to disruptions or security incidents, we may have insufficient recourse against such third parties and we may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of this nature from occurring.

Further, remote work may increase the risks to our information technology systems and data, as remotely working employees utilize network connections, computers and devices outside our premises or network, including working at home, while in transit or in public locations.

Disruptions of our information technology systems or those of our third-party vendors and other contractors and consultants, or security breaches could result in the loss, misappropriation and/or unauthorized access, use, or disclosure of, or the prevention of access to, confidential information (including trade secrets or other intellectual property or proprietary business information) and claims by our counterparties that we have failed to comply with legal or contractual obligations, which could result in financial, legal, business, and reputational harm to us.

There can be no assurance that the limitations of liability in our contracts would be enforceable or adequate to protect us from liabilities and damage and we may not have adequate insurance coverage to cover losses, or all types of costs, expenses and losses, we could incur with respect to security breaches or disruptions. The successful assertion of one or more large claims against us that exceeds our available insurance coverage, or results in changes to our insurance policies (including premium increases or the imposition of large deductible or co-insurance requirements), could have an adverse effect on our business. In addition, we cannot be sure that our existing insurance coverage and coverage for errors and omissions will continue to be available on acceptable terms or that our insurers will not deny coverage as to any future claim.

We are an "emerging growth company" and a "smaller reporting company" and the reduced reporting requirements applicable to emerging growth companies or smaller reporting companies could make our common stock less attractive to investors.

We are an "emerging growth company" as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including (i) not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, (ii) reduced disclosure obligations regarding executive compensation in this prospectus and our periodic reports and proxy statements and (iii) exemptions from the requirements of holding nonbinding advisory stockholder votes on executive compensation and stockholder approval of any golden parachute payments not approved previously. In addition, as an emerging growth company, we are only required to provide two years of audited financial statements and two years of selected financial data in this prospectus.

We could be an emerging growth company for up to five years following the completion of this offering, although circumstances could cause us to lose that status earlier, including if we are deemed to be a "large accelerated filer," which occurs when the market value of our common stock that is held by non-affiliates equals or exceeds $700.0 million as of the prior June 30, or if we have total annual gross revenue of $1.235 billion or more during any fiscal year before that time, in which cases we would no longer be an emerging growth company as of the following December 31, or if we issue more than $1.0 billion in non-convertible debt during any three-year period before that time, in which case we would no longer be an emerging growth company immediately.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to take advantage of the benefits of this extended transition period. Our financial statements may therefore not be comparable to those of companies that comply with such new or revised accounting standards. Until the date that we are no longer an "emerging growth company" or affirmatively and irrevocably opt out of the exemption provided by Section 7(a)(2)(B) of the Securities Act, upon issuance of a new or revised accounting standard that applies to our financial statements and that has a different effective date for public and private companies, we will disclose the date on which adoption is required for non-emerging growth companies and the date on which we will adopt the recently issued accounting standard.

We are also a "smaller reporting company" as defined in the Exchange Act. We may continue to be a smaller reporting company after this offering if either (i) the market value of our common stock held by non-affiliates is less than $250.0 million, measured as of the last business day of our most recently completed second quarter or (ii) our annual revenue is less than $100.0 million during the most recently completed fiscal year and the market value of our common stock held by non-affiliates is less than $700.0 million. We may continue to be a smaller reporting company even after we cease to be an emerging growth company, so we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements, we are not required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Risks Related to Our Reliance on Third Parties

We may, in the future, seek to enter into collaborations or other agreements with third parties for the discovery, development and commercialization of product candidates, if approved, and we may not be successful in doing so. If those collaborations are not successful, we may not be able to capitalize on the market potential of azelaprag and any other current or future product candidates.

We may in the future seek third-party collaborators for research, development and commercialization of azelaprag or future product candidates. Biopharmaceutical companies are our prior and likely future collaborators for any marketing, distribution, development, licensing or broader collaboration arrangements. With respect to our existing collaboration agreements, and what we expect will be the case with any future collaboration agreements, we have and would expect to have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Moreover, our ability to generate revenues from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements.

Collaborations involving our technology currently pose, and will continue to pose, the following risks to us:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations and may not perform their obligations as expected;
- collaborators may de-emphasize or not pursue development and commercialization of any product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus, including as a result of a sale or disposition of a business unit or development function, or available funding or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with any product candidates if the collaborators believe that competitive products are

more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;

- a collaborator with marketing and distribution rights to multiple products may not commit sufficient resources to the marketing and distribution of our product, if approved, relative to other products;
- collaborators may not properly obtain, maintain, defend or enforce our intellectual property rights or may use our proprietary information and intellectual property in such a way as to invite litigation or other intellectual property related proceedings that could jeopardize or invalidate our proprietary information and intellectual property or expose us to potential litigation or other intellectual property related proceedings;
- disputes may arise between the collaborators and us that result in the delay or termination of the research, development or, if approved, commercialization of any product candidates or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or, if approved, commercialization of the applicable product candidates;
- collaboration agreements may not lead to development or, if approved, commercialization of product candidates in the most efficient manner or at all; and
- if a future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or, if approved, commercialization program could be delayed, diminished or terminated.

If our collaborations do not result in the successful development and commercialization of product candidates, or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. Furthermore, even if we receive such payments, they will likely result in payment obligations under license agreements with our licensors, which could be substantial. If we do not receive the funding we expect under these collaboration agreements, or if the funding is substantially offset by payment obligations to our licensors, our development of product candidates could be delayed, and we may need additional resources to develop product candidates. In addition, if one of our collaborators terminates its agreement with us, we may find it more difficult to find a suitable replacement collaborator or attract new collaborators, and our development programs may be delayed or the perception of us in the business and financial communities could be adversely affected.

As a result of the foregoing, our current and any future collaboration agreements may not lead to development or commercialization of our product candidates in the most efficient manner or at all. Moreover, if a collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program could be delayed, diminished or terminated. Any failure to successfully develop or commercialize our product candidates pursuant to our current or any future collaboration agreements could have a material and adverse effect on our business, financial condition, results of operations and prospects.

We rely, and intend to continue to rely, on third parties to conduct our clinical trials and perform some of our research and preclinical studies. If these third parties do not satisfactorily carry out their contractual duties, fail to comply with applicable regulatory requirements or do not meet expected deadlines, our development programs may be delayed or subject to increased costs or we may be unable to obtain regulatory approval, each of which may have an adverse effect on our business, financial condition, results of operations and prospects.

We do not have the ability to independently conduct all aspects of our clinical trials ourselves. As a result, we are dependent on third parties to conduct our ongoing and planned clinical trials of azelaprag and any future product candidates, as well as potentially preclinical studies of certain future product candidates. The timing of

the initiation and completion of these trials will therefore be partially controlled by such third parties and may result in delays to our development programs. Since such third parties partially control the progress of these trials, they may also publish the data related to these trials prior to obtaining or without our approval for doing so. For example, we expect CROs, independent clinical investigators and consultants to play a significant role in the conduct of these trials and the subsequent collection and analysis of data. However, these investigators, CROs and other third parties are not our employees, and we will not be able to control all aspects of their activities. Nevertheless, we are responsible for ensuring that each clinical trial is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the investigators, CROs and other third parties does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA for product candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, clinical trial investigators and clinical trial sites. If we or any of our CROs or clinical trial sites fail to comply with applicable GCP requirements, the data generated in our clinical trials may be deemed unreliable, and the FDA may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA will determine that our clinical trials comply with GCPs. In addition, our clinical trials must be conducted with product produced under current Good Manufacturing Practices (cGMP) regulations. Our failure or the failure of third parties on whom we rely to comply with these regulations may require us to stop and/or repeat clinical trials, which would delay the regulatory approval process.

There is no guarantee that any such CROs, clinical trial investigators or other third parties on which we rely will devote adequate time and resources to our development activities or perform as contractually required. In addition, these third parties may be subject to supply chain or inflationary pressures that limit their ability to achieve anticipated timelines or result in a greater cost to us. For example, we are aware of recurrent shortages of non-human primates available for preclinical studies and although that is not expected to impact our current business, if we begin new product development programs we could be subject to longer development times or difficulty completing necessary research. If any of these third parties fail to meet expected deadlines, adhere to our clinical protocols or meet regulatory requirements, otherwise perform in a substandard manner, or terminate their engagements with us, the timelines for our development programs may be extended or delayed or our development activities may be suspended or terminated. If our clinical trial site terminates for any reason, we may experience the loss of follow-up information on subjects enrolled in such clinical trial unless we are able to transfer those subjects to another qualified clinical trial site, which may be difficult or impossible.

For example, we entered into a material transfer agreement with Lilly, under which Lilly has agreed to manufacture and supply us with a certain quantity (which may be increased by mutual consent) of tirzepatide so we can sponsor a clinical trial in which azelaprag and tirzepatide are co-administered concomitantly or sequentially. If we experience difficulties procuring such products, we could be delayed or even prevented from proceeding with the clinical trials of our product candidates.

In addition, with respect to investigator-sponsored trials that may be conducted, we would not control the design or conduct of these trials, and it is possible that the FDA will not view these investigator-sponsored trials as providing adequate support for future clinical trials or market approval, whether controlled by us or third parties, for any one or more reasons, including elements of the design or execution of the trials or safety concerns or other trial results. We expect that such arrangements will provide us certain information rights with respect to the investigator-sponsored trials, including access to and the ability to use and reference the data, including for our own regulatory submissions, resulting from the investigator-sponsored trials. However, we would not have control over the timing and reporting of the data from investigator-sponsored trials, nor would we own the data from the investigator-sponsored trials. If we are unable to confirm or replicate the results from the investigator-sponsored trials or if negative results are obtained, we would likely be further delayed or prevented from advancing further clinical development. Further, if investigators or institutions breach their obligations with respect to the clinical development of our product candidates, or if the data proves to be inadequate compared to the firsthand knowledge we might have gained had the investigator-sponsored trials been sponsored and

conducted by us, then our ability to design and conduct any future clinical trials ourselves may be adversely affected. The investigators may design clinical trials with clinical endpoints that are more difficult to achieve, or in other ways that increase the risk of negative clinical trial results compared to clinical trials that we may design on our own. Negative results in investigator-sponsored clinical trials could have a material adverse effect on our efforts to obtain regulatory approval for our product candidates and the public perception of our product candidates. Additionally, the FDA may disagree with the sufficiency of our right of reference to the preclinical, manufacturing or clinical data generated by these investigator-sponsored trials, or our interpretation of preclinical, manufacturing or clinical data from these investigator-sponsored trials. If so, the FDA may require us to obtain and submit additional preclinical, manufacturing, or clinical data.

Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors for whom they may also be conducting clinical trials or other pharmaceutical product development activities that could harm our competitive position. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, regulatory approval for azelaprag and any future product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our products.

The manufacture of pharmaceutical products, including our product candidates, such as azelaprag, is complex. Our third-party manufacturers may encounter difficulties in production, which could delay or entirely halt their ability to supply our product candidates for clinical trials or, if approved, for commercial sale.

We do not have any manufacturing facilities, and we currently contract with certain third-party manufacturers, which are located in China. We rely, and expect to continue to rely, on third parties for the manufacture of our product candidates and related raw materials for preclinical and clinical testing, product development purposes, to support regulatory application submissions, as well as for commercial manufacture if any of our product candidates obtain regulatory approval. In addition, we expect to contract with analytical laboratories for release and stability testing of our product candidates. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts and cause the FDA to withdraw certain designations, including orphan drug designation. For example, we cannot be sure to what extent the supply chain issues caused by geopolitical uncertainty and public health epidemics, may impact our ability to procure sufficient supplies for the development of our product candidates and what, if any, impact that may have on our facilities and operations in the region, including but not limited to a decrease or disruption of production, increased costs of production or other interruptions in our supply chain. In addition, any disruption in production or inability of our manufacturers, specifically in China, to produce adequate quantities to meet our needs, whether as a result of a natural disaster or other causes, could impair our ability to operate our business on a day-to-day basis and to continue our development of our product candidates.

Furthermore, since some of our third-party manufacturers are located in China, we are exposed to the possibility of product supply disruption and increased costs in the event of changes in the policies of the United States or Chinese governments, political unrest or unstable economic conditions in China. In addition, certain Chinese biotechnology companies may become subject to trade restrictions, sanctions, other regulatory requirements, or proposed legislation by the U.S. government, which could restrict or even prohibit our ability to work with such entities, thereby potentially disrupting the supply of material to us. For example, the recently proposed BIOSECURE Act introduced in the U.S. House of Representatives, as well as a substantially similar bill in the U.S. Senate, target U.S. government contracts, grants and loans for entities that use equipment and services from certain named Chinese biotechnology companies. If enacted as presently proposed, the BIOSECURE Act would, among other things, prohibit U.S. federal agencies from entering into or renewing any contract with any entity that uses biotechnology equipment or services produced or provided by a "biotechnology company of concern" to perform that contract as well as authorize the U.S. government to name additional

Chinese "biotechnology companies of concern." The BIOSECURE Act defines a "biotechnology company of concern" to include WuXi Apptec and its affiliates (WuXi). We are presently party to agreements with WuXi, pursuant to which WuXi provides development and manufacturing services to us. If these bills become law, or similar laws are passed, they would have the potential to severely restrict our ability to work with Chinese biotechnology manufacturing companies without losing the ability to contract with, or otherwise receive funding from, the U.S. government. We cannot predict what actions may ultimately be taken with respect to trade relations between the United States and China or other countries, what products and services may be subject to such actions or what actions may be taken by China or the other countries in retaliation.

Any of these matters could materially adversely affect our business, financial condition and results of operations. In addition, disruptions in logistics routes and transportation capabilities could disrupt our supply chain. And, if we experience unexpected spikes in demand over time, we risk running out of our necessary supplies.

We may be unable to enter into additional agreements with third-party manufacturers or suppliers on favorable terms. Our anticipated reliance on a limited number of third party-manufacturers or suppliers exposes us to the following risks:

- reliance on the third party for regulatory, compliance and quality assurance;
- reliance on the third party for product development, analytical testing and data generation to support regulatory applications;
- operations of our third-party manufacturers or suppliers could be disrupted by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier, the issuance of an FDA Form 483 notice or warning letter or other enforcement action by the FDA or other regulatory authority;
- the possible breach of the manufacturing agreement by the third party;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how;
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us;
- carrier disruptions or increased costs that are beyond our control; and
- failure to deliver our drugs under specified storage conditions and in a timely manner.

Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside of the United States. If the FDA determines that our CDMOs are not in compliance with FDA laws and regulations, including those governing cGMPs, the FDA may not approve a new drug application (NDA) until the deficiencies are corrected or we replace the manufacturer in our application with a manufacturer that is in compliance. Moreover, our failure, or the failure of our third-party manufacturers and suppliers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products. In addition, approved products and the facilities at which they are manufactured are required to maintain ongoing compliance with extensive FDA requirements and the requirements of other similar agencies, including ensuring that quality control and manufacturing procedures conform to cGMP requirements. As such, our CDMOs are subject to continual review and periodic inspections to assess compliance with cGMPs. Furthermore, although we do not have day-to-day control over the operations of our CDMOs, we are responsible for ensuring compliance with applicable laws and regulations, including cGMPs.

Our product candidates and any products that we may develop may compete with other product candidates and products for access to manufacturing facilities. As a result, we may not obtain access to these facilities on a

priority basis or at all. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us.

As we prepare for later-stage clinical trials and potential commercialization, we will need to take steps to increase the scale of production of our product candidates. We have not yet scaled up the manufacturing process for any of our product candidates apart from azelaprag and may need to scale further to support future supply needs for any of our product candidates. Third-party manufacturers may be unable to successfully increase the manufacturing capacity for any of our product candidates in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up or commercial activities. For example, if microbial, viral or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination.

Any performance failure on the part of our existing or future manufacturers could delay clinical development or regulatory approval. We expect to have an arrangement in place for a redundant supply or a second source for the active pharmaceutical ingredients of API in 2024. If our current CDMOs cannot perform as agreed, we may be required to replace such CDMOs. Although we believe that there are several potential alternative manufacturers who could manufacture our product candidates, we may incur added costs and delays in identifying and qualifying any such replacement manufacturer or be able to reach agreement with any alternative manufacturer. In this case, our clinical trials supply could be delayed significantly as we establish alternative supply sources. In addition, if we are required to change CDMOs for any reason, we will be required to verify that the new CDMO 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 candidate according to the specifications previously submitted to the FDA or another regulatory authority. The delays associated with the verification of a new CDMO could negatively affect our ability to develop product candidates or commercialize our products 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. Further, our third-party manufacturers may experience manufacturing or shipping difficulties due to resource constraints or as a result of natural disasters, labor disputes, unstable political environments or public health epidemics.

Our current and anticipated future dependence upon others for the manufacture of our product candidates or products may adversely affect our future profit margins and our ability to commercialize any products that obtain regulatory approval on a timely and competitive basis.

If we, or any contract manufacturers or suppliers we engage, 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 and our third-party contractors are subject to numerous federal, state, local and foreign 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, including any available insurance. We could also be held liable for unexpected safety events that could happen in our business offices.

In addition, our leasing and operation of real property may subject us to liability pursuant to certain of these laws or regulations. Under existing United States environmental laws and regulations, current or previous owners

or operators of real property and entities that disposed or arranged for the disposal of hazardous substances may be held strictly, jointly and severally liable for the cost of investigating or remediating contamination caused by hazardous substance releases, even if they did not know of and were not responsible for the releases.

We could incur significant costs and liabilities which may adversely affect our financial condition and operating results for failure to comply with such laws and regulations, including, among other things, civil or criminal fines and penalties, property damage and personal injury claims, costs associated with upgrades to our facilities or changes to our operating procedures, or injunctions limiting or altering our operations.

Although we maintain liability insurance to cover us for costs and expenses we may incur due to injuries to our employees, 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, which are becoming increasingly more stringent, 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.

Risks Related to Intellectual Property

If we do not obtain patent term extension for any product candidates we may develop, our business may be harmed.

Depending upon the timing, duration and specifics of any FDA regulatory approval of azelaprag and any other product candidates we may develop and our technology, our U.S. patents or one or more U.S. patents that may issue in the future based on a patent application that we license or own may be eligible for limited patent term extension under the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent extension term of up to five years as compensation for 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, only one patent may be extended and only those claims covering the approved product, a method for using it or a method for manufacturing it may be extended. The application for the extension must be submitted prior to the expiration of the patent for which extension is sought and within 60 days of FDA approval. A patent that covers multiple products for which approval is sought can only be extended in connection with one of the approvals.

However, we may not be granted an extension 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 applicable time period or the scope of patent protection afforded could be less than we request. In addition, to the extent we wish to pursue patent term extension based on a patent that we in-license from a third party, we would need the cooperation of that third party. If we are unable to obtain patent term extension or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Patent terms may be insufficient to protect our competitive position on azelaprag and any future 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 filing date. Various patent term adjustments or extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering azelaprag or any future product candidates are obtained, once the patent life has expired, we

may be open to competition from competitive products, including generics. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products identical or similar to ours.

Obtaining and maintaining our patent protection is dependent 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 U.S. Patent and Trademark Office (USPTO) and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and/or applications. We have systems in place to remind us to pay these fees, and we employ an outside firm and/or rely on our outside counsel to pay these fees due to the USPTO and non-U.S. governmental patent agencies. 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.

Changes in U.S. patent and ex-U.S. patent laws could diminish the value of patents in general, thereby impairing our ability to protect our current or future product candidates.

Changes in either the patent laws or interpretation of the patent laws in the United States or in other jurisdictions could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. In the United States, numerous recent changes to the patent laws and proposed changes to the rules of the USPTO may have a significant impact on our ability to protect our technology and enforce our intellectual property rights.

For example, the Leahy-Smith Act includes a number of significant changes to United States patent law. These changes include provisions that affect the way patent applications are prosecuted, redefine prior art, provide more efficient and cost-effective avenues for competitors to challenge the validity of patents, and enable third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent at USPTO-administered post- grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings.

Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action.

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 the 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 Act, the United States transitioned to a first-to-file system in which, assuming that the other statutory 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. As such, the Leahy-Smith Act and its

implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, the patent positions of companies in the development and commercialization of pharmaceuticals and biologics are particularly uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents once obtained. Depending on future actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our patent rights and our ability to protect, defend and enforce our patent rights in the future. For example, in the case, Assoc. for Molecular Pathology v. Myriad Genetics, Inc., the U.S. Supreme Court held that claims to certain DNA molecules are not patentable. In Amgen Inc. v. Sanofi, the Federal Circuit held that claims with functional language may face high hurdles in fulfilling the enablement requirement. Recent decisions raise questions regarding the award of patent term adjustment (PTA) for patents where related patents have been issued without a PTA. Thus, it cannot be said with certainty how PTA will or will not be viewed in future and whether patent expiration dates may be impacted. We cannot predict how this and future decisions by the courts, the U.S. Congress or the USPTO may impact the value of our patents. Any similar adverse changes in the patent laws of other jurisdictions could also have a material adverse effect on our business, financial condition, results of operations and prospects.

Furthermore, in Europe, a new unitary patent system took effect June 1, 2023, which will significantly impact European patents, including those granted before the introduction of such a system. Under the unitary patent system, European applications have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the Unitary Patent Court (UPC). As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. Patents granted before the implementation of the UPC will have the option of opting out of the jurisdiction of the UPC and remaining as national patents in the UPC countries. Patents that remain under the jurisdiction of the UPC will be potentially vulnerable to a single UPC-based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. We cannot predict with certainty the long-term effects of any potential changes.

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

Our current or future trademarks or trade names may be challenged, infringed, circumvented or declared generic or descriptive or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest.

During trademark registration proceedings, we may receive rejections of our applications by the USPTO or in other foreign jurisdictions. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we are unable to establish name recognition based on our trademarks and trade names, 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. Although 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.

Moreover, any name we have proposed to use with our therapeutic candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. Similar requirements exist in Europe. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA (or an equivalent administrative body in a foreign jurisdiction) objects to any of our proposed proprietary product names, it may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark. At times, competitors or other third parties 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 registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. If we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

Intellectual property rights do not necessarily address all potential threats to our business.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to develop products that are similar to our product candidates but that are not covered by the claims of the patents that we own or license;
- we or our licensors or collaborators might not have been the first to make the inventions covered by the issued patents or patent application that we own or license;
- we or our licensors or collaborators might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that the pending patent applications we own or license will not lead to issued patents;
- issued patents that we own or license may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may have an adverse effect on our business;
- we may fail to adequately protect and police our trademarks and trade secrets; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, it could significantly harm our business, financial condition, results of operations and prospects.

Our rights to develop and commercialize our lead product candidate, azelaprag, as well as certain future products, are or may be subject to the terms and conditions of license agreements. We have in the past

licensed, and may in future license, certain patent rights and proprietary technology from third parties that are important or necessary to the development of our product candidates. For example, On April 5, 2021, we entered into an exclusive license agreement (the Amgen Agreement) with Amgen Inc. (Amgen), pursuant to which we have an exclusive, worldwide license, with the right to sublicense (subject to certain conditions), under Amgen's rights in specified patents relating to Amgen's clinical-stage apelin receptor APJ agonist azelaprag (named AMG 986 by Amgen) as well as their other APJ agonists. The Amgen Agreement imposes various diligence, milestone payment, royalty, insurance, indemnification and other obligations on us. If we breach any material obligation, or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages and Amgen may have the right to terminate the license. If the license is terminated, we may be unable to develop, manufacture, sell, or use azelaprag and Amgen may allow a competitor to license the covered technology instead. For more information regarding this agreement, please see "Business—Material Agreements."

Out-license agreements we may enter into in the future may include exclusivity terms limiting our ability to develop product candidates that may compete with the relevant licensed target or product. If such exclusivity restrictions prevent us from developing or commercializing our technologies in a way that we deem necessary to gain or maintain our competitive advantage, it may have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

We may not have complete control in the preparation, filing, prosecution, maintenance, enforcement and defense of patents and patent applications covering the technology that we license from third parties. For example, under the Amgen Agreement, we have the first right to file, prosecute, maintain and enforce the licensed patents, and Amgen has the option to take over prosecution, maintenance and enforcement activities should we decline to take such actions. Amgen also has the right to comment on prosecution and maintenance activities, and cooperate on enforcement activities. It is possible that our licensors' enforcement of patents against infringers or defense of such patents against challenges of validity or claims of enforceability may be less vigorous than if we had conducted them ourselves, or may not be conducted in accordance with our best interests. We cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced and defended in a manner consistent with the best interests of our business. If our licensors fail to prosecute, maintain, enforce and defend such patents, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, our right to develop and commercialize any of our product candidates we may develop that are the subject of such licensed rights could be adversely affected and we may not be able to prevent competitors from making, using and selling competing products.

Our licensors may have relied on third-party consultants or collaborators or on funds from third parties such that our licensors are not the sole and exclusive owners of the patents we in-licensed. If other third parties have ownership rights to our in-licensed patents, the license granted to us in jurisdictions where the consent of a co-owner is necessary to grant such a license may not be valid and such co-owners may be able to license such patents to our competitors, and our competitors could market competing products and technology. In addition, our rights to our in-licensed patents and patent applications are dependent, in part, on inter-institutional or other operating agreements between the joint owners of such in-licensed patents and patent applications. If one or more of such joint owners breaches such inter-institutional or operating agreements, our rights to such in-licensed patents and patent applications may be adversely affected. Any of these events could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

If we breach our license agreements it could have a material adverse effect on our commercialization efforts for azelaprag and any future product candidates.

We are party to the Amgen Agreement that enables us to utilize certain of Amgen's intellectual property in the development and commercialization of azelaprag, and we may in the future enter into more such license agreements with third parties under which we license the use, development and commercialization rights to current or future product candidates or technology from third parties.

These intellectual property license agreements may require us to comply with various obligations, including diligence obligations such as development and commercialization obligations, as well as potential royalty and milestone payments and other obligations. If we fail to comply with our obligations under any of these license agreements, use the licensed intellectual property in an unauthorized manner, we are subject to bankruptcy-related proceedings or otherwise materially breach any of these license agreements, the terms of the license granted may be materially modified, such as by rendering currently exclusive licenses non-exclusive, or it may give our licensors the right to terminate the applicable license agreement, in whole or in part. Generally, the loss of or termination of our rights under the Amgen Agreement, or any other licenses we may acquire in the future, could harm our business, financial condition, results of operations and prospects.

We may also, in the future, enter into license agreements with third parties under which we are a sublicensee. If our sublicense or fails to comply with its obligations under its upstream license agreement with its licensor, the licensor may have the right to terminate the upstream license, which may result in termination of our sublicense. If this were to occur, we would no longer have rights to the applicable intellectual property unless we are able to secure our own direct license with the owner of the relevant rights, which we may not be able to do on reasonable terms, or at all, which may impact our ability to continue to develop and commercialize product candidates incorporating the relevant intellectual property.

Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues. Disputes may arise between us and our licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the Amgen Agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patent and other intellectual property rights to third parties under collaborative development relationships;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization product candidates, and what activities satisfy those diligence obligations;
- the calculation of total payment amount due if we develop multiple products under the license agreement(s);
- our right to transfer or assign the license;
- the 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
- whether and the extent to which inventors are able to contest the assignment of their rights to our licensors.

If disputes over intellectual property that we have licensed or license in the future prevent or impair our ability to maintain our current licensing arrangements on acceptable terms or at all, we may be unable to successfully develop and commercialize the affected product candidates, which could have material adverse effect on our business. In addition, if disputes arise as to ownership of licensed intellectual property, our ability to pursue or enforce the licensed patent rights may be jeopardized. If we or our licensors fail to adequately protect this intellectual property, our ability to commercialize our products could suffer. Further, certain of our future license agreements with third parties may limit or delay our ability to consummate certain transactions, may impact the value of those transactions or may limit our ability to pursue certain activities (e.g., we may in the future enter into license agreements that are not assignable or transferable, or that require the licensor’s express consent in order for an assignment or transfer to take place).

Third-party claims of intellectual property infringement may prevent or delay our product discovery and development efforts.

Our commercial success depends in part on our ability to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including interference, derivation, *inter partes* review, post grant review, and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that our product candidates and/or proprietary technologies infringe their intellectual property rights. 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 developing our product candidates. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to our product candidates and programs. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others. Moreover, it is not always clear to industry participants, including us, which patents cover various types of drugs, products or their methods of use or manufacture that may be relevant to our product candidates. Thus, because of the large number of patents issued and patent applications filed in our fields, there may be a risk that third parties may allege they have patent rights encompassing our product candidates, technologies or methods. If any such patent were to be asserted against us, we may have defenses against any such action, including that these patents would not be infringed by our product candidates and/or that these patents are not valid. However, if these patents were asserted against us and our defenses to such an action were unsuccessful, unless we obtain a license to these patents, which may not be available on commercially reasonable terms, or at all, we could be liable for damages and precluded from commercializing azelaprag in certain indications, which could have a material adverse effect on our business, financial condition, cash flows or results of operations.

If a third-party claims that we infringe its intellectual property rights, we may face a number of issues, including, but not limited to:

- infringement and other intellectual property claims which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management's attention from our core business;
- substantial damages for infringement, which we may have to pay if a court decides that the product candidate or technology at issue infringes on or violates the third party's rights, and, if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner's attorneys' fees;
- a court prohibiting us from developing, manufacturing, marketing or selling our product candidates, or from using our proprietary technologies, unless the third party licenses its product rights to us, which it is not required to do;
- if a license is available from a third party, we may have to pay substantial royalties, upfront fees and other amounts, and/or grant cross-licenses to intellectual property rights for our products, if any; and
- redesigning our product candidates or processes so they do not infringe, which may not be possible or may require substantial monetary expenditures and time.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

Third parties may assert that we are employing their proprietary technology without authorization. Generally, conducting clinical trials and other development activities in the United States is protected under the

Safe Harbor exemption as set forth in 35 U.S.C. § 271. If and when azelaprag or any future product candidate is approved by the FDA, a certain third party may then seek to enforce its patent by filing a patent infringement lawsuit against us. While we do not believe that any claims of such patent that could otherwise materially adversely affect commercialization of our product candidates, if approved, are valid and enforceable, we may be incorrect in this belief, or we may not be able to prove it in a litigation. In this regard, patents issued in the United States by law enjoy a presumption of validity that can be rebutted only with evidence that is "clear and convincing," a heightened standard of proof. There may be third-party patents of which we are currently unaware with claims to materials, formulations, methods of manufacture or methods for treatment related to 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, molecules used in or formed during the manufacturing process, or the product candidate itself, the holders of any such patents may be able to block our ability to commercialize the product candidate unless we obtained a license under the applicable patents, or until such patents expire or they are finally determined to be held invalid or unenforceable. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, manufacturing process or methods of use, the holders of any such patent may be able to block our ability to develop and commercialize the product candidate unless we obtained a license or until such patent expires or is finally determined to be held invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, or at all, our ability to commercialize our product candidates may be impaired or delayed, which could in turn significantly harm our business. Even if we obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Parties making claims against us may seek and 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, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Even if such a license is available, it may be non-exclusive, which could result in our competitors gaining access to the same intellectual property. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize our product candidates, which could harm our business significantly.

Lastly, we may need to indemnify our customers and distributors against claims relating to the infringement of intellectual property rights of third parties related to our product candidates, including azelaprag. Third parties may assert infringement claims against our customers or distributors. These claims may require us to initiate or defend protracted and costly litigation on behalf of our customers or distributors, regardless of the merits of these claims. If any of these claims succeed, we may be forced to pay damages on behalf of our customers, suppliers or distributors, or may be required to obtain licenses for the product candidates or services they use. If we cannot obtain all necessary licenses on commercially reasonable terms, our customers may be forced to stop using our products, if approved, or services.

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

Although we have pending patent applications in the United States and other countries, filing, prosecuting, maintaining, enforcing and defending patents 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, further, may export otherwise 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 product candidates, and our patents, the patents of our licensors, 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 many foreign countries do not favor the enforcement of patents and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or our licensors' patents or marketing of competing products in violation of our proprietary rights. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents or the patents of our licensors at risk of being invalidated or interpreted narrowly and our patent applications or the patent applications of our licensors 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.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to patent protection, we rely on the protection of our trade secrets, including unpatented know-how, technology and other proprietary information to maintain our competitive position. Although we have taken steps to protect our trade secrets and unpatented know-how, including entering into confidentiality agreements with third parties, and confidential information and inventions agreements with employees, consultants and advisors, we cannot provide any assurances that all such agreements have been duly executed, and any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is 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.

Moreover, third parties may still obtain this information or may come upon this or similar information independently, and we would have no right to prevent them from using that technology or information to compete with us. 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 would be harmed. If we do not apply for

patent protection prior to such publication or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized.

Third-party claims of intellectual property infringement, misappropriation or other violations against us or our collaborators could be expensive and time consuming and may prevent or delay the development and commercialization of our product candidates.

Our commercial success depends in part on our ability to avoid infringing, misappropriating and otherwise violating the patents and other intellectual property rights of third parties. There is a substantial amount of complex litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including interference, derivation and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. Such challenges may result in loss of exclusivity 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 products and techniques without payment, or limit the duration of the patent protection of our technology. As discussed above, recently, due to changes in U.S. law referred to as patent reform, new procedures including inter partes review and post-grant review have also been implemented. As stated above, this reform adds uncertainty to the possibility of challenge to our patent rights in the future.

Numerous U.S. and foreign issued patents and pending patent applications owned by third parties exist in the fields in which we are commercializing or plan to commercialize azelaprag. As the biotechnology and pharmaceutical industries expand and more patents are issued, and as we gain greater visibility and market exposure as a public company, the risk increases that azelaprag or any future product candidates, and commercializing activities may give rise to claims of infringement of the patent rights of others. We cannot assure you that azelaprag or any future product candidates will not infringe existing or future patents owned by third parties. We may not be aware of patents that have already been issued for which a third party, such as a competitor in the fields in which we are developing azelaprag or our future product candidates, might accuse us of infringing. It is also possible that patents owned by third parties of which we are aware, but which we do not believe we infringe or that we believe we have valid defenses to any claims of patent infringement, could be found to be infringed by us. It is not unusual that corresponding patents issued in different countries have different scopes of coverage, such that in one country a third-party patent does not pose a material risk, but in another country, the corresponding third-party patent may pose a material risk to azelaprag and any future product candidates. As such, we monitor third-party patents in the relevant pharmaceutical markets. In addition, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that we may infringe.

In the event that any third-party claims that we infringe their patents or that we are otherwise employing their proprietary technology without authorization and initiates litigation against us, even if we believe such claims are without merit, a court of competent jurisdiction could hold that such patents are valid, enforceable and infringed by us. Defense of infringement claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and other employee resources from our business, and may impact our reputation. In the event of a successful claim of infringement against us, we may be enjoined from further developing or commercializing the infringing products or technologies. In addition, we may be required to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties and/or redesign our infringing products or technologies, which may be impossible or require substantial time and monetary expenditure. Such licenses may not be available on commercially reasonable terms or at all. Even if we are able to obtain a license, the license would likely obligate us to pay license fees or royalties or both, and the rights granted to us might be nonexclusive, which could result in our competitors gaining access to the same intellectual property. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms or at all, we may be unable to commercialize the infringing products or technologies or such commercialization efforts may be significantly

delayed, which could in turn significantly harm our business. In addition, we may in the future pursue patent challenges with respect to third-party patents, including as a defense against the foregoing infringement claims. The outcome of such challenges is unpredictable.

Even if resolved in our favor, the foregoing proceedings could be very expensive, particularly for a company of our size, and time-consuming. Such proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such proceedings adequately. Some of our competitors may be able to sustain the costs of litigation or administrative proceedings more effectively than we can because of greater financial resources. Such proceedings may also absorb significant time of our technical and management personnel and distract them from their normal responsibilities. Uncertainties resulting from such proceedings could impair our ability to compete in the marketplace. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition or results of operations.

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

We or our licensors may be subject to claims that former employees, consultants, collaborators or other third parties have an interest in our patent rights, any potential trade secrets, or other intellectual property as an inventor, co-inventor or owner of any potential trade secrets. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates and other proprietary technologies we may develop. Litigation may be necessary to defend against these and other claims challenging inventorship or our patent rights, any potential 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 and other proprietary technologies we may develop. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Third party claims or litigation alleging infringement of patents or other proprietary rights, or seeking to invalidate our patents or other proprietary rights, may delay or prevent the development and commercialization of our current or future product candidates or technologies.

Our commercial success depends in part on our avoiding infringement and other violations of the patents and proprietary rights of third parties. The intellectual property landscape around obesity and metabolic diseases drug development is highly dynamic and there is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biopharmaceutical industry. Potential litigation could include patent infringement lawsuits, derivation and administrative law proceedings, *inter partes* review and post-grant review before the USPTO, as well as oppositions and similar processes in foreign jurisdictions. As the fields of treating obesity and metabolic diseases continue to expand and more patents are issued, and as we gain greater visibility and market exposure as a public company, the risk increases that our product candidates or other business activities may be subject to claims of infringement of the patent and other proprietary rights of third parties. Third parties may assert that we are infringing their patents or employing their proprietary technology without authorization. Also, there may be 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 or technologies may infringe.

Defense of third-party claims of patent infringement or violation of intellectual property rights involves substantial litigation expense and would be a substantial diversion of management and employee time and resources from our business. Some third parties may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise funds necessary to continue our operations or could otherwise have a material adverse effect on our business, financial condition, results of operations and prospects. There could also be public announcements of the results of hearings, motions, or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Any of the foregoing events could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, third parties may obtain patent rights in the future and claim that use of our product candidates or other technologies infringe upon these rights. If any third-party patents were held by a court of competent jurisdiction to cover our product candidates, or any aspect of their manufacture or use, the holders of any such patents may be able to block our ability to commercialize such product candidate or technology unless we obtain a license under the applicable patents, or until such patents expire. Such a license may not be available on commercially reasonable terms, or at all. In addition, we may be subject to claims that we are infringing other intellectual property rights, such as trademarks or copyrights, or misappropriating the trade secrets of others, and to the extent that our employees, consultants or contractors use intellectual property or proprietary information owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of 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 infringement or other intellectual property claim against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our affected products or technologies, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms.

The scope of a patent claim is a legal determination made by the courts. It is informed by the written disclosure of a patent, the patent's prosecution history, and other intrinsic and extrinsic factors. Our interpretation of a patent claim may not be adopted during a patent litigation alleging infringement by our products. If a court does not adopt our claim interpretation and determines that our product candidates are covered by a third-party patent, we may be held liable for damages. Similarly, we may incorrectly predict whether a third-party patent application will issue with claims that cover one or more of our product candidates. If our claim interpretations are not adopted by the USPTO during prosecution of a third-party patent application, or by a court in a patent infringement dispute, our ability to develop and market our product candidates may be harmed.

Moreover, we, or one of our licensors, may have to participate in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge priority of invention or other features of patentability. If we or our licensors are unsuccessful in any validity (including any patent oppositions) or inventorship disputes to which we or they are subject, we may lose valuable intellectual property rights through the loss of one or more of our owned, licensed or optioned patents, or such patent claims may be narrowed, invalidated or held unenforceable, or through loss of exclusive ownership of or the exclusive right to use our owned or in-licensed patents. In the event of loss of patent rights as a result of any of these disputes, we may be required to obtain licenses from third parties, including parties involved in any such proceedings. If we are unable to obtain such licenses, we may need to cease the development, manufacture and commercialization of one or more of the product candidates or technologies we may develop. The loss of exclusivity or the narrowing of our patent claims

could limit our ability to stop others from using or commercializing similar or identical technology and product candidates. Even if we or our licensors are successful in such a proceeding, it could result in substantial costs and be a distraction to management and other employees.

Furthermore, the patent landscape is crowded and highly competitive. Numerous third-party United States and foreign issued patents and pending patent applications exist in the fields in which we are developing product candidates, and they may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of their merit. Ongoing research and development is taking place by several companies, universities, and other institutions. There can be no assurance that our operations do not, or will not in the future, infringe, misappropriate or otherwise violate existing or future third-party patents or other intellectual property rights. Identification of third-party patent rights that may be relevant to our operations is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases, and publication timelines. We cannot guarantee that any patent searches we may conduct are complete or thorough enough to identify every third-party patent and pending application in the United States and/or abroad that is relevant to or necessary for the development and commercialization of our product candidates in any country.

We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we may be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly. We cannot provide any assurances that third party patents do not exist which might be enforced against our product candidates resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties or other forms of compensation to third parties.

If we are unable to obtain and maintain patent protection or other necessary rights for any of our current or future product candidates and technology, or if the scope of the patent protection obtained is not sufficiently broad or our rights under our patents (owned, co-owned or licensed) is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully commercialize our products and technology may be adversely affected.

Our success is dependent in part on our ability to obtain and maintain proprietary or intellectual property protection in the United States and other countries for our current product candidates or any future product candidates, as well as our core technologies, including our manufacturing know-how. We strive to protect and enhance the proprietary technology, inventions and improvements that are commercially important to the development of our business by seeking, maintaining and defending our intellectual property, whether developed internally or licensed from third parties. We also rely on trade secrets, know-how, continuing technological innovation and in-licensing opportunities to develop, strengthen and maintain our proprietary position in obesity and metabolic disease drug development. Additionally, we intend to utilize regulatory protection afforded through rare drug designations, data exclusivity and market exclusivity as well as patent term extensions, where available.

The patent position of biotechnology and biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has in recent years been the subject of much litigation. The degree of patent protection we require to successfully compete in the marketplace may be unavailable or severely limited in some cases and may not adequately protect our rights or permit us to gain or keep any competitive advantage. We cannot provide any assurances that any of our own or licensed patent applications will mature into issued patents, and cannot provide any assurances that any such patents, if issued, will include claims with a scope sufficient to protect our current and future product candidates or otherwise provide any competitive advantage. Additionally, patents can be enforced only in those jurisdictions in which the patent has issued. Furthermore, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally twenty years after its first nonprovisional U.S. filing. The natural expiration of a patent outside of the United States varies in accordance with provisions of applicable local law, but is generally 20 years from the earliest local filing date. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Given the amount of time

required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized.

Moreover, our exclusive license to azelaprag may be subject to certain retained rights, which may adversely impact our competitive position. See "Business—Material Agreements." Our licensed patent portfolio may not provide us with adequate and continuing patent protection sufficient to exclude others from commercializing products similar to our product candidates, including generic versions of such products. In addition, the patent portfolio licensed to us is, or may be, licensed to third parties outside our licensed field, and such third parties may have certain enforcement rights. Thus, patents licensed to us could be put at risk of being invalidated or interpreted narrowly in litigation filed by or against another licensee or in administrative proceedings brought by or against another licensee in response to such litigation or for other reasons.

Other parties have developed technologies that may be related or competitive to our own and such parties may have filed or may file patent applications, or may have received or may receive patents, claiming inventions that may overlap or conflict with those claimed in our own patent applications or issued patents. Publication of discoveries in the scientific literature lags behind the actual discoveries, and patent applications in the United States and in 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 the inventors of our patents and applications were the first to make the inventions claimed in those patents or pending patent applications, or that they were the first to file for patent protection of such inventions. Further, we cannot assure you that all of the potentially relevant prior art relating to our patents and patent applications has been found. If such prior art exists, it can invalidate a patent or prevent a patent from issuing from a pending patent application. As a result, the issuance, scope, validity and commercial value of our patent rights cannot be predicted with any certainty. Further, 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 patent prosecution process is expensive and time-consuming, and we or our licensors may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. In addition, the scope of the claims initially submitted for examination may be significantly narrowed by the time they issue, if at all. It is also possible that we or our licensors will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. We cannot provide any assurances that we will be able to pursue or obtain additional patent protection based on our research and development efforts, or that any such patents or other intellectual property we generate will provide any competitive advantage.

Even if we acquire patent protection that we expect should enable us to maintain competitive advantage, the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability. Third parties, including former employees, consultants, collaborators and competitors, may challenge the inventorship, scope, validity, or enforceability thereof, which may result in such patents being narrowed, invalidated or held unenforceable. If issued, our patents may be challenged in patent offices in the United States and abroad, or in court. For example, we may be subject to a third party submission of prior art to the USPTO challenging the validity of one or more claims of our patents, once issued. Such submissions may also be made prior to a patent's issuance, precluding the granting of a patent based on one of our patent applications. We may become involved in opposition, reexamination, *inter partes* review, post-grant review, derivation, interference, or similar proceedings in the United States or abroad challenging the claims of our patents, once issued. Furthermore, patents may be challenged in court, once issued. Competitors may claim that they invented the inventions claimed in such patents or patent applications, or may have filed patent applications before the inventors of our patents did. A competitor may also claim that we are infringing its patents and that we therefore cannot practice our technology as claimed under our patent applications and patents, if issued. As a result, one or more claims of our patents may be narrowed or invalidated. In litigation, a competitor could claim that our patents, if issued, are not valid for a number of reasons. If a court agrees, we would lose our rights to those challenged patents.

Even if they are unchallenged, our patents and pending patent applications, if issued, may not provide us with any meaningful protection or prevent competitors from designing around our patent claims to circumvent our

patents by developing similar or alternative technologies or therapeutics in a non-infringing manner. For example, even if we have a valid and enforceable patent, we may not be able to exclude others from practicing our invention if the other party can show that they used the invention in commerce before our filing date or the other party benefits from a compulsory license. If the patent protection provided by the patents and patent applications we hold or pursue with respect to our product candidates is not sufficiently broad to impede such competition, our ability to successfully commercialize our product candidates could be negatively affected, which would harm our business.

Certain regulatory exclusivities may be available, however, the scope of such regulatory exclusivities is subject to change, and may not provide us with adequate and continuing protection sufficient to exclude others from commercializing products similar to our product candidates.

Risks Related to Government Regulation

Disruptions at the FDA, the SEC and other government agencies or comparable regulatory authorities caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, otherwise prevent new products and services from being developed, approved or commercialized in a timely manner or at all, 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.

The ability of the FDA or other regulatory authorities to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, statutory, regulatory and policy changes, and other events that may otherwise affect the FDA's or comparable foreign regulatory authorities' ability to perform routine functions. In addition, government funding of the SEC, and other government agencies or comparable foreign regulatory authorities 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 or other regulatory authorities may also slow the time necessary for new drugs to be reviewed and/or approved, which would adversely affect our business. For example, in 2024, the U.S. government was on the verge of a shutdown and has previously shut down several times, and certain regulatory agencies, such as the FDA and the SEC, had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs, or if geopolitical or global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns or delays could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

In addition, three decisions from the U.S. Supreme Court in July 2024 may lead to an increase in litigation against regulatory agencies that could create uncertainty and thus negatively impact our business. The first decision overturned established precedent that required courts to defer to regulatory agencies' interpretations of ambiguous statutory language. The second decision overturned regulatory agencies' ability to impose civil penalties in administrative proceedings. The third decision extended the statute of limitations within which entities may challenge agency actions. These cases may result in increased litigation by industry against regulatory agencies and impact how such agencies choose to pursue enforcement and compliance actions. However, the specific, lasting effects of these decisions, which may vary within different judicial districts and circuits, is unknown. We also cannot predict the extent to which FDA and SEC regulations, policies, and decisions may become subject to increasing legal challenges, delays, and changes.

Existing, recently enacted and future legislation may increase the difficulty and cost for us to obtain regulatory approval of and commercialize our product candidates and decrease the prices we may obtain.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay regulatory approval of

our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any products for which we obtain regulatory approval.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the regulatory approvals of our product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent regulatory approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs, including costs of pharmaceuticals. There has been heightened governmental scrutiny over the manner in which manufacturers set prices for their products, which has resulted in several presidential executive orders, Congressional inquiries, and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and Medicaid, and reform government program reimbursement methodologies for drug products. For example, on August 2, 2011, the Budget Control Act of 2011 imposed, subject to certain temporary suspension periods, 2% reductions in Medicare payments to providers per fiscal year starting April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2032, unless additional Congressional action is taken. In December 2020, CMS issued a final rule implementing significant manufacturer price reporting changes under the Medicaid Drug Rebate Program, including an alternative rebate calculation for line extensions that is tied to the price increases of the original drug, and Best Price reporting related to certain value-based purchasing arrangements. Under the American Rescue Plan Act of 2021, effective January 1, 2024, the statutory cap on Medicaid Drug Rebate Program rebates that manufacturers pay to state Medicaid programs is eliminated. Elimination of this cap may, in some cases, require pharmaceutical manufacturers to pay more in rebates than they receive on the sale of products.

Recently, several healthcare reform initiatives culminated in the enactment of the Inflation Reduction Act (the IRA) in August 2022, which, among other things, allows United States Health and Human Services (HHS) to directly negotiate the selling price of a statutorily specified number of drugs and biologics each year that CMS reimburses under Medicare Part B and Part D. Only high-expenditure single-source drugs that have been approved for at least 7 years (11 years for single-source biologics) are eligible to be selected for negotiation by CMS, with the negotiated price taking effect two years after the selection year. Negotiations for Medicare Part D products begin in 2024 with the negotiated price taking effect in 2026, and negotiations for Medicare Part B products begin in 2026 with the negotiated price taking effect in 2028. In August 2023, HHS announced the ten Medicare Part D drugs and biologics that it selected for negotiations. HHS will announce the negotiated maximum fair prices by September 1, 2024. This price cap, which cannot exceed a statutory ceiling price, will come into effect on January 1, 2026, and will represent a significant discount from average prices to wholesalers and direct purchasers. The IRA also imposes rebates on Medicare Part D and Part B drugs whose prices have increased at a rate greater than the rate of inflation. In addition, the law eliminates the "donut hole" under Medicare Part D beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and requiring manufacturers to subsidize, through a newly established manufacturer discount program, 10% of Part D enrollees' prescription costs for brand drugs below the out-of-pocket maximum, and 20% once the out-of-pocket maximum has been reached. The IRA also extends enhanced subsidies for individuals purchasing health insurance coverage in Patient Protection and Affordable Care Act (ACA) marketplaces through plan year 2025. The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Manufacturers that fail to comply with the IRA may be subject to various penalties, including significant civil monetary penalties. These provisions may be subject to legal challenges. For example, the provisions related to the negotiation of selling prices of high-expenditure single-source drugs and biologics have been challenged in multiple lawsuits brought by pharmaceutical manufacturers. The outcome of these lawsuits is uncertain, and some IRA drug discount provisions have not been challenged in

litigation. Thus, while it is unclear how the IRA will be implemented, it will likely have a significant impact on the pharmaceutical industry and the pricing of azelaprag or any future product candidates.

At the state level, legislatures are increasingly enacting laws and implementing regulations designed to control pharmaceutical and biological product pricing, including restrictions or prohibitions on certain marketing practices, reporting of specified categories of remuneration provided to health care practitioners, and reporting and justification of price increases greater than a specified level. In some cases, states have designed programs to encourage importation from other countries and bulk purchasing, though the federal government has not yet approved any such plans. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for pharmaceuticals and other healthcare products and services, which could result in reduced demand for azelaprag or any future product candidates or companion diagnostics or additional pricing pressures.

We expect that other healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products.

The insurance coverage and reimbursement status of newly approved products are uncertain. Failure to obtain or maintain coverage and adequate reimbursement for new or current products could limit our ability to market those products and decrease our ability to generate revenue.

Sales of our product candidates, if approved, will depend, in part, on the extent to which such products will be covered by third-party payors, such as government health care programs, commercial insurance and managed healthcare organizations. These third-party payors are increasingly limiting coverage and/or reducing reimbursements for medical products and services. A third-party payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. 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. Further, one payor's determination to provide coverage for a drug product does not ensure that other payors will also provide coverage for the drug product. Coverage policies and third-party payor reimbursement rates may change at any time. In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services (CMS) as CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare. Private payors often, but not always, follow CMS's decisions regarding coverage and reimbursement. Decreases in third-party payor reimbursement or a decision by a third-party payor to not cover any of our product candidates, if approved, could reduce physician usage of our product candidates, and have a material adverse effect on our sales, results of operations and financial condition. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain FDA approvals. Nonetheless, our product candidates may not be considered medically necessary or cost-effective.

Our operations and relationships with healthcare providers, healthcare organizations, customers and third-party payors will be subject to applicable anti-bribery, anti-kickback, fraud and abuse, transparency and other healthcare laws and regulations, which could expose us to, among other things, enforcement actions, criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings.

Our current and future arrangements with healthcare providers, healthcare organizations, third-party payors and customers expose us to broadly applicable anti-bribery, fraud and abuse and other healthcare laws and

regulations that may constrain the business or financial arrangements and relationships through which we research, market, sell and distribute any of our product candidates, if approved. Restrictions under applicable federal and state anti-bribery and healthcare laws and regulations, include the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, individuals and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under a federal and state healthcare program such as Medicare and Medicaid. The term remuneration has been broadly interpreted to include anything of value. 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 federal criminal and civil false claims and civil monetary penalties laws, including the federal False Claims Act, which can be enforced through civil whistleblower or qui tam actions against individuals or entities, and the Federal Civil Monetary Penalties Law, which prohibit, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. Moreover, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act;
- HIPAA and its implementing regulations, which imposes criminal and civil liability, prohibits, among other things, knowingly and willfully executing, or attempting to execute a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services; similar to 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;
- HIPAA, as amended by HITECH, and their respective implementing regulations, which impose obligations on certain healthcare providers, health plans, and healthcare clearinghouses, known as covered entities, as well as their business associates that perform certain services involving the storage, use or disclosure of individually identifiable health information for or on behalf of a covered entity and their covered subcontractors, including mandatory contractual terms, with respect to safeguarding the privacy, security, and transmission of individually identifiable health information, and require notification to affected individuals and regulatory authorities of certain breaches of security of individually identifiable health information;
- the federal Physician Payments Sunshine Act, which requires certain manufacturers of covered drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program, with certain exceptions, to report annually to CMS information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other health care professionals (such as physician assistants and certain advance practices nurses), and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members, with the information made publicly available on a searchable website;
- the Foreign Corrupt Practices Act which prohibits U.S. businesses and their representatives from offering to pay, paying, promising to pay or authorizing the payment of money or anything of value to a foreign official in order to influence any act or decision of the foreign official in his or her official capacity or to secure any other improper advantage in order to obtain or retain business;

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; and
- certain state laws that require biopharmaceutical companies to comply with the biopharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures and drug pricing information, and state and local laws that require the registration of biopharmaceutical sales representatives.

Efforts to ensure that our current and future business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance 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 such requirements, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, the curtailment or restructuring of our operations, loss of eligibility to obtain approvals from the FDA, exclusion from participation in government contracting, healthcare reimbursement or other government programs, including Medicare and Medicaid, integrity oversight and reporting obligations, or reputational harm, any of which could adversely affect our financial results. These risks cannot be entirely eliminated. Any action against us for an alleged or suspected violation could cause us to incur significant legal expenses and could divert our management's attention from the operation of our business, even if our defense is successful. In addition, achieving and sustaining compliance with applicable laws and regulations may be costly to us in terms of money, time and resources.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction. For example, even if the FDA grants regulatory approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. However, a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including additional preclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we or any partner we work with fail to comply with the regulatory requirements in international markets or fail to receive applicable regulatory approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

Adverse side effects or other safety risks associated with azelaprag or any future product candidates we may develop could delay or preclude approval, cause us to suspend or discontinue clinical trials or abandon further development, change the design of our clinical trials, limit the commercial profile of an approved product, or result in significant negative consequences following regulatory approval, if any.

As is the case with small molecules generally, it is likely that there may be adverse side effects associated with the use of azelaprag or any future product candidates. For example, we have observed certain adverse events

such as mild headaches and back pain and dizziness, which were higher in our placebo patients than in our active patients, in our clinical trials of azelaprag. Our clinical trials may reveal significant adverse events not seen in our preclinical studies or prior clinical trials and may result in a safety or tolerability profile that could delay or prevent regulatory approval or market acceptance of azelaprag or any future product candidates. Undesirable or clinically unmanageable side effects observed in our clinical trials for our product candidates could occur and cause us or regulatory authorities to interrupt, delay or halt our clinical trials and could result in more restrictive labeling than anticipated or the delay or denial of regulatory approval by the FDA or other regulatory authorities. If additional adverse events, serious adverse events (SAEs) or other side effects are observed in any of our clinical trials that are atypical of, or more severe than, the known side effects of the respective class of agents that each of our product candidates are a part of, we may have difficulty recruiting participants to our clinical trials, participants may drop out of our trials, or we may be required to abandon those trials or our development efforts of one or more product candidates altogether. Furthermore, clinical trials by their nature utilize a sample of the potential patient population. With a limited number of subjects and limited duration of exposure, rare and severe side effects of our product candidates or those of our competitors may only be uncovered with a significantly larger number of patients exposed to the drug. Undesirable or clinically unmanageable side effects observed in our clinical trials for our product candidates could also occur following discontinuation of azelaprag or any future product candidates with sufficient recovery periods, and we will need to monitor the severity and duration of side effects in our clinical trials. If such effects are more severe, less reversible than we expect or not reversible at all, we may decide or be required to perform additional studies or to halt or delay further clinical development of azelaprag, which could result in the delay or denial of regulatory approval by the FDA or other regulatory authorities. Adverse events and SAEs that emerge during clinical investigation of or treatment with azelaprag or any future product candidates may be deemed to be related to our product candidates. Moreover, if our product candidates are associated with undesirable side effects in clinical trials or have characteristics that are unexpected, we may elect to abandon 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 our product candidates, if approved. This may require longer and more extensive clinical development, or regulatory authorities may increase the amount of data and information required to approve, market or maintain approval for azelaprag or any future product candidates and could result in warnings and precautions in our product labeling or a restrictive REMS. This may also result in an inability to obtain approval of azelaprag or any future product candidates. We, the FDA or other regulatory authorities or an IRB or ethics committee may suspend clinical trials of a product candidate at any time for various reasons, including a belief that participants in such trials are being exposed to unacceptable health risks or adverse side effects. Even if the side effects do not preclude the product candidate from obtaining or maintaining regulatory approval, undesirable side effects may inhibit market acceptance of the approved product due to its tolerability versus other therapies. Further, it is possible that, as we test our product candidates in larger, longer and more extensive clinical trials, including with different dosing regimens, or as the use of our drug candidates becomes more widespread following any regulatory approval, illnesses, injuries, discomforts and other adverse events that were observed in earlier trials, as well as conditions that did not occur or went undetected in previous trials, will be reported by patients. Any of these developments could materially harm our business, financial condition, results of operations and prospects.

We plan to conduct future clinical trials at sites outside the United States. The FDA may not accept data from trials conducted in such locations, and the conduct of trials outside the United States could subject us to additional delays and expense.

We have conducted one Phase 1 trial of azelaprag in a study of older patients in New Zealand. The acceptance by the FDA or other regulatory authorities of trial data from clinical trials conducted outside their jurisdiction may be subject to certain conditions or may not be accepted at all.

Where foreign clinical trial data are not intended to serve as the sole basis for approval, the FDA will not accept the data as support for an application for marketing approval unless the trial is well-designed and well-conducted in accordance with GCP requirements and the FDA is able to validate the data from the trial through

an onsite inspection if deemed necessary. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the U.S. or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which could be costly and time-consuming, and which may result in current or future product candidates that we may develop not receiving approval for commercialization in the applicable jurisdiction.

Conducting clinical trials outside the U.S. also exposes us to additional risks, including risks associated with:

- additional foreign regulatory requirements;
- foreign exchange fluctuations;
- compliance with foreign manufacturing, customs, shipment and storage requirements;
- cultural differences in medical practice and clinical research;
- diminished protection of intellectual property in some countries; and
- interruptions or delays in our trials resulting from geopolitical events, such as war or terrorism.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations, which can harm our business.

U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations prohibit, among other things, companies and their employees, agents, CROs, CDMOs, legal counsel, accountants, consultants, contractors and other partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Export control and sanctions laws may also prohibit or limit our ability to sell or provide our drug candidates to embargoed countries, regions, governments, persons and entities. Violations of these laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We also expect our non-U.S. activities to increase over time. We expect to rely on third parties for research, preclinical studies and clinical trials and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals. We can be held liable for the corrupt or other illegal activities of our personnel, agents, or partners, even if we do not explicitly authorize or have prior knowledge of such activities.

Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences.

Risks Related to Our Common Stock and This Offering

Anti-takeover provisions in our charter documents and under Delaware law could prevent or delay an acquisition of us, which may be beneficial to our stockholders, and may prevent attempts by our stockholders to replace or remove our current management.

Our restated certificate of incorporation and our restated bylaws that will be in effect upon completion of this offering contain provisions that could delay or prevent a change in control of our company. These provisions

could also make it difficult for stockholders to elect directors who are not nominated by current members of our board of directors or take other corporate actions, including effecting changes in our management. These provisions:

- establish a classified board of directors so that not all members of our board of directors are elected at one time;
- permit only the board of directors to establish the number of directors and fill vacancies on the board of directors;
- provide that directors may only be removed "for cause" and only with the approval of two-thirds of our stockholders;
- require super-majority voting to amend some provisions in our restated certificate of incorporation and restated bylaws;
- authorize the issuance of "blank check" preferred stock that our board of directors could use to implement a stockholder rights plan;
- eliminate the ability of our stockholders to call special meetings of stockholders;
- prohibit stockholder action by written consent, which requires all stockholder actions to be taken at a meeting of our stockholders;
- prohibit cumulative voting; and
- establish advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted upon by stockholders at annual stockholder meetings.

In addition, Section 203 of the Delaware General Corporation Law (DGCL), may discourage, delay or prevent a change in control of our company. Section 203 imposes certain restrictions on mergers, business combinations and other transactions between us and holders of 15% or more of our common stock.

The exclusive forum provisions in our organizational documents may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, or employees, or the underwriters of any offering giving rise to such claim, which may discourage lawsuits with respect to such claims.

Our restated certificate of incorporation that will be in effect upon completion of this offering, to the fullest extent permitted by law, will provide that the Court of Chancery of the State of Delaware is the exclusive forum for: any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the DGCL, our restated certificate of incorporation, or our restated bylaws; or any action asserting a claim that is governed by the internal affairs doctrine. This exclusive forum provision does not apply to suits brought to enforce a duty or liability created by the Exchange Act. It could apply, however, to a suit that falls within one or more of the categories enumerated in the exclusive forum provision. This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, or other employees, or the underwriters of any offering giving rise to such claims, which may discourage lawsuits with respect to such claims. Alternatively, if a court were to find the choice of forum provisions contained in our restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, financial condition, results of operations and prospects.

Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all claims brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. Our restated bylaws will provide that the federal district courts of the United States will, to the fullest extent

permitted by law, be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, or the Federal Forum Provision, including for all causes of action asserted against any defendant named in such complaint. For the avoidance of doubt, this provision is intended to benefit and may be enforced by us, our directors, officers, other employees, agents, and the underwriters to any offering giving rise to such complaint, and any other professional person or entity whose profession gives authority to a statement made by that person or entity and who has prepared or certified any part of the documents underlying the offering. Our decision to adopt a Federal Forum Provision followed a decision by the Supreme Court of the State of Delaware holding that such provisions are facially valid under Delaware law. While federal or other state courts may not follow the holding of the Delaware Supreme Court or may determine that the Federal Forum Provision should be enforced in a particular case, application of the Federal Forum Provision means that suits brought by our stockholders to enforce any duty or liability created by the Securities Act must be brought in federal court and cannot be brought in state court, and our stockholders cannot waive compliance with the federal securities laws and the rules and regulations thereunder. Section 27 of the Exchange Act creates exclusive federal jurisdiction over all claims brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. In addition, neither the exclusive forum provision nor the Federal Forum Provision applies to suits brought to enforce any duty or liability created by the Exchange Act. Accordingly, actions by our stockholders to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder must be brought in federal court, and our stockholders cannot waive compliance with the federal securities laws and the rules and regulations thereunder.

Any person or entity purchasing or otherwise acquiring or holding any interest in any of our securities shall be deemed to have notice of and consented to our exclusive forum provisions, including the Federal Forum Provision. These provisions may limit a stockholders' ability to bring a claim, and may result in increased costs for a stockholder to bring such a claim, in a judicial forum of their choosing for disputes with us or our directors, officers, other employees or agents, which may discourage lawsuits against us and our directors, officers, other employees or agents.

The market price of our common stock is likely to be highly volatile, and you could lose all or part of your investment.

The trading price of our common stock following this offering is likely to be highly volatile and subject to wide fluctuations in response to various factors, some of which we cannot control. As a result of this volatility, investors may not be able to sell their common stock at or above the initial public offering price. The market price for our common stock may be influenced by many factors, including the other risks described in this "Risk Factors" section and the following:

- results of preclinical studies and clinical trials of any product candidates, or those of our competitors or our existing or future collaborators or licensing partners;
- the timing and enrollment status of our clinical trials;
- regulatory or legal developments in the United States or other countries, especially changes in laws or regulations applicable to any product candidates;
- the success or failure of competitive products or technologies;
- introductions and announcements of new product candidates by us, any future commercialization partners, or our competitors, and the timing of these introductions or announcements;
- actions taken by regulatory agencies with respect to any product candidates, clinical studies, and, if approved, manufacturing process or sales and marketing terms;
- actual or anticipated variations in our financial results or those of companies that are perceived to be similar to us;
- the success of our efforts to acquire or in-license additional technologies or product candidates;

- developments concerning any future collaborations, including but not limited to those with development and commercialization partners if any product candidates are approved;
- market conditions in the pharmaceutical and biotechnology sectors;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures or capital commitments;
- developments or disputes concerning patents or other proprietary rights, including patents, litigation matters and our ability to obtain patent protection for any product candidates;
- our ability or inability to raise additional capital and the terms on which we are able to raise it, if at all;
- the recruitment or departure of key personnel;
- changes in the structure of healthcare payment systems;
- actual or anticipated changes in earnings estimates, development timelines or changes in stock market analyst recommendations regarding our common stock, other comparable companies or our industry generally;
- our failure or the failure of our competitors to meet analysts' projections or guidance that we or our competitors may give to the market;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- announcement and expectation of additional financing efforts;
- speculation in the press or investment community;
- fluctuations of trading volume of our common stock;
- sales of shares of our common stock by us, insiders or our stockholders;
- the concentrated ownership of our common stock;
- expiration of market stand-off or lock-up agreements;
- changes in accounting principles;
- actions instituted by activist shareholders or others;
- terrorist acts, acts of war or periods of widespread civil unrest;
- natural disasters and other calamities, including global pandemics such as the COVID-19 pandemic; and
- general economic, industry and market conditions, including rising interest rates and inflation.

In addition, the stock market in general, and the markets for pharmaceutical, biopharmaceutical and biotechnology stocks in particular, have experienced extreme price and volume fluctuations that have been often unrelated or disproportionate to the operating performance of the issuer. Furthermore, the trading price of our common stock may be adversely affected by third parties trying to drive down the market price. Short sellers and others, some of whom post anonymously on social media, may be positioned to profit if our stock declines and their activities can negatively affect our stock price. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our actual operating performance. The realization of any of the above risks or any of a broad range of other risks, including those described in this "Risk Factors" section, could have a dramatic and adverse impact on the market price of our common stock.

We do not currently intend to pay dividends on our common stock and, consequently, our stockholders' ability to achieve a return on their investment will be dependent on appreciation of the value of our common stock.

We have never declared or paid cash dividends on our common stock. We currently intend to retain all available funds and any future earnings to support operations and to finance the growth and development of our

business. We do not intend to declare or pay any cash dividends on our capital stock in the foreseeable future. As a result, any investment return on our common stock will be dependent on increases in the value for our common stock, which is not certain. There is no guarantee that shares of our common stock will appreciate in value or even maintain the price at which stockholders have purchased their shares.

If securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our stock, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. We do not have any control over the industry or securities analysts, or the content and opinions included in their reports. We do not currently have and may never obtain research coverage by securities and industry analysts. If no or few securities or industry analysts commence coverage of us, the trading price for our common stock could be impacted negatively. In the event we obtain securities or industry analyst coverage, if any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our preclinical studies and clinical trials and operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of such analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause a decline in our stock price or trading volume.

A sale of a substantial number of shares of our common stock may cause the price of our common stock to decline.

Based on shares of our capital stock outstanding as of June 30, 2024, upon completion of this offering, we will have a total of shares of common stock outstanding. Of these shares, only the shares of common stock sold in this offering, or shares if the underwriters exercise their option to purchase additional shares in full, will be freely tradable, without restriction, in the public market immediately after this offering. Each of our officers, directors and substantially all of our stockholders have entered or will enter into lock-up agreements with the underwriters that, among other things and subject to certain exceptions, restrict their ability to sell or transfer their shares. The lock-up agreements pertaining to this offering will expire 180 days from the date of this prospectus. However, Goldman Sachs & Co. LLC, Morgan Stanley & Co. LLC and Jefferies LLC may, in their sole discretion, permit our officers, directors and other stockholders who are subject to the lock-up agreements to sell shares prior to the expiration of the lock-up agreements. After the lock-up agreements expire, based on shares outstanding as of June 30, 2024, approximately up to an additional shares of common stock will be eligible for sale in the public market, approximately of which shares are held by our officers, directors and their affiliated entities, and will be subject to volume limitations under Rule 144 under the Securities Act.

After this offering, the holders of an aggregate of shares of our outstanding common stock as of June 30, 2024 will have rights, subject to some 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 our stockholders. We also intend to register shares of common stock that we may issue under our equity incentive plans. Once we register these shares, they will be able to be sold freely in the public market upon issuance, subject to the 180-day lock-up period under the lock-up agreements described above and in the section titled “Underwriting.” See the section titled “Description of Capital Stock—Registration Rights” for additional information.

We cannot predict what effect, if any, sales of our shares in the public market or the availability of shares for sale will have on the market price of our common stock. However, future sales of substantial amounts of our common stock in the public market, including shares issued upon exercise of our outstanding options, or the perception that such sales may occur, could adversely affect the market price of our common stock.

We also expect that significant additional capital may be needed in the future to continue our planned operations. To raise capital, 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. To the extent that additional capital is raised through the sale and issuance of shares of our common stock or other securities convertible into shares of our common stock, our stockholders will be diluted. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares of our common stock, could reduce the market price of our common stock.

We will have broad discretion in the use of the net proceeds from this offering and may not use them effectively.

Our management will have broad discretion in the application of the net proceeds from this offering, including for any of the purposes described in the section titled "Use of Proceeds," and you will be relying on the judgment of our management regarding the application of these proceeds. You will not have the opportunity, as part of your investment decision, to assess whether we are using the proceeds appropriately. Our management might not apply our net proceeds in ways that ultimately increase the value of your investment. If we do not invest or apply the net proceeds from this offering in ways that enhance stockholder value, we may fail to achieve expected financial results, which could cause our stock price to decline. Pending their use, we may invest the net proceeds from this offering in a manner that does not produce income or that loses value.

No public market for our common stock currently exists, and an active and liquid trading market for our common stock may never develop. As a result, you may not be able to resell your shares of common stock at or above the initial public offering price.

Prior to this offering, no market for our common stock existed and an active trading market for our common stock may never develop or be sustained following this offering. The initial public offering price for our common stock was determined through negotiations with the underwriters and the negotiated price may not be indicative of the market price of our common stock after this offering. This price will not necessarily reflect the price at which investors in the market will be willing to buy and sell our shares following this offering, and the market value of our common stock may decrease from the initial public offering price. As a result of these and other factors, you may be unable to resell your shares of our common stock at or above the initial public offering price. The lack of an active market may impair your ability to sell your shares of common stock at the time you wish to sell them or at a price that you consider reasonable. The lack of an active market may also reduce the fair market value of your shares of common stock. Furthermore, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic collaborations or acquire companies or products by using our shares of common stock as consideration.

You will experience immediate and substantial dilution as a result of this offering and raising additional capital in the future may cause dilution to our stockholders, including purchasers of common stock in this offering, restrict our operations or require us to relinquish rights to our technologies or product candidates.

You will suffer immediate and substantial dilution with respect to the common stock you purchase in this offering. If you purchase common stock in this offering, assuming an initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and assuming that the underwriters do not exercise their option to purchase additional common stock in this offering, you will incur immediate and substantial dilution of $ per share, representing the difference between the assumed initial public offering price of $ per share and our pro forma net tangible book value per share as of June 30, 2024 after giving effect to this offering and the conversion of all outstanding redeemable convertible preferred stock upon the completion of this offering. Following the completion of this offering, investors purchasing common stock in this offering will have contributed % of the total amount invested by stockholders since inception, but will only own % of the shares of common stock outstanding. For a further description of the dilution you will experience immediately after this offering, see the section titled "Dilution."

General Risk Factors

Our current in-person operations are located in Richmond, California, and we or the third parties on whom we depend may be adversely affected by natural disasters, terrorist activity, pandemics, geo-political actions in the United States and in foreign countries, and other events beyond our control, and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster. Geo-political actions could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications or those of any current or future licensors and the maintenance, enforcement or defense of our issued patents or those of any current or future licensors.

While we are currently a remote-based company with a majority of our employees working remotely, our current in-person operations are located in our research facility in Richmond, California. Any unplanned event, such as flood, fire, explosion, earthquake, extreme weather condition, pandemic, medical epidemic, power shortage, telecommunication failure or other natural or manmade accidents or incidents that result in us being unable to fully utilize our facilities, or the manufacturing facilities of our CDMOs may have a material and adverse effect on our ability to operate our business and have significant negative consequences on our financial and operating conditions. If our facilities, or the manufacturing facilities of our CDMOs, are unable to operate because of an accident or incident or for any other reason, including an inability to use all or a significant portion of our headquarters, damages to critical infrastructure, such as our research facilities or the manufacturing facilities of our CDMOs, or other disruptions to operations, even for a short period of time, any or all of our research and development programs may be harmed. Any business interruption could have a material and adverse effect on our business, financial condition, results of operations and prospects.

Our employees often conduct business outside of any facilities leased by us. These locations may be subject to additional security and other risk factors due to the limited control of our employees. The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business. As part of our risk management policy, we maintain insurance coverage at levels that we believe are appropriate for our business. However, in the event of an accident or incident at these facilities, we cannot assure you that the amounts of insurance will be sufficient to satisfy any damages and losses.

Unstable market and economic conditions and adverse developments affecting the financial services industry, such as actual events or concerns involving inflation, liquidity, defaults or nonperformance by financial institutions or transactional counterparties, could adversely affect our current and projected business operations, and its financial condition and results of operations.

From time to time, the global credit and financial markets have experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. The financial markets and the global economy may also be adversely affected by the current or anticipated impact of military conflict, terrorism or other geopolitical events. Sanctions imposed by the United States and other countries in response to such conflicts, including the one in Ukraine, may also adversely impact the financial markets and the global economy, and any economic countermeasures by the affected countries or others could exacerbate market and economic instability. Russia’s ongoing incursion of Ukraine has created extreme volatility in the global capital markets and is expected to have further global economic consequences, including disruptions of the global supply chain and energy markets; it is possible that the ensuing Israel-Hamas conflict may have similar effects. In addition, adverse developments that affect financial institutions, such as events involving liquidity that are rumored or actual, have in the past and may in the future lead to market-wide liquidity problems. For example, in March 2023, Silicon Valley Bank (SVB), one of our banking partners, was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation (FDIC) as receiver. We previously kept substantially all of our cash and investments with SVB, the substantial majority of which was held in a custodial account with another institution, for which SVB

Asset Management was the advisor. While we were afforded full access to our cash and investments with SVB, we may be impacted by other disruptions to the U.S. banking system, including potential delays in our ability to transfer funds whether held with SVB or otherwise. The closure of any additional national or regional commercial banks could lead to further economic instability. Although the Department of the Treasury, the Federal Reserve and the FDIC have taken steps to mitigate these risks, widespread demands for customer withdrawals or other liquidity needs of financial institutions for immediately liquidity may still occur in the future. We regularly maintain cash balances at third-party financial institutions in excess of the FDIC insurance limit and there is no guarantee that the federal government would 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 have not experienced any adverse impact to our liquidity or to our current and projected business operations, financial condition or results of operations, uncertainty remains over liquidity concerns in the broader financial services industry, and our business, our business partners, or industry as a whole may be adversely impacted in ways that we cannot predict at this time. 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.

In addition, if any of our suppliers or other parties with whom we conduct business are unable to access funds pursuant to such instruments or lending arrangements with any 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, 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.

We will incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, and particularly after we are no longer an emerging growth company or smaller reporting company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of Nasdaq and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition and results of operations. Moreover, we expect these rules and regulations to substantially increase our legal and financial compliance costs and to make some activities more time consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain sufficient coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers. The increased costs will decrease our net income or increase our net loss, and the increased costs may require us to reduce costs in other areas of our business.

Moreover, these rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

We may be subject to securities litigation, which is expensive and could divert management attention.

The market price of our common stock is likely to be volatile. The stock market in general, and Nasdaq and biopharmaceutical 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, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs, divert our management's attention and resources from other business concerns and damage our reputation, which could seriously harm our business, financial condition, results of operations and prospects.

SPECIAL NOTE REGARDING FORWARD LOOKING STATEMENTS

This prospectus contains forward-looking statements. In some cases, you can identify forward- looking statements by terms such as "believe," "may," "will," "should," "potentially," "estimate," "continue," "anticipate," "intend," "target," "could," "would," "project," "plan," "expect" and similar expressions that convey uncertainty of future events or outcomes, although not all forward-looking statements contain these words. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in the section titled "Risk Factors" and elsewhere in this prospectus. Moreover, we operate in a competitive and rapidly changing environment, and new risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this prospectus may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

The forward-looking statements in this prospectus include, among other things, statements about:

- our plans to develop and commercialize our lead product candidate, azelaprag, if approved, for the treatment of obesity and our NLRP3 inhibitor, if approved, for the treatment of neuroinflammation;
- the initiation, timing, progress, results and costs of our preclinical studies and clinical trials for azelaprag, or any future preclinical studies and clinical trials of future research and development programs;
- current and future agreements with third parties in connection with our ongoing STRIDES clinical trial and any future clinical trials for azelaprag in combination with GLP-1R agonists;
- our ability to obtain the quantity of tirzepatide, semaglutide or other GLP-1R agonists required to meet the clinical needs for our ongoing and planned Phase 2 clinical trials and any future clinical trials for azelaprag in combination with those products;
- the timing of and our ability to obtain and maintain regulatory approvals for azelaprag, and any future product candidates the timing of and our ability to obtain and maintain regulatory approvals for azelaprag, and any future product candidates;
- our expectations regarding expenses, future revenue, capital requirements and our ability to obtain funding for our operations, including funding necessary to complete further clinical development and commercialization of azelaprag and further discovery, development and commercialization of any future product candidates, if approved;
- estimates of the addressable market for our current and any future product candidates, and market growth;
- our expectations regarding demand for, and market acceptance of, our product candidates, if approved;
- our ability to market or commercialize any product candidates we may develop and to compete effectively with existing competitors and new market entrants;
- our ability to obtain, maintain, protect and enforce intellectual property and proprietary rights;
- our ability to expand our pipeline of product candidates;
- the potential effects of extensive government regulations relating to our industry;
- our ability to operate our business without infringing, misappropriating or otherwise violating the intellectual property rights and proprietary technology of third parties;
- our ability to attract and retain key management and technical personnel;
- our expectations regarding any future collaboration and current or future licensing arrangements with third parties, including our ability to reach development milestones under such agreements;

- the impact of natural disasters, terrorist activity, pandemics and other events beyond our control on any of the above or any other aspect of our business operations;
- general global macroeconomic, industry and market conditions in either domestic or international markets, as well as economic conditions specifically affecting industries in which we operate, including but not limited to, actual or perceived instability in the banking industry, potential uncertainty with respect to the U.S. federal debt ceiling and budget and potential government shutdowns related thereto, labor shortages, supply chain disruptions, potential recession, inflation and changing interest rates;
- the impact of natural or man-made global events on our business, including political instability and miliary hostilities in multiple geographies, such as the conflicts in Ukraine, the Middle East and tensions between China and Taiwan;
- sales of our stock by us, our insiders or our stockholders, as well as the anticipation of lock-up releases or expiration of market stand-off or lock-up agreements;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing; and
- our expected use of the net proceeds from this offering and our existing cash and cash equivalents.

We caution you that the foregoing list may not contain all of the forward-looking statements made in this prospectus.

The forward-looking statements made in this prospectus relate only to events or information as of the date on which the statements are made in this prospectus. You should not rely upon forward- looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this prospectus to conform these statements to actual results or to changes in our expectations, except as required by law. The Private Securities Litigation Reform Act of 1995 and Section 27A of the Securities Act do not protect any forward-looking statements that we make in connection with this offering.

You should read this prospectus and the documents that we reference in this prospectus and have filed with the SEC as exhibits to the registration statement of which this prospectus is a part with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect. We qualify all of the forward-looking statements in this prospectus by these cautionary statements.

In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this prospectus, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and you are cautioned not to unduly rely upon these statements.

MARKET AND INDUSTRY DATA

This prospectus contains estimates and other statistical data made by independent parties and by us relating to our industry and the markets in which we operate, including our general expectations and market position, market opportunity, the incidence of certain medical conditions and other industry data. In some cases, we do not expressly refer to the sources from which these data are derived.

These data, to the extent they contain estimates or projections, involve a number of assumptions and limitations. Industry publications and other reports we have obtained from independent parties may state that the data contained in these publications or other reports have been obtained in good faith or from sources considered to be reliable, but they do not guarantee the accuracy or completeness of such data. The industry in which we operate is subject to risks and uncertainties due to a variety of factors, including those described in the sections titled “Risk Factors” and “Special Note Regarding Forward-Looking Statements.” These and other factors could cause results to differ materially from those expressed in these publications and reports.

USE OF PROCEEDS

We estimate that the net proceeds from this offering will be approximately $ million, or approximately $ million if the underwriters exercise their option to purchase additional shares of our common stock in full, based upon the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

Each $1.00 increase or decrease in the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease, as applicable, the net proceeds to us from this offering by $ million, assuming the number of shares offered, as set forth on the cover page of this prospectus, remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase or decrease of 1,000,000 shares in the number of shares of our common stock offered would increase or decrease, as applicable, the net proceeds that we receive from this offering by $ million, assuming that the assumed initial public offering price remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. The information discussed above is illustrative only and will adjust based on the actual initial public offering price and other terms of this offering determined at pricing.

The principal purposes of this offering are to increase our financial flexibility, to obtain additional capital to support our operations, to create a public market for our common stock and to facilitate our access to the public equity markets. We currently intend to use the net proceeds from this offering, together with our existing cash and cash equivalents as follows:

- approximately $ million to $ million to advance the continued development of azelaprag for the treatment of obesity in our STRIDES clinical trial in combination with tirzepatide, a Phase 2 clinical trial in combination with semaglutide, and the manufacture of drug products to support Phase 3 azelaprag trials sufficient for registration;
- approximately $ million to $ million to initiate an insulin sensitivity proof-of-concept trial of azelaprag monotherapy to support potential indication expansion;
- approximately $ million to $ million to advance the clinical development of an NLRP3 inhibitor for the treatment of neuroinflammation through the submission of an IND followed by the initiation of a Phase 1 clinical trial; and
- for other research and development activities and potential expansion of our pipeline, as well as for working capital and other general corporate purposes.

Based on our current operating plan, we believe that our existing cash and cash equivalents, together with the net proceeds from this offering, will be sufficient for us to fund our operations . We have based this estimate on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we expect. Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical drugs, we are unable to estimate the exact amount of our working capital requirements.

The expected use of our existing cash and cash equivalents and the net proceeds from this offering represents our intentions based upon our current plans and business conditions, which could change in the future as our plans and business conditions evolve. The amounts we actually expend in these areas, and the timing thereof, may vary significantly from our current intentions and will depend on a number of factors, including the progress of our current and planned clinical trials, regulatory feedback, the success of research and development efforts, the results and timing of any future preclinical studies and clinical trials, any new collaborations or licenses we may enter into, cash generated from future operations and actual expenses to operate our business, and other factors described in the section titled “Risk Factors.” We may also use a portion of the net proceeds of this offering to in-license, acquire or invest in complementary businesses, products or technologies, or to obtain the right to use such complementary technologies. We have no commitments with respect to any acquisition or investment, and we are not currently involved in any negotiations with respect to any such transaction.

As a result, we cannot predict with any certainty all of the particular uses for the net proceeds or the amounts that we will actually spend on the uses set forth above. Accordingly, our management will have broad discretion in the application of the net proceeds, and investors will be relying on the judgment of our management regarding the application of the net proceeds of this offering.

The expected net proceeds of this offering, together with our existing cash and cash equivalents, will not be sufficient for us to fund azelaprag, our NLRP3 inhibitor or any other future product candidates, if any, through regulatory approval, and we will need to raise substantial additional capital to complete the development and potential commercialization of our product candidates, if approved.

Pending the uses described above, we intend to invest the net proceeds from this offering in short-term, investment-grade interest-bearing securities such as money market accounts, certificates of deposit, commercial paper and guaranteed obligations of the U.S. government.

DIVIDEND POLICY

We have never declared or paid any cash dividends on our common stock. We currently intend to retain all available funds and any future earnings, if any, for use in the operation of our business and do not anticipate paying any cash dividends on our common stock in the foreseeable future. Any future determination to declare dividends will be made at the discretion of our board of directors and will depend on our financial condition, operating results, capital requirements, general business conditions and other factors that our board of directors may deem relevant. Our ability to pay cash dividends on our capital stock in the future may also be limited by any restrictions contained in any future financing instruments or by the terms of any preferred securities we may issue or agreements governing any indebtedness we may incur.

CAPITALIZATION

The following table sets forth our cash and cash equivalents and capitalization as of June 30, 2024:

- on an actual basis;
- on a pro forma basis, giving effect to (i) the automatic conversion of all outstanding shares of our redeemable convertible preferred stock as of June 30, 2024 into an aggregate of shares of our common stock and the related reclassification of the carrying value of the redeemable convertible preferred stock to permanent equity in connection with the completion of this offering, (ii) the issuance of shares of common stock pursuant to the net exercise of warrants to purchase shares of common stock and (iii)) the filing and effectiveness of our restated certificate of incorporation in connection with the completion of this offering; and
- on a pro forma as adjusted basis giving effect to (i) the pro forma adjustments described above, and (ii) the issuance and sale of shares of our common stock in this offering based upon the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The pro forma and pro forma as adjusted information set forth below is illustrative only and will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing.

You should read this table together with the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and the related notes, each included elsewhere in this prospectus.

	June 30, 2024		
	Actual	Pro Forma[1]	Pro Forma As Adjusted[1]
	(unaudited) (in thousands, except share and per share amounts)		
Cash and cash equivalents	$ 159,085	$	$
Redeemable Convertible preferred stock, par value $0.00001 per share; 93,066,066 shares authorized, 93,066,065 shares issued and outstanding, actual; no shares authorized, issued and outstanding, pro forma and pro forma as adjusted	$ 342,831	$	$
Stockholders' (deficit) equity:			
Preferred stock, par value $0.00001 per share; no shares authorized, issued and outstanding, actual; shares authorized, no shares issued and outstanding, pro forma and pro forma as adjusted			
Common stock, par value $0.00001 per share; 132,700,000 shares authorized, 7,692,086 shares issued and outstanding, actual; shares authorized, shares issued and outstanding, pro forma; shares authorized, shares issued and outstanding, pro forma as adjusted	$ 1		
Additional paid-in capital	10,976		
Accumulated other comprehensive income	167		
Accumulated deficit	(208,275)		
Total stockholders' (deficit) equity	(197,131)		
Total capitalization	$ 145,700	$	$

(1) Each $1.00 increase or decrease in the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease, as applicable, each of our pro forma as adjusted cash and cash equivalents, additional paid-in capital, total stockholders' (deficit) equity and total capitalization by approximately $ million, assuming that the number of shares offered, as set forth on the cover page of this prospectus, remains the same and

after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase or decrease of 1,000,000 shares in the number of shares of our common stock offered in this offering would increase or decrease, as applicable, each of our pro forma as adjusted cash and cash equivalents, additional paid-in capital, total stockholders' (deficit) equity and total capitalization by approximately $ million, assuming the assumed initial public offering price remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

If the underwriters' option to purchase additional shares is exercised in full, our pro forma as adjusted cash, cash equivalents and investments, additional paid-in capital, total stockholders' equity (deficit) and total capitalization as of June 30, 2024, would be $ million, $ million, $ million, and $ million respectively.

The number of shares of our common stock to be outstanding after this offering on a pro forma and pro forma as adjusted basis set forth in the table above is based on shares of our common stock outstanding as of June 30, 2024, after giving effect to the automatic conversion of all shares of our outstanding redeemable convertible preferred stock as of June 30, 2024 into an aggregate of shares of our common stock in connection with the completion of this offering, and excludes:

- 20,183,532 shares of our common stock issuable upon the exercise of stock options outstanding as of June 30, 2024 under our 2015 Plan, with a weighted-average exercise price of $1.89 per share;
- shares of our common stock issuable upon the exercise of stock options granted after June 30, 2024 under our 2015 Plan, with a weighted-average exercise price of $ per share;
- 30,000 shares of our common stock issuable upon the exercise of a warrant outstanding as of June 30, 2024, with an exercise price of $0.72 per share;
- 111,436 shares of our common stock issuable upon the exercise of warrants outstanding as of June 30, 2024, with an exercise price of $2.30 per share;
- shares of our common stock reserved for future issuance under our 2024 Plan, which will become effective in connection with this offering (including shares reserved for issuance under our 2015 Plan, which shares will be added to the 2024 Plan upon its effectiveness); and
- shares of our common stock to be reserved for future issuance under our ESPP, which will become effective in connection with this offering.

DILUTION

If you invest in our common stock in this offering, your ownership interest will be immediately diluted to the extent of the difference between the initial public offering price per share of our common stock in this offering and the pro forma as adjusted net tangible book value per share of our common stock immediately after this offering.

Net tangible book value per share is determined by dividing our total tangible assets (which excludes deferred offering costs) less our total liabilities and redeemable convertible preferred stock by the number of shares of our common stock outstanding. Our historical net tangible book deficit as of June 30, 2024 was $ million, or $ per share, based on shares of our common stock outstanding as of that date.

After giving effect to the automatic conversion of all outstanding shares of our redeemable convertible preferred stock as of June 30, 2024 into an aggregate of shares of our common stock and the related reclassification of the carrying value of the redeemable convertible preferred stock to permanent equity in connection with this offering, our pro forma net tangible book value as of June 30, 2024 would have been $ million, or $ per share of our common stock.

After giving further effect to the sale of shares of common stock in this offering by us at the assumed initial public offering price of $ per share (the midpoint of the price range set forth on the cover page of this prospectus), and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of June 30, 2024 would have been $ million, or approximately $ per share. This amount represents an immediate increase in pro forma net tangible book value of $ per share to our existing stockholders and an immediate dilution in pro forma net tangible book value of approximately $ per share to new investors participating in this offering.

Dilution per share to new investors is determined by subtracting pro forma as adjusted net tangible book value per share after this offering from the initial public offering price per share paid by new investors. The following table illustrates this dilution (without giving effect to any exercise by the underwriters of their option to purchase additional shares):

Assumed initial public offering price per share		$
Historical net tangible book value (deficit) per share as of June 30, 2024	$	
Pro forma increase in historical net tangible book value per share as of June 30, 2024 attributable to the pro forma adjustments described above		
Pro forma net tangible book value per share as of June 30, 2024		
Increase in pro forma net tangible book value per share attributable to new investors participating in this offering		
Pro forma as adjusted net tangible book value per share after this offering		
Dilution per share to new investors participating in this offering		$

Each $1.00 increase or decrease in the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease, as applicable, the pro forma as adjusted net tangible book value per share after this offering by $ per share, and dilution per share to new investors in this offering by $ per share, assuming the number of shares offered, as set forth on the cover page of this prospectus, remains the same, and after deducting the estimated underwriting discounts and commissions and the estimated offering expenses payable by us. Similarly,

each increase or decrease of 1,000,000 shares in the number of shares of our common stock offered in this offering would increase or decrease, as applicable, our pro forma net tangible book value per share after this offering by approximately $ million per share and pro forma as adjusted net tangible book value by approximately $ million per share, and dilution per share to new investors in this offering by $ per share, assuming the initial public offering price per share remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. The pro forma as adjusted information is illustrative only, and we will adjust this information based on the actual initial public offering price and other terms of this offering determined at pricing.

If the underwriters exercise their option to purchase additional shares in full, the pro forma as adjusted net tangible book value after the offering would be approximately $ per share, the increase in pro forma as adjusted net tangible book value per share to existing stockholders would be approximately $ per share and the dilution to new investors in this offering would be $ per share, assuming an initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus.

The following table shows, as of June 30, 2024, on a pro forma as adjusted basis described above, the differences between the existing stockholders and the new investors purchasing shares in this offering at the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, with respect to the number of shares purchased from us, the total consideration paid, which includes net proceeds received from the issuance of common and redeemable convertible preferred stock and cash received from the exercise of stock options, and the weighted-average price paid per share:

	Shares Purchased		Total Consideration		Weighted-Average Price Per Share
(in thousands, except share and per share amounts)	Number	Percent	Amount	Percent	
Existing stockholders before this offering		%	$	%	$
New investors participating in this offering		%	$	%	$
Total		100.0%	$	100.0%	

Each $1.00 increase or decrease in the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease, as applicable, total consideration paid by new investors, total consideration paid by all stockholders and the weighted-average price per share paid by all stockholders by approximately $ million, $ million and $ per share, respectively, assuming that the number of shares offered, as set forth on the cover page of this prospectus, remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase or decrease of 1,000,000 shares in the number of shares of our common stock offered in this offering would increase or decrease, as applicable, total consideration paid by new investors, total consideration paid by all stockholders and the weighted-average price per share paid by all stockholders by approximately $ million, $ million and $ per share, respectively, assuming the assumed initial public offering price of $ per share remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

In addition, to the extent that any outstanding options are exercised, investors in this offering will experience further dilution.

Except as otherwise indicated, the above discussion and tables assume no exercise of the underwriters' option to purchase additional shares. If the underwriters exercise their option to purchase additional shares in full, our existing stockholders would own % and our new investors would own % of the total number of shares of our common stock outstanding upon the completion of this offering.

The foregoing tables and calculations (other than historical net tangible book value) are based on shares of our common stock outstanding as of June 30, 2024, after giving effect to the automatic conversion of all shares of our outstanding redeemable convertible preferred stock as of June 30, 2024 into an aggregate of shares of our common stock in connection with the completion of this offering, and excludes:

- 20,183,532 shares of our common stock issuable upon the exercise of stock options outstanding as of June 30, 2024 under our 2015 Plan, with a weighted-average exercise price of $1.89 per share;
- shares of our common stock issuable upon the exercise of stock options granted after June 30, 2024 under our 2015 Plan, with a weighted-average exercise price of $ per share;
- 30,000 shares of our common stock issuable upon the exercise of a warrant outstanding as of June 30, 2024 with an exercise price of $0.72 per share;
- 111,436 shares of our common stock issuable upon the exercise of warrants outstanding as of June 30, 2024 with an exercise price of $2.30 per share;
- shares of our common stock reserved for future issuance under our 2024 Plan, which will become effective in connection with this offering (including shares reserved for issuance under our 2015 Plan, which shares will be added to the 2024 Plan upon its effectiveness); and
- shares of our common stock to be reserved for future issuance under our ESPP, which will become effective in connection with this offering.

Our 2024 Plan and ESPP provide for automatic annual increases in the number of shares of common stock reserved thereunder, and our 2024 Plan provides for increases to the number of shares that may be granted thereunder based on shares under our 2015 Plan that expire, are tendered to or withheld by us for payment of an exercise price or for satisfying tax withholding obligations or are forfeited or otherwise repurchased by us. See the section titled “Executive Compensation—Equity Compensation Plans and Other Benefit Plans” for additional information.

To the extent that these outstanding stock options are exercised, new stock options are issued or we issue additional shares of our common stock in the future, there will be further dilution to new investors. In addition, we may choose to raise additional capital because of market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans. If we raise additional capital through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

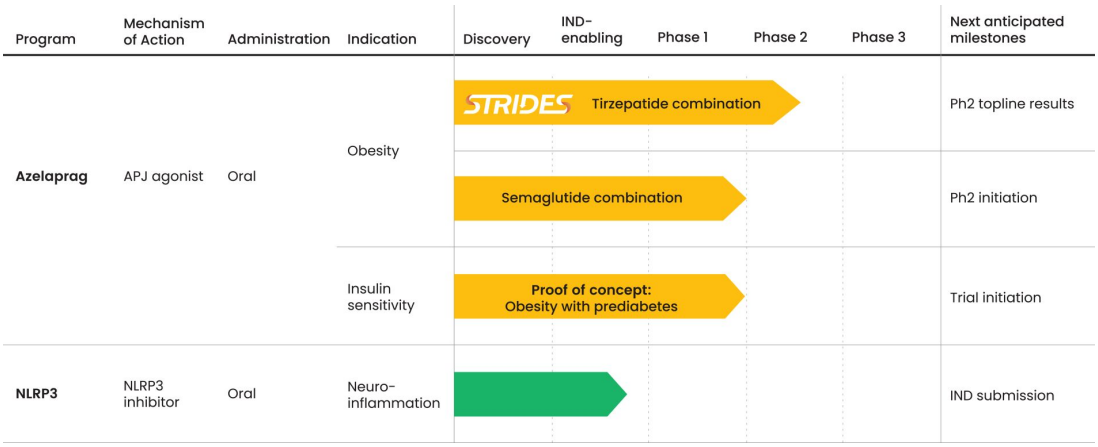
MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with our consolidated financial statements and the related notes and other financial information included elsewhere in this prospectus. This discussion and analysis and other parts of this prospectus contain forward-looking statements based upon our current plans and expectations that involve risks, uncertainties and assumptions, such as statements regarding our plans, objectives, expectations, intentions and beliefs. Our actual results and the timing of events could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth under the section titled "Risk Factors" and elsewhere in this prospectus. You should carefully read the section titled "Risk Factors" to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements. Please also see the section titled "Special Note Regarding Forward-Looking Statements."

Overview

We are a clinical-stage biopharmaceutical company developing therapeutic product candidates for metabolic diseases, such as obesity, by targeting the biology of human aging. Our technology platform and differentiated human datasets enable us to identify promising targets based on insights into molecular changes that drive aging. Our primary focus is metabolic disease, one of the greatest global healthcare challenges. Azelaprag, our lead product candidate, is an orally available small molecule that has been well-tolerated in over 240 individuals across seven Phase 1 clinical trials. In preclinical obesity models, azelaprag demonstrated the ability to more than double the weight loss induced by a glucagon-like-peptide-1 receptor (GLP-1R) agonist while also restoring healthy body composition and improving muscle function. These preclinical results are supported by our Phase 1b clinical trial in older adults on bed rest where we observed decreased muscle atrophy, preservation of muscle quality and improved metabolism in subjects treated with azelaprag over a 10-day period. We plan to assess azelaprag's potential to drive significant improvements in weight loss when combined with a GLP-1R agonist in two Phase 2 clinical trials. While the results of these preclinical studies and early clinical trials have demonstrated the potential use of azelaprag for the treatment of metabolic disease, they may not be predictive of the results of later-stage clinical trials. The ongoing STRIDES clinical trial will assess azelaprag in combination with tirzepatide, marketed as Zepbound® by Eli Lilly (Lilly), with topline results anticipated in . The second Phase 2 clinical trial will assess azelaprag in combination with semaglutide, marketed as Wegovy® by Novo Nordisk, with initiation expected in . We believe these trials will directly support our ultimate therapeutic goal of developing an all-oral combination product for obesity. We also intend to initiate an insulin sensitivity proof-of-concept trial of azelaprag monotherapy in to support potential indication expansion. We are also developing orally-available small molecule brain-penetrant NLRP3 inhibitors for the treatment of diseases driven by neuroinflammation. We anticipate submitting an Investigational New Drug application (IND) for an NLRP3 inhibitor in and, if cleared, initiating a Phase 1 clinical trial in .

Our portfolio of product candidates is summarized in the figure below:



Since our inception in 2015, we have devoted substantially all of our efforts to organizing and staffing our company, business planning, raising capital, establishing our intellectual property portfolio, acquiring or discovering product candidates, research and development activities for our product candidates, establishing arrangements with third parties for the manufacture of our product candidates and component materials, and providing general and administrative support for these operations. We do not have any products approved for sale and have not generated any revenue from product sales. To date, we have financed our operations primarily with proceeds from sales of shares of our redeemable convertible preferred stock. From inception, through June 30, 2024, we have raised aggregate gross proceeds of approximately $320.7 million through the sale and issuance of our common stock, redeemable convertible preferred stock and convertible promissory notes. Our primary uses of capital are, and we expect will continue to be, research and development services, compensation and related expenses, and general overhead costs.

We have incurred significant operating losses and negative cash flows since inception. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of azelaprag and any future product candidates. Our net losses were $26.6 million and $28.3 million for the six months ended June 30, 2024 and 2023, respectively, and $63.9 million and $39.7 million for the years ended December 31, 2023 and 2022, respectively. As of June 30, 2024, we had an accumulated deficit of $208.3 million. We expect to continue to incur net operating losses for the foreseeable future, and we expect our research and development expenses, general and administrative expenses, and capital expenditures will increase substantially in connection with our ongoing activities, particularly if, and as, we:

- continue to progress the development of our lead product candidate, azelaprag;
- explore additional indications for our existing product candidates;
- discover and develop any future product candidates;
- obtain, expand, maintain, defend and enforce our intellectual property portfolio;
- manufacture, or have manufactured, preclinical, clinical and potentially commercial supplies of azelaprag and any future product candidates;
- seek regulatory approvals for azelaprag or any future product candidates that successfully complete clinical trials, if any;
- establish a sales, marketing and distribution infrastructure to commercialize azelaprag or any future product candidates, if approved;

- seek to identify, evaluate and establish licenses, collaborations or other strategic partnerships;
- hire additional clinical, scientific and management personnel, as well as administrative staff to support the growth of our business;
- add operational, financial and management information systems and personnel; and
- incur additional legal, accounting and other costs associated with operating as a public company following the completion of this offering.

Our net losses may fluctuate significantly from period to period, depending on the timing of factors above.

We will not generate revenue from product sales unless and until we successfully complete clinical development and obtain regulatory approval for a product candidate. In addition, if we obtain regulatory approval for a product candidate and do not enter into a third-party commercialization partnership, we expect to incur significant expenses related to developing our commercialization capability to support product sales, marketing, manufacturing and distribution activities.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through equity offerings, debt financings or other capital sources, which could include licenses, collaborations, or other strategic partnerships. Adequate additional funds may not be available to us on acceptable terms, or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of our existing stockholders may be diluted, and the terms of these securities may include liquidation or other preferences that could adversely affect the rights of such stockholders. Debt financing, if available, may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, which could adversely impact our ability to conduct our business. If we raise additional funds through licenses, collaborations, or other strategic partnerships with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research program or product candidates, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. There is no assurance that we will ever be profitable or generate positive cash flow from operating activities. Our ability to raise additional funds may also be adversely impacted by potential worsening global macroeconomic, industry and market conditions in either domestic or international markets, as well as economic conditions specifically affecting industries in which we operate, including but not limited to, actual or perceived instability in the banking industry, potential uncertainty with respect to the U.S. federal debt ceiling and budget and potential government shutdowns related thereto, labor shortages, supply chain disruptions, potential recession, inflation and changing interest rates and political instability and miliary hostilities in multiple geographies, such as the conflicts in Ukraine, the Middle East and tensions between China and Taiwan.

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

We oversee and manage third party Contract Development and Manufacturing Organizations (CDMOs) to support development and manufacture of azelaprag for our preclinical and clinical trials. We expect to enter into commercial supply agreements with commercial manufacturers prior to any potential regulatory approval of azelaprag or any future product candidates. We continue to develop a commercial route for azelaprag manufacture in alignment with our program timeline. We believe our current manufacturers are able to supply the upcoming clinical trials and additional CDMOs may be on-boarded at later stages of clinical and commercial development.

As of June 30, 2024, we had $159.1 million in cash and cash equivalents. Based on our current operating plan, we estimate that our existing cash and cash equivalents as of the date of this prospectus, together with the net proceeds from this offering, will be sufficient to fund our operations and capital expenses through . However, we have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect.

Exclusive License Agreement with Amgen, Inc.

On April 5, 2021, we entered into an exclusive license agreement (the Amgen Agreement) with Amgen Inc. (Amgen) pursuant to which Amgen granted us an exclusive, worldwide license, with the right to sublicense (subject to certain conditions), under Amgen's rights in specified patents relating to Amgen's proprietary compound, AMG 986, a novel apelin J receptor agonist, to research, develop, and commercialize AMG 986 in all diagnostic, preventative or therapeutic uses. Amgen also granted us a non-exclusive, worldwide license, with the right to sublicense (subject to certain conditions), under Amgen's rights in specified know-how relating to AMG 986, including research reports, clinical data, manufacturing processes, regulatory documents, and other information pertaining to AMG 986, to research, develop, and commercialize AMG 986 in all diagnostic, preventative or therapeutic uses. Although we maintain the exclusive rights described above with respect to the specified patents, Amgen retains research-only rights solely for Amgen's internal research. All right, title and interest to inventions conceived or created by a party under the Amgen Agreement that are exclusively related to AMG 986 will be owned exclusively by us, regardless of inventorship.

Under the Amgen Agreement, we are obligated to use commercially reasonable efforts to develop and commercialize at least one licensed product in each of the United States, European Union, Japan and the rest of the world ("ROW"). If we fail to materially develop or commercialize such products for twelve months in the United States, European Union, Japan, or ROW, and such failure is not due to reasons out of our control, in addition to other available remedies, Amgen may terminate our agreement with respect to the failing region, subject to a cure period.

In consideration for the rights granted under the Amgen Agreement, we paid an upfront fee of $1.0 million and issued Amgen 846,152 shares of our Series C redeemable convertible preferred stock which will automatically convert into shares of our common stock in connection with the completion of this offering. Additionally, we may also be required to pay up to an additional $120.0 million in the aggregate for future development, regulatory and commercial milestone payments, as well as tiered royalties at percentages ranging in the low- to upper-single digits on future net sales by us and our sublicensees of licensed products, if any. Royalties are paid on a product-by-product basis and commence with respect to a particular country upon the first commercial sale in such country and terminate in such country on the latest to occur of the date on which such product is no longer covered by a valid claim in such country, the loss of regulatory exclusivity for such product in such country, and for a specified time period after the first commercial sale of such product in such country. Such royalties may be decreased if, among other reasons, we are required to pay a third party for rights to intellectual property for the exploitation of a licensed product in a given country, but in no event be reduced in aggregate by a specified percentage.

The term of the Amgen Agreement will end on a licensed product-by-licensed product basis and country-by-country basis upon the expiration of our obligation to pay royalties to Amgen with respect to such licensed products in such countries. We may terminate the Amgen Agreement in its entirety for convenience upon a specified written notice period. Amgen has the right to terminate the agreement if we, or one of our affiliates or sublicensees, challenges the patentability, enforceability, or validity of a licensed patent, subject to a cure period. Additionally, either party will be able to terminate the Amgen Agreement for the other party's uncured material breach or bankruptcy.

For a more detailed description of this agreement, see the section titled "Business—Material Agreements" and Note 9 to our audited consolidated financial statements included elsewhere in this prospectus.

Components of Our Results of Operations

Revenue

We have not generated any product revenue since our inception and do not expect to generate any revenue from the sale of products or from other sources in the near future, if at all. If our development efforts for our lead product candidate, azelaprag or additional product candidates that we may develop in the future are successful and result in marketing approval or if we enter into collaboration or license agreements with third parties, we may generate revenue in the future from a combination of product sales or payments from such collaboration or license agreements.

Operating Expenses

Our operating expenses consist of (i) research and development expenses and (ii) general and administrative expenses.

Research and Development Expense

Research and development expenses account for a significant portion of our operating expenses and consist primarily of costs incurred in connection with the discovery, preclinical development, clinical development and manufacturing of azelaprag and potential future product candidates, and include:

Direct Costs:

- expenses incurred under agreements with contract research organizations (CROs) that are primarily engaged in the oversight and conduct of our clinical trials; CDMOs that are primarily engaged to provide drug substance and product for our clinical trials, research and development programs, as well as investigative sites and consultants that conduct our clinical trials, preclinical studies and other scientific development services;
- the cost of acquiring and manufacturing preclinical and clinical trial materials, including manufacturing registration and validation batches;
- costs of outside consultants, including their fees and related travel expenses;
- costs related to compliance with quality and regulatory requirements; and
- payments made under third-party licensing agreements.

Indirect Costs:

- personnel-related expenses including, salaries, bonuses, benefits, stock-based compensation expenses and other related costs for individuals involved in research and development activities; and
- allocated facilities and other expenses not directly tied to a program.

We expense research and development costs as incurred. We recognize direct development costs based on an evaluation of the progress to completion of specific tasks using information provided to us by our vendors or our estimate of the level of service that has been performed at each reporting date. Payments for these development activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and are reflected in our financial statements as prepaid expenses or accrued expenses.

A significant portion of our research and development costs to date have been third-party direct costs, which we track on an individual product candidate basis after a product candidate progresses to the clinic. However, our indirect costs are not directly tied to any one program and are deployed across our programs. As such, we do not

track these costs on a specific program basis. We utilize third party contractors for our research and development activities and CDMOs for our manufacturing activities and we do not have our own manufacturing facilities.

Research and development activities are central to our business model. We expect that our research and development expenses will continue to increase substantially for the foreseeable future as we advance azelaprag into multiple Phase 2 clinical trials, the NLRP3 inhibitors that we are developing for the treatment of neuroinflammation toward the submission of an IND application (IND) and into a Phase 1 clinical trial, continue to discover and develop additional product candidates, expand our headcount and costs related to our existing and potential future intellectual property licenses. Later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. There are numerous factors associated with the successful development and commercialization of any product candidates we may develop in the future, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. Additionally, future commercial and regulatory factors beyond our control will impact our clinical development program and plans.

Our research and development expenses may vary significantly in the future based on factors, such as:

- the number and scope of preclinical and IND-enabling studies;
- per patient trial costs;
- the number of trials required for approval;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- the number of patients that participate in the trials;
- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring requested by regulatory agencies;
- the duration of patient participation in the trials and follow-up;
- the cost and timing of manufacturing our product candidates;
- the phase of development of our product candidates;
- the efficacy and safety profile of our product candidates;
- the extent to which we establish additional collaboration or license agreements; and
- whether we choose to partner any of our product candidates and the terms of such partnership.

Any changes in the outcome of any of these variables with respect to the development of azelaprag or any future product candidates in preclinical and clinical development could mean a significant change in the costs and timing associated with the development of these product candidates. For example, if the U.S. Food and Drug Administration, European Medicines Agency or another regulatory authority were to delay our planned start of clinical trials or require us to conduct clinical trials or other testing beyond those that we currently expect, or if we experience significant delays in enrollment in any clinical trials following the applicable regulatory authority's acceptance and clearance, we could be required to expend significant additional financial resources and time to complete clinical development than we currently expect. We may never obtain regulatory approval for any product candidates that we develop.

The successful development of azelaprag or any product candidates we may develop in the future is highly uncertain. Therefore, we cannot reasonably estimate or know the nature, timing and estimated costs of the efforts

that will be necessary to complete the development and commercialization of azelaprag and any other product candidates we may develop. We are also unable to predict when, if ever, material net cash inflows will commence from the sale of azelaprag or any future product candidate, if approved. This is due to the numerous risks and uncertainties associated with product development.

General and Administrative Expense

General and administrative expenses consist primarily of personnel-related expenses, including salaries, bonuses benefits and stock-based compensation expenses for individuals in executive, finance, corporate, business development and administrative functions. Other significant general and administrative expenses include legal fees relating to patent, intellectual property and corporate matters, and fees paid for accounting, consulting and other professional services, and allocated expenses for rent, insurance and other operating costs.

We expect that our general and administrative expenses will continue to increase in the foreseeable future as our business expands to support our continued research and development activities, including any future clinical trials. These increases will likely include increased costs related to the hiring of additional personnel and fees to outside consultants, among other expenses. We also anticipate increased expenses associated with being a public company, including costs for audit, legal, regulatory and tax-related services related to compliance with the rules and regulations of the SEC, listing standards applicable to companies listed on a national securities exchange, director and officer insurance premiums and investor relations costs. In addition, if we obtain regulatory approval for our current product candidate or any product candidates we may develop in the future and do not enter into a third-party commercialization collaboration, we expect to incur significant expenses related to building a sales and marketing team to support product sales, marketing and distribution activities.

Other (Income) Expense, Net

Interest Expense

Interest expense consists of interest incurred on both our convertible promissory notes and term loan.

Interest and Other Income

Interest and other income primarily consist of interest income generated from interest bearing cash accounts.

Gain (Loss) from Changes in Fair Value of Warrants and Derivative Liabilities

Gain (loss) on changes in fair value consists of assessed changes in fair value of liabilities carried at fair value, including warrants to purchase our common stock and the embedded derivative liability associated with our convertible promissory notes.

Loss on Extinguishment of Convertible Promissory Notes

Loss on extinguishment of convertible promissory notes consists of the difference between the carrying value of our convertible promissory notes (including accrued interest) and related embedded derivative liability and the fair value of shares issued upon conversion of our convertible promissory notes into our Series D-1 Redeemable Convertible Preferred Stock in February 2024.

Income Taxes

Since our inception, we have not recorded any income tax benefits for the net losses we have incurred in each period or for our research and development tax credits, as we believe, based upon the weight of available evidence, that it is more likely than not that all of our net operating loss carryforwards and tax credits will not be

realized. As of December 31, 2023, we had U.S. federal and state net operating loss carryforwards of $83.8 million and $13.4 million, respectively, which expire at various dates beginning in 2035. These attributes may be subject to Section 382 limitation and we have not performed a formal assessment. As of the six months ended June 30, 2024 and 2023, and the years ended December 31, 2023 and 2022, we have recorded a full valuation allowance against our deferred tax assets.

Results of Operations

Comparison of the Six Months Ended June 30, 2024 and 2023

The following table summarizes our results of operations for each of the periods presented (in thousands, except percentages):

	Six Months Ended June 30,			
	2024	2023	$ Change	% Change
	(unaudited)			
Operating expenses:				
Research and development	$ 19,792	$ 17,272	$ 2,520	15%
General and administrative	8,290	7,645	645	8
Total operating expenses	28,082	24,917	3,165	13
Loss from operations	$(28,082)	$(24,917)	$(3,165)	13
Other income (expense), net:				
Interest expense	(1,660)	(2,832)	1,172	(41)
Interest and other income	3,497	1,553	1,944	125
Loss from changes in fair value on derivative liability and warrants	(78)	(2,075)	1,997	(96)
Loss on extinguishment of convertible promissory notes	(250)	—	(250)	(100)
Total other income (expense), net	1,509	(3,354)	4,863	(145)
Net loss	$(26,573)	$(28,271)	$ 1,698	(6)%

Research and Development Expenses

The following table summarizes our research and development expenses for each of the periods presented (in thousands, except percentages):

	Six Months Ended June 30			
	2024	2023	$ Change	% Change
	(unaudited)			
Direct costs:				
azelaprag	$ 7,215	$ 2,632	$ 4,583	174%
Other programs	2,078	4,939	(2,861)	(58)
Indirect costs:				
Personnel-related expenses (including stock-based compensation expense)	7,690	6,665	1,025	15
Allocated facility and other expenses	2,809	3,036	(227)	(7)
Total research and development expenses	$ 19,792	$ 17,272	$ 2,520	15%

Research and development expenses increased by $2.5 million from $17.3 million for the six months ended June 30, 2023 to $19.8 million for the six months ended June 30, 2024. The increase was primarily attributable to a $4.6 million increase in costs related to the clinical development of azelaprag as it progressed

toward Phase 2 trials in combination with a GLP-1R agonist and a $1.0 million increase in personnel-related expenses (including stock-based compensation expense) primarily due to increased salaries and related expenses; a $2.9 million decrease in direct costs related to other programs, as we have focused our development spend primarily on azelaprag and a $0.2 million decrease in allocated facility and other expenses primarily related to lab services.

General and Administrative Expenses

General and administrative expenses increased by $0.7 million from $7.6 million for the six months ended June 30, 2023 to $8.3 million for the six months ended June 30, 2024. The increase was primarily attributable to an increase in stock-based compensation expense associated with option grants issued in April 2024 to employees and executives.

Other Income (Expense), Net

Other income, net increased by approximately $4.9 million from $3.4 million of other expense for the six months ended June 30, 2023 to $1.5 million of other income for the six months ended June 30, 2024. This increase in other income was primarily attributable to a $1.9 million increase in interest income driven by our higher cash and cash equivalents balance, a $2.0 million decrease in losses from changes in fair value primarily related to the embedded derivative liability associated with our convertible promissory notes as these notes converted into Series D-1 redeemable convertible preferred stock in February 2024, and a $1.2 million decrease in interest expense as our convertible promissory notes converted into Series D-1 redeemable convertible preferred stock in February 2024. These increases were partially offset by a $0.3 million loss on extinguishment of convertible promissory notes associated with conversion of the convertible promissory notes into Series D-1 redeemable convertible preferred stock in February 2024.

Comparison of the Years Ended December 31, 2023 and 2022

The following table summarizes our results of operations for each of the periods presented (in thousands, except percentages):

	Year Ended December 31,			
	2023	2022	$ Change	% Change
Operating expenses:				
Research and development	$ 33,886	$ 30,522	$ 3,364	11%
General and administrative	14,514	9,447	5,067	54
Total operating expenses	48,400	39,969	8,431	21
Loss from operations	(48,400)	(39,969)	(8,431)	21
Other income (expense), net:				
Interest expense	(7,794)	(241)	(7,553)	N/A
Interest and other income	2,431	465	1,966	423
Gain (loss) from changes in fair value on derivative liability and warrants	(10,091)	23	(10,114)	N/A
Total other (income) expense, net	(15,454)	247	(15,701)	N/A
Net loss	$(63,854)	$(39,722)	$(24,132)	61%

Research and Development Expenses

The following table summarizes our research and development expenses for each of the periods presented (in thousands, except percentages):

	Year Ended December 31, 2023	2022	$ Change	% Change
Direct costs:				
azelaprag	$ 6,443	$ 4,624	$ 1,819	39%
Other programs	9,450	10,508	(1,058)	(10)
Indirect costs:				
Personnel-related expenses (including stock-based compensation expense)	13,726	12,675	1,051	8
Allocated facility and other expenses	4,267	2,715	1,552	57
Total research and development expenses	$ 33,886	$ 30,522	$ 3,364	11%

Research and development expenses increased by $3.4 million from $30.5 million for the year ended December 31, 2022 to $33.9 million for the year ended December 31, 2023. This increase was primarily attributable to a $1.8 million increase in costs related to the clinical development of azelaprag as it progressed toward phase 2 trials in combination with a GLP-1R agonist; a $1.1 million increase in personnel-related expenses (including stock-based compensation expense) primarily due to increased salaries and related expenses; a $1.6 million increase in allocated facility and other expenses primarily due to an increase in lab supplies and services; and a $1.1 million decrease in direct costs related to other programs, as we have focused our development spend primarily on azelaprag.

General and Administrative Expenses

General and administrative expenses increased by $5.1 million from $9.4 million for the year ended December 31, 2022 to $14.5 million for the year ended December 31, 2023. This increase was primarily attributable to a $3.2 million increase in personnel-related costs including stock-based compensation expense related to increased headcount; and a $1.9 million increase in professional fees related to legal, consulting, and IT costs.

Other Income (Expense), Net

Other expense, net increased by approximately $15.7 million from $0.2 million of income for the year ended December 31, 2022 to $15.5 million of expense for the year ended December 31, 2023. This increase is primarily attributable to a $10.1 million increase in losses from changes in fair value related to the embedded derivative liability associated with our convertible promissory notes and a $7.6 million increase in interest expense related to increased borrowings. These increases are partially offset by a $2.0 million increase in interest and other income as a result of higher cash balances and increased interest rates on our cash and cash equivalents.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have incurred significant losses in each period and on an aggregate basis. We have not yet commercialized any product candidates, and we do not expect to generate revenue from sales of any product candidates or from other sources for the foreseeable future, if at all. As of June 30, 2024, we had $159.1 million in cash and cash equivalents, and we had an accumulated deficit of $208.3 million. To date, we have financed our operations primarily with proceeds from sales of shares of our redeemable convertible preferred stock. From inception through June 30, 2024, we have raised aggregate gross proceeds of approximately $320.7 million through the sale and issuance of our common stock, redeemable convertible preferred stock and convertible promissory notes.

In May 2022, we entered into a loan and security agreement (the Loan Agreement) with SVB Innovative Credit Growth Fund IX, LP and Innovative Credit Growth Fund VIII-A, LP pursuant to which we were able to borrow up to an aggregate of $25.0 million across two potential tranches until December 31, 2023 (the Term Loan). The Loan Agreement has a floating interest rate of the higher of the Wall Street Journal Prime rate plus 4.00% or 7.5%. The amounts borrowed under the Loan Agreement are scheduled to mature on April 1, 2026 and commencing on November 1, 2023 we are required to make monthly principal payments. In addition, we will also be required to pay a final payment fee equal to 4.4% of the total amount borrowed. As of June 30, 2024, we had $11.0 million outstanding under the Loan Agreement.

Cash Flows

The following table provides information regarding our cash flows for each of the periods presented (in thousands):

	Year Ended December 31,		Six Months Ended June 30,	
	2023	2022	2024	2023
			(unaudited)	
Net cash used in operating activities	$ (37,362)	$ (36,181)	$ (31,453)	$(21,096)
Net cash used in investing activities	(266)	(103)	(35)	(167)
Net cash provided by financing activities	34,941	2,499	165,614	35,992
Effects of exchange rate changes on cash, cash equivalents, and restricted cash	—	246	2	30
Net increase (decrease) in cash, cash equivalents, and restricted cash	$ (2,687)	$ (33,539)	$134,128	$ 14,759

Net Cash Used in Operating Activities

Net cash used in operating activities for the year ended December 31, 2023 was $37.4 million, and was primarily due to our net loss of $63.9 million, which included a non-cash charges of $10.1 million related to losses from changes in fair value on warrants and derivative liabilities, $6.5 million related to non-cash interest expense, and $3.0 million related to stock-based compensation expense. Partially offsetting the increase in net cash used in operating activities was a $3.7 million increase in accrued expenses and other current liabilities and a $3.3 million increase in deferred grant income.

Net cash used in operating activities for the year ended December 31, 2022 was $36.2 million, and was primarily due to our net loss of $39.7 million, which included a non-cash charge of $2.5 million related to stock-based compensation expense.

Net cash used in operating activities during the six months ended June 30, 2024 was $31.5 million, and was primarily due to our net loss of $26.6 million, a $5.8 million decrease in accrued expenses and other current liabilities related to operating activities, a $1.2 million decrease in accounts payable related to operating activities, and a $1.6 million increase in prepaid expenses and other current assets related to operating activities.

Net cash used in operating activities during the six months ended June 30, 2023 was $21.1 million, and was primarily due to our net loss of $28.3 million, which included non-cash charges of $1.5 million related to stock-based compensation expense, $2.6 million of non-cash interest expense, and $2.1 million related to losses from changes in fair value on warrants and derivative liabilities.

Net Cash Used in Investing Activities

Net cash used in investing activities for the years ended December 31, 2023 and December 31, 2022 was $0.3 million and $0.1 million, respectively.

Net cash used in investing activities for the six months ended June 30, 2024 and 2023 was less than $0.1 million and $0.2 million, respectively.

Net Cash Provided by Financing Activities

Net cash provided by financing activities for the year ended December 31, 2023 was $34.9 million, primarily resulting from proceeds of $23.5 million received from the issuance and sale of convertible promissory notes, net of issuance costs, $12.5 million in proceeds received from our Term Loan, net of issuance costs, partially offset by $1.0 million of Term Loan principal payments.

Net cash provided by financing activities for the year ended December 31, 2022 was $2.5 million, resulting from proceeds received from our Term Loan, net of issuance costs.

Net cash provided by financing activities during the six months ended June 30, 2024 was $165.6 million, resulting from $169.5 million in net proceeds from the issuance and sale of our Series D redeemable convertible preferred stock and $0.4 million in proceeds from stock option exercises partially offset by $3.0 million in principal payments on our Term Loan, and $1.3 million in deferred offering cost payments.

Net cash provided by financing activities during the six months ended June 30, 2023 was $36.0 million, resulting from proceeds of $23.5 million received from the issuance and sale of convertible promissory notes and $12.5 million in proceeds from the Term Loan.

Funding Requirements

Our primary uses of capital are, and we expect will continue to be, research and development services, compensation and related expenses and general overhead costs. We expect to continue to incur significant expenses and operating losses for the foreseeable future. In addition, upon the closing of this offering, we expect to incur additional costs associated with operating as a public company. We anticipate that our expenses will increase significantly in connection with our ongoing activities.

Based on our current operating plan, we estimate that our existing cash and cash equivalents as of the date of this prospectus, without taking into consideration the net proceeds from this offering, will be sufficient to fund our projected operations and capital expenses through at least the next 12 months from the date of this prospectus. In addition, based on our current operating plan, we estimate that our existing cash and cash equivalents, together with the net proceeds from this offering, will be sufficient to fund our operations and capital expenses through . However, we have based these estimates on assumptions that may prove to be wrong, and we could exhaust our capital resources sooner than we expect.

Because of the numerous risks and uncertainties associated with research, development and commercialization of product candidates, we are unable to estimate the exact amount of our working capital requirements. Our future funding requirements will depend on, and could increase significantly as a result of, many factors, including:

- the timing, cost and progress of preclinical and clinical development activities;
- the cost of regulatory submissions and timing of regulatory approvals;
- the number and scope of preclinical and clinical programs we decide to pursue;
- the progress of the development efforts of parties with whom we may in the future enter into licenses, collaborations or other strategic partnerships;
- the timing and amount of milestone and other payments we are obligated to make under our Amgen Agreement or any future license agreements;

- the cash requirements of any future acquisitions or discovery of product candidates;
- our ability to establish and maintain licenses, collaborations or other strategic partnerships with third parties on favorable terms, if at all;
- the costs involved in prosecuting and enforcing patent and other intellectual property claims;
- the costs of manufacturing our product candidates by third parties;
- the cost of commercialization activities if azelaprag or any future product candidates are approved for sale, including marketing, sales and distribution costs;
- our efforts to enhance operational systems and hire additional personnel, including personnel to support development of our product candidates; and
- our need to implement additional internal systems and infrastructure, including financial and reporting systems to satisfy our obligations as a public company.

A change in the outcome of any of these or other variables with respect to the development of azelaprag or any product or development candidate we may develop in the future could significantly change the costs and timing associated with our development plans. Further, our operating plans may change in the future, and we may need additional funds to meet operational needs and capital requirements associated with such operating plans.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through equity offerings, debt financings or other capital sources, which could include licenses, collaborations, or other strategic partnerships. We currently have no credit facility or committed sources of capital. Adequate additional funds may not be available to us on acceptable terms, or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of our existing stockholders may be diluted, and the terms of these securities may include liquidation or other preferences that could adversely affect the rights of such stockholders. Debt financing, if available, may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, that could adversely impact our ability to conduct our business. If we raise additional funds through licenses, collaborations, or other strategic partnerships with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research program or product candidates, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. There is no assurance that we will ever be profitable or generate positive cash flow from operating activities.

Contractual Obligations and Other Commitments

For more information on the Amgen Agreement, see the section titled “Business—Material Agreements.”

Lease Obligations

We lease office and lab space at our corporate headquarters in Richmond, California (the Headquarters Lease). The Headquarters lease is accounted for as an operating lease and expires on August 31, 2025. As of June 30, 2024, our non-cancellable lease obligations were $0.4 million, of which $0.3 million is due within the next 12 months.

Purchase and Other Obligations

We enter into contracts in the normal course of business with CROs, CDMOs and other third-party vendors for preclinical research studies and testing, clinical trials and testing and manufacturing services. Most contracts

do not contain minimum purchase commitments and are cancellable by us upon written notice. Payments due upon cancellation consist of payments for services provided or expenses incurred, including non-cancelable obligations of our service provided up to one year after the date of cancellation.

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 United States Generally Accepted Accounting Principles (GAAP). The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets and liabilities and the reported amounts of income and expenses during the reporting period. We continually evaluate our estimates and judgments used in preparing our consolidated financial statements and related disclosures. All estimates affect reported amounts of assets, liabilities, income and expenses. These estimates and judgments are also based on historical experience and other factors that are believed to be reasonable under the circumstances. Materially different results can occur as circumstances change and additional information becomes known.

Although our significant accounting policies are described in more detail in Note 2 to each of our audited consolidated financial statements and unaudited condensed consolidated financial statements included elsewhere in this prospectus, 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.

Accrued and Prepaid Research and Development Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued and prepaid third-party research and development expenses as of each balance sheet date. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf, and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. The majority of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met. We make estimates of our accrued and prepaid expenses as of each balance sheet date based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary. The significant estimates in our accrued and prepaid research and development expenses include the costs incurred for services performed by our vendors in connection with research and development activities for which we have not yet been invoiced.

We base our expenses related to research and development activities on our estimates of the services received and efforts expended pursuant to quotes and contracts with vendors that conduct research and development activities on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the research and development expense. 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 the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepaid balance accordingly. Non-refundable advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made.

Although we do not expect our estimates to be materially different from amounts incurred, if our estimates of the status and timing of services performed differ from the actual status and timing of services performed, it could result in us reporting amounts that are too high or too low in any particular period. To date, there have been no material differences between our estimates of such expenses and the amounts incurred.

Stock-Based Compensation

Compensation cost for our stock-based payments to employees, non-employees and directors, are based on estimated fair value of the awards on the date of grant. Our stock-based compensation awards are generally subject to service-based vesting conditions. Compensation expense related to awards to employees, directors and non-employees with service-based vesting conditions is recognized on a straight-line basis based on the grant date fair value over the associated service period of the award, which is generally the vesting term.

The fair value of each stock option is estimated on the grant date using the Black-Scholes option pricing model, which requires inputs based on certain subjective assumptions, including:

- Risk-Free Interest Rate—The risk-free interest rate is based on the U.S. Treasury zero coupon issues in effect at the time of grant for periods corresponding with the expected term of option.
- Expected Term—We use the simplified method (based on the mid-point between the vesting date and the end of the contractual term) to estimate the expected term of the option. Management has limited historical information to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior our stock option grants. The simplified method makes the assumption that the employee will exercise share options evenly over the period when the share options are vested and ending on the date when the share options would expire.
- Expected Volatility—Since our shares are not publicly traded, expected volatility is estimated based on the average historical volatility of similar entities with publicly traded shares. When selecting comparable publicly traded biopharmaceutical companies on which we have based our expected stock price volatility, we selected companies with comparable characteristics, including enterprise value, risk profiles, development stage, and with historical share price information sufficient to meet the expected term of the stock-based awards.
- Expected Dividend Yield—We have never paid dividends on our common stock and have no plans to pay dividends on our common stock. Therefore, we used an expected dividend yield of zero.
- Estimated Fair Value of Common Stock—The estimated fair value of the shares of common stock underlying stock options was determined by our board of directors. Because there was no public market for our common stock, our board of directors determined fair value of the common stock at the time of grant of the options by considering a number of objective and subjective factors including important developments in our operations, valuations performed by an independent third party, sales of redeemable convertible preferred stock, actual operating results and financial performance, the conditions in the biotechnology industry and the economy in general, the stock price performance and volatility of comparable public companies, and the lack of liquidity of the our common stock, among other factors.

See Note 7 to each of our audited consolidated financial statements and unaudited condensed consolidated financial statements included elsewhere in this prospectus for information concerning certain of the specific assumptions we used in applying the Black-Scholes option pricing model to determine the estimated fair value of our stock options granted in the years ended December 31, 2023 and 2022, and in the six months ended June 30, 2024 and 2023.

We recorded stock-based compensation expense of $2.4 million and $1.5 million for the six months ended June 30, 2024 and 2023, respectively. As of June 30, 2024, there was $19.2 million of unrecognized stock-based compensation expense related to unvested stock options, to be recognized over a weighted-average period of 3.3 years. In future periods, we expect our stock-based compensation expense to increase, due in part to our existing unrecognized stock-based compensation expense and as we grant additional stock-based awards to continue to attract and retain our employees.

Based on an assumed initial public offering price of $ per share, which is the midpoint of the estimated price range set forth on the cover page of this prospectus, the aggregate intrinsic value of vested and unvested stock options outstanding as of 2024 was $ million and $ million, respectively.

Common Stock Valuations

As there has been no public market for our common stock prior to this offering, the estimated fair value of our common stock underlying our stock-based awards has been determined by our board of directors as of each option grant date with input from management, considering our most recently available third-party valuations of common stock and our board of directors' assessment of additional objective and subjective factors that it believed were relevant and which may have changed from the date of the most recent valuation through the date of the grant. These third-party valuations were performed in accordance with the guidance outlined in ASC 718, *Compensation*, and the guidance provided by the American Institute of Certified Public Accountants' *Accounting and Valuation Guide, Valuation of Privately-Held-Company Equity Securities Issued as Compensation* (the Practice Aid).

For valuations performed prior to January 21, 2022, in accordance with the Practice Aid, we determined the Option Pricing Method (OPM) was the most appropriate method for determining the fair value of our common stock based on our stage of development and other relevant factors. Within the OPM framework, the backsolve method for inferring the total equity value implied by a recent financing transaction involves the construction of an allocation model that takes into account our capital structure and the rights, preferences and privileges of each class of stock, then assumes reasonable inputs for the other OPM variables (expected time to liquidity, volatility and risk-free rate). The total equity value is then iterated in the model until the model output value for the equity class sold in a recent financing round equals the price paid in that round. In determining the estimated fair value of the common stock, our board of directors also considered the fact that the stockholders could not freely trade the common stock in the public markets. Accordingly, we applied discounts to reflect the lack of marketability of our common stock based on the weighted-average expected time to liquidity.

For valuations performed after January 21, 2022, in accordance with the Practice Aid, we determined the hybrid method was the most appropriate method for determining the fair value of our common stock based on our stage of development and other relevant factors. The hybrid method is a probability-weighted expected return method (PWERM), where the equity value in one or more scenarios is calculated using an OPM. The PWERM is a scenario-based methodology that estimates the fair value of common stock based upon an analysis of future values for the company, assuming various outcomes. The common stock value is based on the probability-weighted present value of expected future investment returns considering each of the possible outcomes available as well as the rights of each class of stock. The future value of the common stock under each outcome is discounted back to the valuation date at an appropriate risk-adjusted discount rate and probability weighted to arrive at an indication of value for the common stock. A discount for lack of marketability of the common stock is then applied to arrive at an indication of value for the common stock.

Given the absence of a public trading market, our board of directors, with input from management, considered numerous objective and subjective factors to determine the fair value of common stock. The factors included, but were not limited to:

- contemporaneous valuations performed by an independent third-party valuation firm;
- our stage of development and material risks related to our business;
- the progress of our research and development programs, including the status and results of preclinical studies and clinical trials;
- our business conditions and projections;
- recent sales of our redeemable convertible preferred stock;

- the rights, preferences and privileges of our redeemable convertible preferred stock relative to those of our common stock;
- lack of marketability of our common and redeemable convertible preferred stock as a private company;
- our operating results and financial performance;
- the likelihood of achieving a liquidity event, such as an initial public offering or sale of our company, in light of prevailing market conditions;
- the trends, developments and conditions in the life sciences and biopharmaceutical industry sectors;
- analysis of initial public offerings and the market performance and stock price volatility of similar public companies in the life sciences and biopharmaceutical sectors; and
- the economy in general.

Once a public trading market for our common stock has been established in connection with the completion of this offering, it will no longer be necessary for our board of directors to estimate the fair value of our common stock in connection with our accounting for granted stock options and other such awards we may grant, as the fair value of our common stock will be determined based on the quoted market price of our common stock.

Convertible Promissory Notes and Embedded Derivative Liability

In February 2023, we issued four convertible promissory notes with an aggregate principal amount of $23.5 million (the Convertible Promissory Notes). The Convertible Promissory Notes contained equity conversion options and certain repayment features, that were identified as a single compound embedded derivative requiring bifurcation from the Convertible Promissory Notes. The Convertible Promissory Note embedded derivative liability was initially measured at fair value on issuance and was subject to remeasurement at each reporting period with changes in fair value recognized in the change in fair value of warrants and derivative liabilities caption of the consolidated statements of operations and comprehensive loss. Upon the closing of the Series D redeemable convertible preferred stock financing in February 2024 (the Series D Financing), the Convertible Promissory Notes (including accrued interest) and the related embedded derivative liability converted into 11,887,535 shares of our Series D-1 redeemable convertible preferred stock, resulting in an extinguishment of the Convertible Promissory Notes and settlement of the embedded derivative liability.

We estimated the fair value of the embedded derivative liability related to the Convertible Promissory Notes on issuance and at each reporting period using a with-and-without scenario analysis. The estimated probability and timing of underlying events triggering the conversion and liquidity repayment features as well as discount rates, volatility and share prices were inputs used to determine the estimated fair value of the embedded derivative.

The estimate for the embedded derivative liability was based, in part, on subjective assumptions. Changes to these assumptions could have had a significant impact on the fair value, and the change in fair value, of the derivative liability as well as interest expense.

See Note 2 to each of our audited consolidated financial statements and unaudited condensed consolidated financial statements included elsewhere in this prospectus for information concerning the accounting treatment of the Convertible Promissory Notes.

Internal Controls Over Financial Reporting

A company's internal control over financial reporting is a process designed by, or under the supervision of, a company's principal executive and principal financial officers, or persons performing similar functions, and effected by a company's board of directors, management and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with

generally accepted accounting principles. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that it is reasonably possible that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis.

In connection with our preparation and the audit of our consolidated financial statements as of and for the years ended December 31, 2023 and 2022, management identified material weaknesses, as defined under the Exchange Act and by the Public Company Accounting Oversight Board (United States), in our internal control over financial reporting. The material weaknesses we identified related to the overall control environment as we had insufficient internal resources with appropriate accounting and finance knowledge and expertise to design, implement, document and operate effective internal controls around our financial reporting process and the lack of effective information technology general controls.

We intend to and have begun to implement measures designed to improve our internal control over financial reporting to remediate these material weaknesses, including formalizing our processes and internal control documentation and strengthening supervisory reviews by our financial management; hiring additional qualified accounting and finance personnel with technical accounting and financial reporting experience in the application of complex areas of GAAP, engaging financial consultants and collaborating with our internal audit consultants to enable the implementation of internal control over financial reporting and improving segregation of duties among accounting and finance personnel in the preparation and review of account reconciliations and journal entries. We will also review and improve the design of our general information technology controls including managing user access and privileged access, managing changes in the information system and segregation of duties with the systems supporting our accounting and reporting processes.

While we are implementing these measures, we cannot assure you that these efforts will remediate our material weaknesses in a timely manner, or at all, or prevent misstatements of our financial statements in the future. If we are unable to successfully remediate our material weaknesses, or identify any future material weaknesses, the accuracy and timing of our financial reporting may be adversely affected, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports, and the market price of our common stock may decline as a result.

Emerging Growth Company and Smaller Reporting Company Status

Under Section 107(b) of the JOBS Act an “emerging growth company” can delay the adoption of new or revised accounting standards until such time as those standards would apply to private companies. We have elected this exemption to delay adopting new or revised accounting standards until such time as those standards apply to private companies. Where allowable we have early adopted certain standards as described in Note 2 of each of our audited consolidated financial statements and unaudited condensed consolidated financial statements included elsewhere in this prospectus. As a result, our consolidated financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates. We will continue to remain an “emerging growth company” until the earliest of the following: (i) the last day of the fiscal year following the fifth anniversary of the date of the completion of this offering; (ii) the last day of the fiscal year in which our total annual gross revenue is equal to or more than $1.235 billion; (iii) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

We are also a “smaller reporting company,” meaning that the market value of our stock held by non-affiliates plus the proposed aggregate amount of gross proceeds to us as a result of this offering is less than $700.0 million and our annual revenue is less than $100.0 million during the most recently completed fiscal year. We may continue to be a smaller reporting company after this offering if either (i) the market value of our stock held by non-affiliates is less than $250.0 million or (ii) our annual revenue is less than $100.0 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700.0 million.

If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Recent Accounting Pronouncements

In November 2023, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures, which requires disclosure of incremental segment information on an annual and interim basis. This ASU is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024 on a retrospective basis. We are currently evaluating the potential impact that this standard may have on our consolidated financial statements and related disclosures.

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures, to improve its income tax disclosure requirements. Under the ASU, entities must annually (i) disclose specific categories in the rate reconciliation, (ii) provide additional information for reconciling items that meet a quantitative threshold, and (iii) disclose more detailed information about income taxes paid, including by jurisdiction; pretax income (or loss) from continuing operations; and income tax expense (or benefit). The ASU is effective for fiscal years beginning after December 15, 2024, with early adoption permitted. We do not expect this update to have a material impact on our consolidated financial statements.

Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our cash equivalents are held in money market funds that are invested in U.S. Treasury securities and our Term Loan has a variable interest rate that fluctuates with the U.S. prime rate.

Interest income is sensitive to changes in the general level of interest rates. However, due to the short-term maturities of our cash equivalents, we do not believe a hypothetical 100 basis point increase or decrease in interest rates during any of the periods presented would have had a material impact on our consolidated financial statements included elsewhere in this prospectus.

Interest expense is sensitive to changes in the general level of interest rates as our Term Loan incurs interest at a floating per annum rate equal to the U.S. prime rate plus 4.00% with an interest rate floor of 7.5%. However, we do not believe a hypothetical 100 basis point increase or decrease in interest rates during any of the periods presented would have had a material impact on our consolidated financial statements included elsewhere in this prospectus.

Credit Risk

Our primary exposure to credit risk is through financial instruments and consist primarily of cash and cash equivalents. We regularly maintain deposits in accredited financial institutions in excess of federally insured limits. As of June 30, 2024, we held cash deposits at Silicon Valley Bank in excess of FDIC insured limits.

Foreign Currency Exchange Risk

All of our employees and our operations are currently located in the United States and our expenses are generally denominated in U.S. dollars. We therefore are not currently exposed to significant market risk related

to changes in foreign currency exchange rates. However, we have contracted with and may continue to contract with non-U.S. vendors who we may pay in local currency. Our operations may be subject to fluctuations in foreign currency exchange rates in the future. To date, foreign currency transaction gains and losses have not been material to our financial statements, and we have not had a formal hedging program with respect to foreign currency. We do not believe a hypothetical 100 basis point increase or decrease in exchange rates during any of the periods presented would have had a material effect on our consolidated financial statements included elsewhere in this prospectus.

Effects of Inflation

Inflation generally affects us by increasing our cost of labor and research and development costs. We do not believe that inflation had a material effect on our business, results of operations, or financial condition, or on our consolidated financial statements included elsewhere in this prospectus.

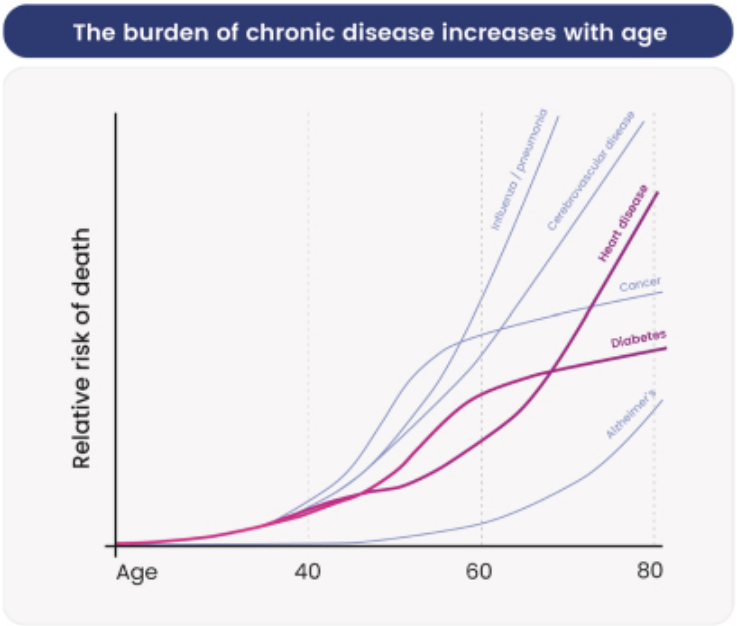
BUSINESS

Overview

We are a clinical-stage biopharmaceutical company developing therapeutic product candidates for metabolic diseases, such as obesity, by targeting the biology of human aging. Our technology platform and differentiated human datasets enable us to identify promising targets based on insights into molecular changes that drive aging. Our primary focus is metabolic disease, one of the greatest global healthcare challenges. Azelaprag, our lead product candidate, is an orally available small molecule that has been well-tolerated in over 240 individuals across seven Phase 1 clinical trials. In preclinical obesity models, azelaprag demonstrated the ability to more than double the weight loss induced by a glucagon-like-peptide-1 receptor (GLP-1R) agonist while also restoring healthy body composition and improving muscle function. These preclinical results are supported by our Phase 1b clinical trial in older adults on bed rest where we observed decreased muscle atrophy, preservation of muscle quality and improved metabolism in subjects treated with azelaprag over a 10-day period. We plan to assess azelaprag's potential to drive significant improvements in weight loss when combined with a GLP-1R agonist in two Phase 2 clinical trials. While the results of these preclinical studies and early clinical trials have demonstrated the potential use of azelaprag for the treatment of metabolic disease, they may not be predictive of the results of later-stage clinical trials. The ongoing STRIDES clinical trial will assess azelaprag in combination with tirzepatide, marketed as Zepbound® by Lilly with topline results anticipated in . The second Phase 2 clinical trial will assess azelaprag in combination with semaglutide, marketed as Wegovy® by Novo Nordisk, with initiation expected in . We believe these trials will directly support our ultimate therapeutic goal of developing an all-oral combination product for obesity. We also intend to initiate an insulin sensitivity proof-of-concept trial of azelaprag monotherapy in to support potential indication expansion. We are also developing orally available small molecule brain-penetrant NLRP3 inhibitors for the treatment of diseases driven by neuroinflammation. We anticipate submitting an IND for an NLRP3 inhibitor in and, if cleared, initiating a Phase 1 clinical trial in .

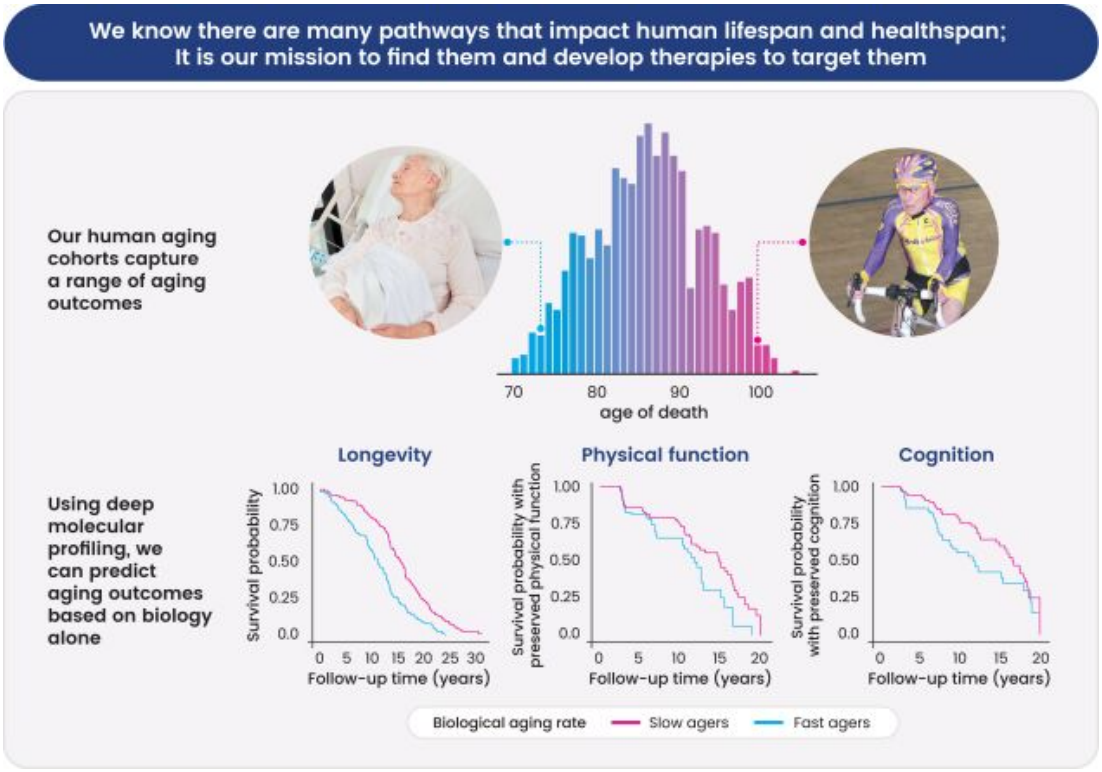
Our approach: Targeting human aging biology to treat chronic metabolic diseases

The burden of many serious and chronic diseases—including cardiovascular disease and diabetes—increases with age.



Age is a key risk factor for mortality from many chronic diseases in the United States, including cardiometabolic diseases like heart disease and diabetes. (Source: National Center for Health Statistics).

However, there is substantial natural variation in the human population, resulting in a broad range of aging trajectories and outcomes, with some people experiencing much longer lifespans as well as delayed disease onset. We created our company to identify biological pathways associated with longer, healthier human lifespans and to develop pharmaceutical products that can modulate these pathways with the intent to prevent and reverse specific diseases, focusing on metabolic diseases.

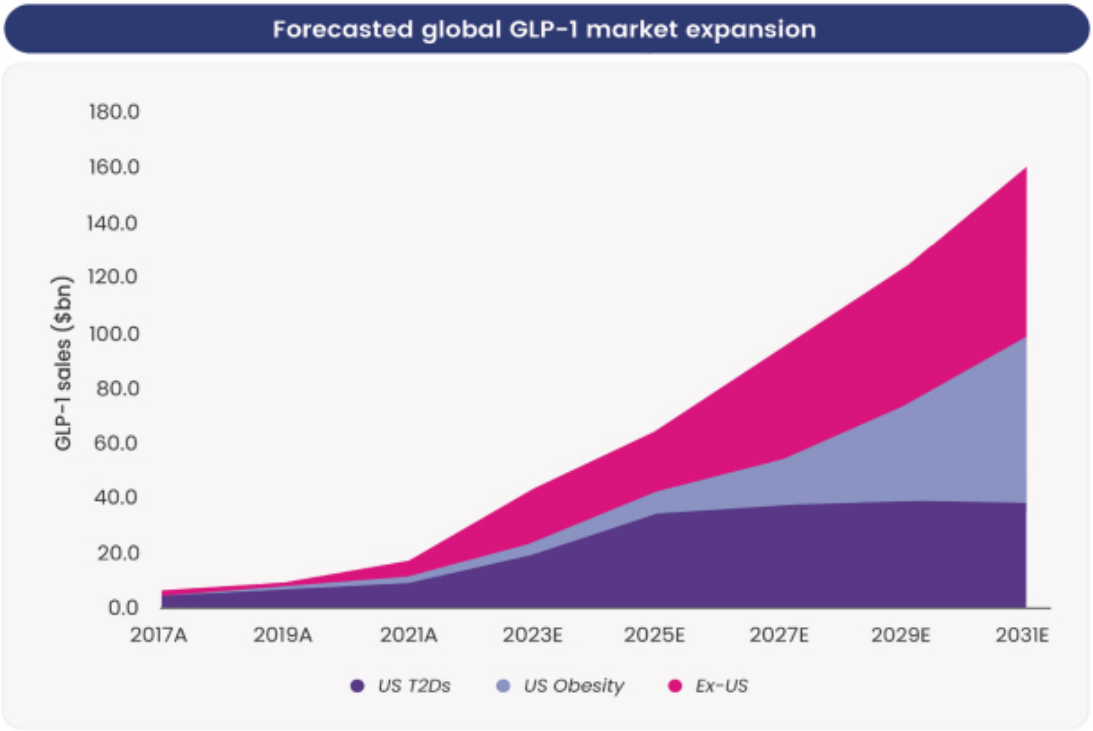


We capture a range of aging outcomes in our human aging cohorts, including functional and cognitive decline, disease incidence and mortality. In this example, deep, serial profiling of circulating proteins in these participants was used to understand the biology that drives these outcomes.

Our approach starts with human data. We examine the impact of the molecular changes that happen naturally as people age and study how these changes drive both functional decline (e.g., loss of muscle strength) and disease risk (e.g., obesity, insulin resistance, dyslipidemia, hypertension). To develop new insights into the biological drivers of aging, we have generated proprietary longitudinal human datasets based on exclusive access to a unique resource: serial biobanked human samples coupled with health records and functional measurements collected for up to 50 years, capturing individual aging trajectories measured over several decades. We analyze these samples using state-of-the-art molecular profiling technologies, measuring thousands of biologically relevant molecules, and then apply computational tools to the resulting data to extract potential drivers of a long and healthy lifespan.

The BioAge platform encompasses over 50 million molecular data points spanning over 10 thousand individual participant profiles and over 50 years of follow-up.

We have selected chronic metabolic diseases as our primary focus within age related chronic diseases, given their high prevalence and resulting potential for impact on population health. Chronic metabolic diseases represent some of the largest addressable therapeutics markets. Through our approach, we expect to target outsized commercial opportunities, initially within the obesity and diabetes landscape. For instance, according to third-party estimates, the global market for GLP-1R agonists, including those used to treat diabetes, is expected to grow to $150 billion by 2031.



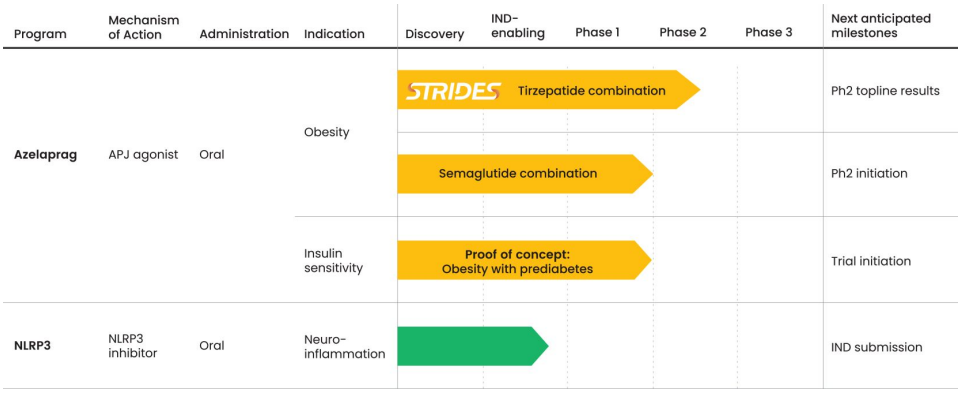
According to third-party estimates, the global GLP-1R market across obesity and type 2 diabetes is expected to exceed $150 billion globally by 2031, largely driven by expansion of the obesity commercial potential.

Our Pipeline

We are building a pipeline of platform-derived therapeutics targeting chronic metabolic disease. Our lead product candidate, azelaprag, is an orally available small molecule agonist of the apelin receptor (APJ) where activation has the potential to recapitulate many of the benefits of exercise. We are developing azelaprag for the treatment of obesity in combination with GLP-1R agonists with the goal of increasing overall weight loss, with the potential to also improve tolerability and body composition. We have initiated one Phase 2 clinical trial of azelaprag in combination with tirzepatide and plan to initiate a second Phase 2 clinical trial of azelaprag in combination with semaglutide. The ongoing STRIDES clinical trial will assess azelaprag in combination with tirzepatide, marketed as Zepbound® by Lilly, with topline results anticipated in . The second Phase 2 clinical trial will assess azelaprag in combination with semaglutide, marketed as Wegovy® by Novo Nordisk, with initiation expected in .

To support potential indication expansion, we also intend to initiate an insulin sensitivity proof-of-concept trial with azelaprag monotherapy in . We are also developing a series of oral small molecule inhibitors of NLRP3, a key driver of inflammation which is linked to many diseases including obesity. We anticipate submitting an IND for an NLRP3 inhibitor in , and, if cleared, initiating a Phase 1 clinical trial in . From our platform, we have several additional targets with product candidates in discovery stages, and we are also continuously seeking to identify and develop further promising targets.

Our portfolio of product candidates is summarized in the figure below:



Our lead product candidate, azelaprag: an orally available, small molecule APJ agonist that has the potential to recapitulate the effects of exercise

Leveraging our platform, we found that apelin levels decrease with age and that higher levels of apelin are predictive of both improved physical function and increased longevity. Apelin is a type of signaling molecule released in response to exercise known as an exerkine, which has the potential to recapitulate many of the downstream benefits of exercise when administered. Azelaprag is an orally available, small molecule agonist of APJ that we are developing for the treatment of obesity.

In December 2022, we announced results demonstrating a statistically significant maintenance of muscle size and quality in participants administered 240 mg of azelaprag as compared to placebo from our Phase 1b clinical trial in 21 healthy volunteers ≥65 years old over 10 days of bed rest, of which 10 received placebo. We also observed several metabolic benefits in subjects dosed with azelaprag, including significantly higher rates of muscle protein synthesis as well as preservation of predicted resting energy expenditure and cardiorespiratory fitness. Azelaprag was also observed to shift the levels of circulating proteins in a way that is highly overlapping with endurance exercise, further supporting that it may be able to mimic some global effects of exercise at the protein level.

Across seven Phase 1 clinical trials conducted between us and Amgen, azelaprag has been well-tolerated in over 240 individuals, with an adverse event rate similar to placebo.

We are advancing azelaprag as a treatment for obesity, where our key therapeutic goal is to achieve injectable-like overall weight loss in an all-oral combination with an incretin, with the potential to also improve tolerability and body composition.

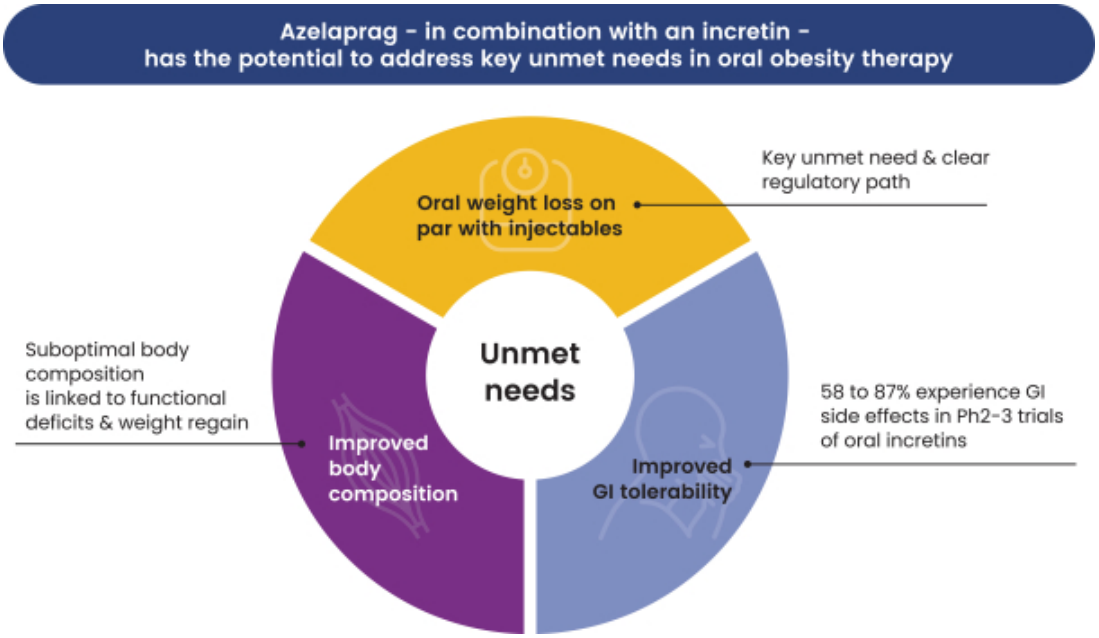
Similar to how exercise increases weight loss in obese patients on incretins, administration of azelaprag in combination with GLP-1R agonists resulted in potent synergistic increase in weight loss achieved in a preclinical model of diet-induced obesity. The addition of azelaprag was shown to approximately double total weight loss while restoring body composition and muscle function to that of lean controls, without any significant additional decrease in energy intake. The addition of azelaprag was also observed to significantly reduce non-fasting glucose levels. While the results of these preclinical studies and early clinical trials have demonstrated the potential use of azelaprag for the treatment of metabolic disease, they may not be predictive of the results of later-stage clinical trials.

The evolving obesity treatment landscape: we believe azelaprag addresses multiple key unmet needs

Obesity is associated with a range of adverse health outcomes such as insulin resistance, dyslipidemia and increased blood pressure that can be reduced or even completely resolved with weight loss, with outcomes largely proportional to the amount of weight lost. Until recently, pharmaceutical treatments for obesity had limited efficacy and furthermore were associated with side effects that led to poor tolerability. The development of a class of drugs known as incretins has dramatically changed the treatment landscape.

GLP-1R agonists are part of the incretin class, which mimics the effects of hormones released after eating and are used to treat metabolic diseases. Certain injectable GLP-1R agonists have recently been approved for the treatment of diabetes and obesity. However, there continues to be significant interest by pharmaceutical companies in oral obesity medications given strong patient preference and fewer supply chain challenges compared to injectables, including cold-chain requirements and high manufacturing costs.

Despite the recent approvals of such injectable GLP-1R agonists, there remain important unmet needs for people struggling with obesity, including improved oral efficacy, tolerability and body composition:



Key unmet needs for weight loss regimens include increased weight loss in an all-oral regimen, improved tolerability and improved body composition.

- *Oral efficacy*: Overall weight loss with oral incretins has lagged injectables, potentially because the most advanced orals have a single target (GLP-1R) whereas some injectables have combined multiple mechanisms. For example, subjects taking oral semaglutide (50 mg), currently the most advanced oral drug in this class, achieved 15.1% weight loss at week 68 compared to 20.9% at week 72 for patients being administered tirzepatide, (15 mg), a dual GLP-1R / GIP agonist, which is currently the leading weight loss injectable. Clinical trial results suggest efficacy of injectable incretins may increase further. For example, retatrutide, which combines three different incretin mechanisms, achieved 24.2% overall weight loss at week 48 in a Phase 2 clinical trial. Furthermore, oral doses that achieve more competitive efficacy have often been observed to come with the tradeoff of worsened tolerability.
- *Tolerability*: Current GLP-1R agonists are not well-tolerated by all patients. Across obesity trials of injectable semaglutide and tirzepatide, up to 44% of subjects experienced gastrointestinal side effects such as nausea, diarrhea, and vomiting, which contributes to a discontinuation rate of up to 17%. The incidence of gastrointestinal adverse events is even higher with other oral GLP-1R agonists in late-stage third-party clinical trials. Because these adverse effects are dose-dependent, we believe combination approaches with APJ agonists may provide an opportunity to achieve weight reduction goals using a lower and therefore potentially more tolerable dose of GLP-1R agonists.
- *Body composition*: The benefits of weight loss mediated by GLP-1R agonists can be compromised by suboptimal body composition—the balance of lean and fat mass. In older patients, up to half of the weight loss is comprised of lean body mass, which is primarily muscle. Suboptimal body composition has been linked to several adverse treatment outcomes including rebound weight gain and impaired physical function, especially in older patients.

We are currently planning Phase 2 clinical trials with azelaprag in combination with injectable GLP-1R agonists, as these drugs are approved, however our ultimate objective is to develop an all-oral weight loss combination with an oral incretin. Dosing oral incretin drugs in combination with orally administered azelaprag could provide well-tolerated weight loss in line with that achieved by injectable agonists alone, as well as superior body composition.

Our azelaprag clinical development strategy

We are initiating two Phase 2 clinical trials of azelaprag in combination with GLP-1R agonists. STRIDES, the first clinical trial, is an ongoing clinical trial in combination with tirzepatide in approximately 220 obese individuals aged 55 and over, an age group that represents 35-40% of the adult obese population in the US. We are initially focusing on these older patients because the strong muscle and metabolic benefits of azelaprag observed in our Phase 1b clinical trial were achieved in older patients. The goal of the STRIDES clinical trial is to establish proof of concept for enhanced weight loss. The primary endpoint of this trial will be weight loss at 24 weeks. In addition, biomarkers, changes in body composition and glucose control will be assessed as exploratory endpoints. We anticipate topline results in .

We have a material transfer agreement with Lilly, under which Lilly has agreed to provide us with tirzepatide in connection with our STRIDES clinical trial of azelaprag in obesity. Lilly's Chorus clinical development organization is advising and assisting on all aspects of the Phase 2 STRIDES clinical trial design and execution, enabling us to benefit from Lilly's extensive clinical experience in this space, while retaining all rights to azelaprag.

The goals of our second Phase 2 clinical trial are to demonstrate:

- A GLP-1R-like agonist class effect.
- Efficacy in a wider population that includes younger patients.
- Overall weight loss achieved after 52 weeks of treatment.

To that end, we intend to combine azelaprag with semaglutide in our second Phase 2 clinical trial and enroll approximately 300 obese individuals ages 18 and older. Trial initiation is anticipated in . The primary endpoint of this Phase 2 clinical trial will be weight loss at 52 weeks, with similar exploratory endpoints to the tirzepatide combination trial.

While we are currently planning Phase 2 clinical trials with azelaprag in combination with injectable GLP-1R agonists, as these drugs are already approved, our ultimate objective is to develop an all-oral weight loss combination with an oral incretin.

In parallel, we intend to initiate an insulin sensitivity proof-of-concept trial of azelaprag monotherapy in to support potential indication expansion. The goal of this clinical trial is to assess the potential direct benefits of azelaprag, informing potential subsequent development for treatment of obesity with comorbid type 2 diabetes in combination with a GLP-1R agonist.

We are also developing orally available, brain-penetrant inhibitors of NLRP3, a key target for neuroinflammation

We are developing brain-penetrant, structurally novel small molecule inhibitors of NLRP3 that have a novel binding site. NLRP3 is a component of a multi-protein complex referred to as the inflammasome. Inactivation of NLRP3 in mice has been shown to significantly extend lifespan and sustain physical and cognitive function. NLRP3-driven neuroinflammation has been linked to both obesity and neurodegenerative diseases. We intend to submit an IND for an NLRP3 inhibitor with the FDA and, if cleared, initiate a Phase 1 trial to evaluate safety, tolerability, pharmacokinetics and pharmacodynamics in healthy volunteers.

Our team

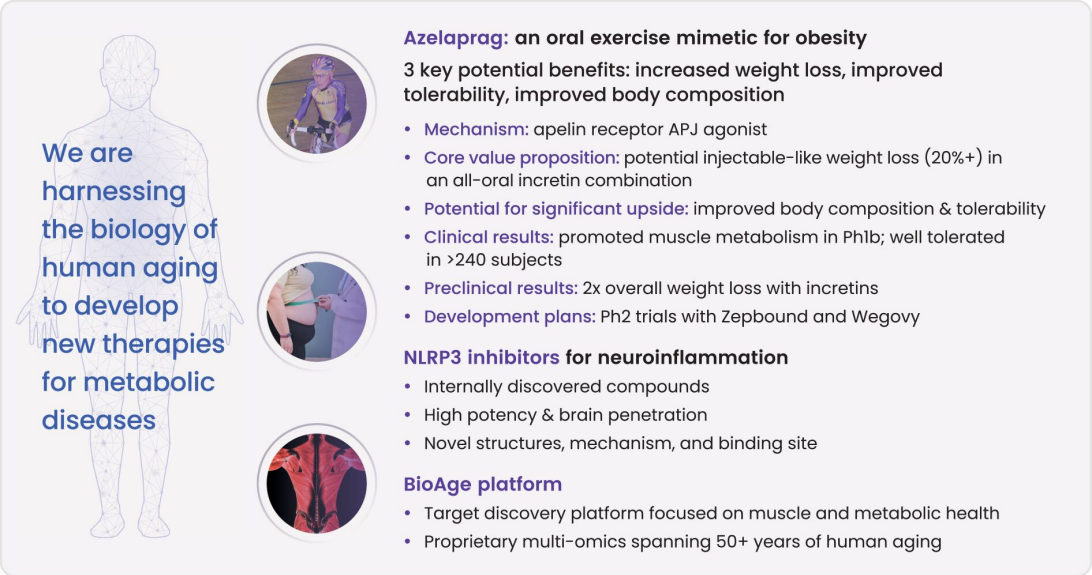
We have assembled a leadership team of experts in aging biology and drug development. Our senior team consists of the following members:

- Kristen Fortney, Ph.D., our Chief Executive Officer and co-founder. Dr. Fortney has extensive experience in aging biology, genetics and bioinformatics and systems biology from her work at Stanford and the University of Toronto.
- Eric Morgen, M.D., our Chief Operating Officer and co-founder. Dr. Morgen was previously on the faculty at the University of Toronto, where his research focused on biomarker discovery and characterization in high-dimensional datasets from human cohorts.
- Dov Goldstein, M.D., our Chief Financial Officer. Dr. Goldstein previously served as Chief Financial Officer at Vicuron Pharmaceuticals Inc. and Loxo Oncology Inc., as well as a Managing Partner at Aisling Capital. He was most recently the Chief Financial Officer and Chief Business Officer of Indapta Therapeutics, Inc.
- Paul Rubin, M.D., our Chief Medical Officer. Dr. Rubin has over 35 years of experience in the biotechnology industry and has led 12 compounds to U.S. approval, with five led from discovery through approval, including Lunesta® and Xopenex®. He most recently served as Executive Vice President Research and Development at miRagen Therapeutics, Inc. and was previously Chief Medical Officer at XOMA Corporation and Executive Vice President Research and Development at Sepracor.
- Ann Neale, our Chief Development Officer. Ms. Neale has over 30 years of experience in the biotechnology industry. She was most recently Senior Vice President of Development Operations at Principia BioPharma Inc. (acquired by Sanofi S.A.), where she led operations and resourcing strategy for multiple global early- and late-phase clinical programs.
- Peng Leong, Ph.D., our Chief Business Officer. Dr. Leong has extensive experience in the biotech industry, previously serving in healthcare investment banking at Piper Jaffray and as Head of General Medicine Business Development at Merck KgaA and Chief Business Officer at Kazia Therapeutics Limited.
- BJ Sullivan, Ph.D., our Chief Strategy Officer. Dr. Sullivan was previously in L.E.K. Consulting's life sciences practice, where he advised biopharma companies on growth strategy and M&A.
- George Hartman, Ph.D. leads our drug discovery efforts. Dr. Hartman is a co-founder of Novira Therapeutics, Inc. and previously served as executive director of medicinal chemistry at Merck & Co., Inc. where he and his group identified and brought 12 drug candidates into Phase 2 or Phase 3 clinical trials.

We have raised over $300 million to date from a leading syndicate of biotechnology investors, including a16z Bio + Health, Khosla Ventures, Sofinnova Investments, Longitude Capital, RA Capital, Cormorant Asset Management, Kaiser Permanente, and Horsley Bridge.

Our Strategy

Our goal is to develop a focused portfolio of therapies for metabolic disease by targeting the biology of human aging. Below is a summary of key product candidate and platform differentiation.



Our strategy is to:

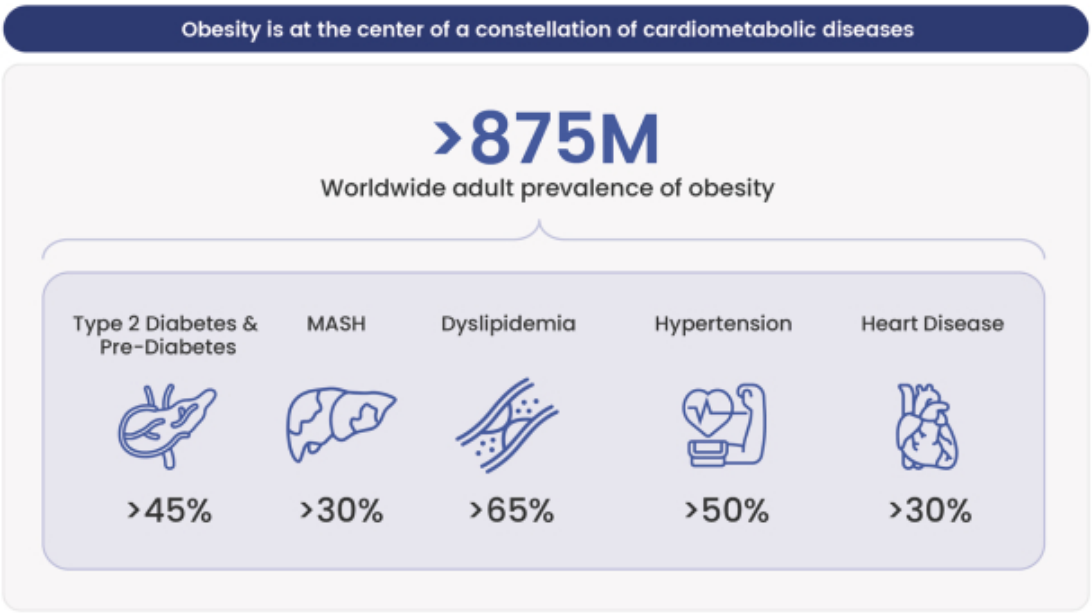
- **Apply novel insights into aging biology to build a pipeline of therapeutics to transform the treatment of chronic metabolic diseases.** Our platform provides unique insights into human aging biology spanning over 50 years. These insights enabled the identification of both apelin and NLRP3 as targets. We also have several discovery-stage programs targeting this novel biology, which we will continue to advance. We plan to grow this pipeline over time, both internally and potentially through partnerships with pharmaceutical companies that have complementary datasets and capabilities.
- **Efficiently advance the clinical development of azelaprag as a novel exercise mimetic for the treatment of obesity.** We believe that azelaprag has the potential to transform the treatment of obesity by increasing weight loss quantity and quality. We have initiated a Phase 2 clinical trial of azelaprag in obese adults 55 years of age and above in combination with tirzepatide. Topline results are anticipated in . We intend to initiate a second Phase 2 clinical trial of azelaprag in combination with semaglutide with the goal of demonstrating a GLP-1R class effect and efficacy in younger individuals, 18 of age and above. Initiation is anticipated in .
- **Establish azelaprag as a key component of all-oral obesity therapy.** We believe that our ongoing and planned Phase 2 clinical trials of azelaprag in combination with a subcutaneous GLP-1R agonist will provide valuable readthrough and serve as a key step in advancing a tolerable, all-oral, combination therapy for obesity that has the potential to rival and exceed the efficacy of currently marketed injectable therapies.
- **Maximize the potential of azelaprag in adjacent indications, including diabetes.** We believe azelaprag has the potential for additive efficacy in all indications where GLP-1R agonists have been

shown to benefit patients. Additionally, we believe azelaprag has the potential to improve insulin sensitivity and glucose control incremental to that achieved with weight loss and thus has significant potential value to obese individuals with comorbid type 2 diabetes. We intend to initiate an insulin sensitivity proof-of-concept trial of azelaprag monotherapy in .

- **Advance our orally available, brain-penetrant inhibitors of NLRP3 for the treatment of neuroinflammation.** We have internally discovered a potent, selective, and structurally novel inhibitor of NLRP3, with potential to treat the neuroinflammation that has been linked to both metabolic and neurodegenerative diseases. We intend to submit an IND for an NLRP3 inhibitor by and, if cleared, initiate a Phase 1 clinical trial of our highly differentiated brain-penetrant NLRP3 inhibitor, in .
- **Selectively partner our product candidates to maximize patient impact and shareholder value.** According to third-party estimates, the global market opportunity for metabolic diseases is very large, with GLP-1Rs and incretins obesity alone expected to grow to $150 billion by 2031. Given the resulting activity and investment of pharmaceutical companies in the therapeutic area, we may selectively partner our product candidates to accelerate the path to market in multiple large indications and maximize shareholder value.

Our Approach: Targeting aging biology to treat chronic metabolic diseases

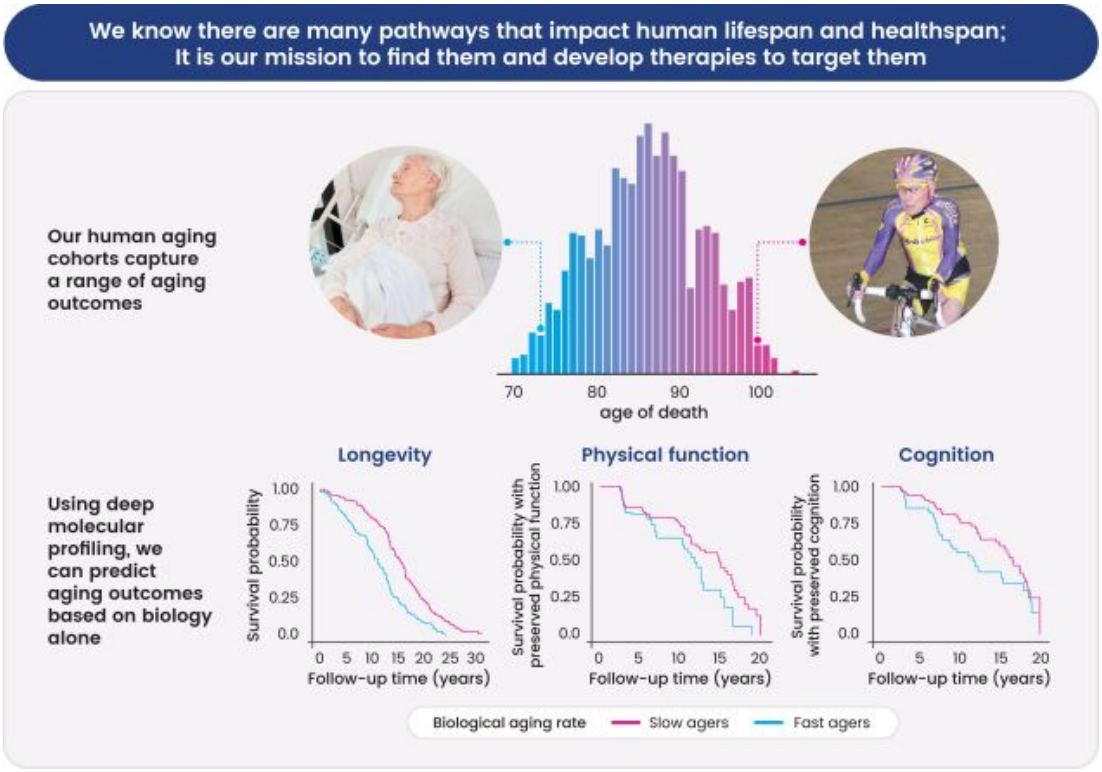
Aging is a root cause of metabolic diseases. Obesity, type 2 diabetes, metabolic dysfunction-associated steatohepatitis and atherosclerosis are all strongly associated with age, with prevalence rising sharply after middle age. Globally, over 875 million adults age 20+ are obese. Among obese patients, the prevalence of cardiometabolic morbidities is high. Obesity itself has been described as an accelerated aging condition, as it increases the risk of both morbidity and mortality from age-related chronic disease.



Global prevalence of obesity and major comorbidities. MASH = Metabolic dysfunction-associated steatohepatitis. Heart disease includes congestive heart failure (3.5%), ischemic heart disease (8%) and myocardial infarction (21%).

Our approach to improving metabolic health span starts with human data. To identify biological pathways that promote healthy aging, we have generated proprietary longitudinal human datasets comprising clinical measures and molecular data – including deep profiling of circulating proteins and metabolites – from biobanked

samples collected serially over decades. By analyzing the aging trajectories of thousands of individuals at the molecular and phenotypic level, we can take advantage of the natural variation in human aging biology and outcomes to identify the special molecular features of people who age well, with greater longevity and delayed onset of disability and disease. Through these analyses, we have discovered key pathways and targets, such as apelin signaling, which is targeted by our lead product candidate azelaprag, with the potential to preserve metabolic health over the course of aging.

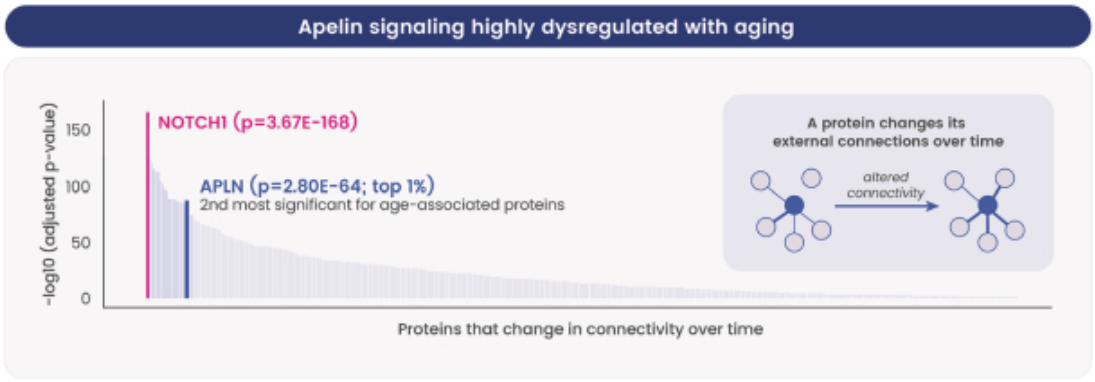


We capture a range of aging outcomes in our human aging cohorts, including functional and cognitive decline, disease incidence and mortality. In this example, deep, serial profiling of circulating proteins in these participants was used to understand the biology that drives these outcomes.

Our human data-driven approach enables us to prioritize metabolic aging targets which we believe have a higher probability of translational success. Drug targets with support from human genetic studies are more than twice as likely to be approved than targets that lack such validation, highlighting the value of human molecular evidence. We believe our focus on molecular pathway activity during the course of healthy human aging allows the selection of targets for which long-term modulation is predicted to be safe and effective. By analyzing metabolic disease through the lens of human aging, we seek to develop therapeutics that activate beneficial pathways, or inhibit deleterious ones, with the potential to prevent or reverse diseases and improve overall health.

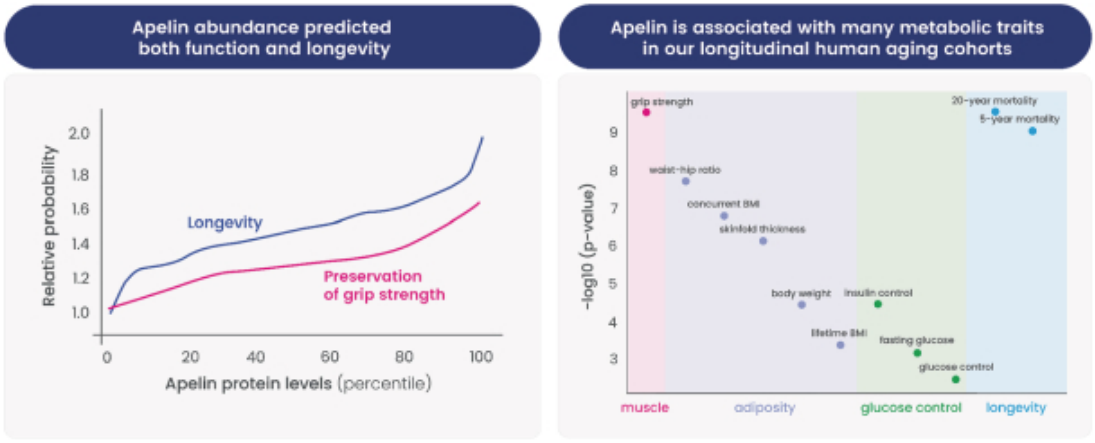
Levels of the exercise-secreted protein apelin predicted both function and longevity in our longitudinal human aging cohorts

The aging process is characterized by profound dysregulation in many biological systems. Using a systems biology approach and examining protein network changes over decades in our longitudinal human aging cohorts, we found that the apelin protein network was highly significantly altered with aging, ranking second among proteins whose overall levels also significantly change with age.



Protein networks change with age: their pattern of connectivity to other proteins is altered and dysregulated over time. Apelin (APLN) signaling is among the most dysregulated over 20 years of aging in our longitudinal human aging cohorts. It ranks second among proteins whose levels also significantly change over those 20 years. NOTCH1, the most dysregulated protein in our analysis, is a well-established mediator of age-related disease.

Furthermore, we then observed that higher levels of circulating apelin were associated with both increased longevity and preservation of physical function (i.e., subjects with higher apelin levels lived longer, with improved health). We also observed that apelin levels are significantly associated with a range of metabolic traits in our human aging cohorts. These results led us to the therapeutic hypothesis that augmenting apelin signaling could provide therapeutic benefits in age-related disease.



Higher apelin protein levels predicted improved longevity and grip strength in our human aging cohorts (left). Levels were also associated with traits related to muscle function, adiposity, glucose control, and longevity (right). Glucose and insulin control measure the ability to regulate blood glucose increases via insulin secretion after a glucose challenge.

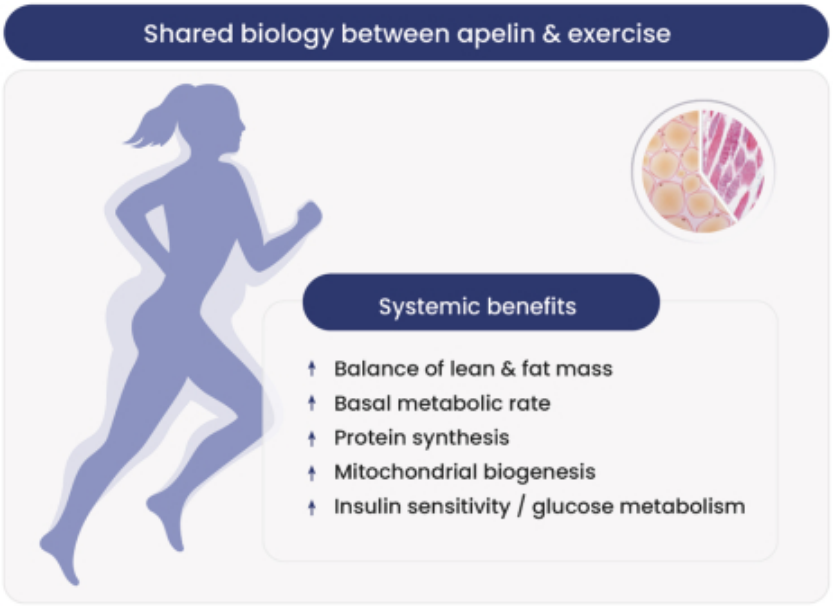
Enhancing apelin signaling can recapitulate many of the benefits of exercise

Apelin is a peptide hormone referred to as an exerkine, a signaling molecule released by skeletal muscle in response to exercise that mediates many of the beneficial metabolic and functional adaptations to physical activity.

Comparing the physiological effects of enhanced apelin signaling to those of exercise reveals multiple areas of overlap:

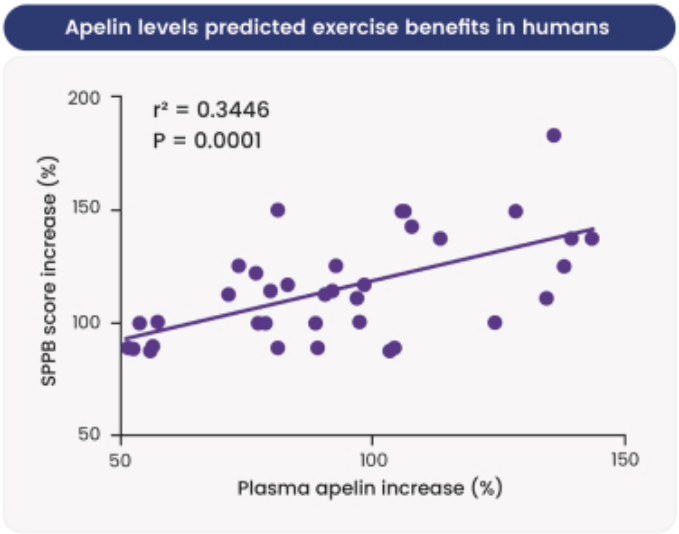
- Both apelin and exercise have a beneficial effect on body composition, improving the ratio of lean to fat mass. The proportion of lean mass is a very strong predictor of functional capacity, metabolic health, and cardiovascular outcomes than (and more predictive absolute lean mass or absolute fat mass).
- In skeletal muscle, both apelin signaling and exercise boost protein synthesis, mitochondrial biogenesis and basal metabolic rate, thereby increasing resting energy expenditure.
- In both muscle and adipose tissue, apelin and exercise increase insulin sensitivity, resulting in upregulation of glucose uptake and metabolism.

This striking congruence between the actions of apelin and exercise suggests that this peptide acts as a key molecular transducer of the systemic exercise response, and that targeting the apelin/APJ axis may be able to mimic many of the benefits of physical activity sometimes referred to as "exercise in a pill".



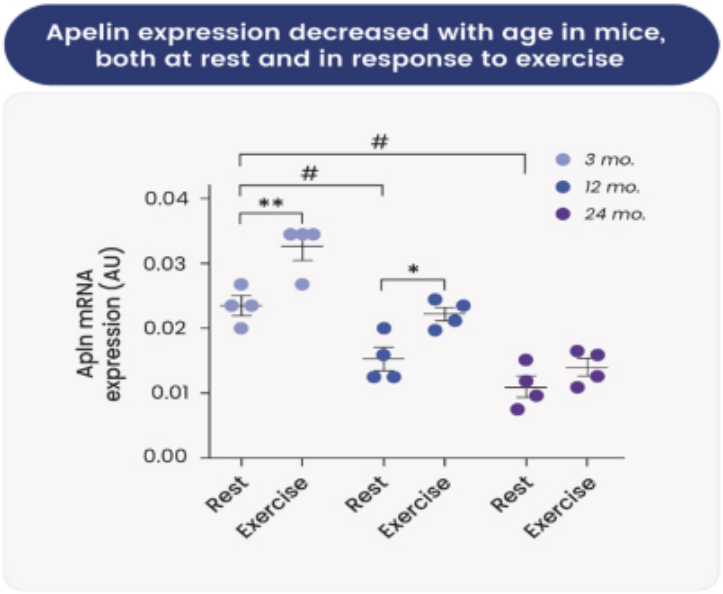
Apelin and exercise have similar physiological benefits.

Exercise ameliorates many of the negative health outcomes associated with aging. Circulating apelin levels increase acutely after exercise, with the magnitude of this response strongly predicting physical performance in older adults.



In a third-party preclinical study, apelin levels were significantly correlated with the benefits of exercise over 6 months. Older people (> 70y) with the greatest increase in plasma apelin levels after 6 months of an exercise program had the highest improvement in Short Physical Performance Battery (SPPB) test score. Apelin measurements were taken from 34 individuals. r^2 represents the correlation coefficient, a statistical measure of the strength of a linear relationship between two variables. A correlation coefficient of -1 describes a perfect negative, or inverse, correlation. A coefficient of 1 shows a perfect positive correlation, or a direct relationship. A correlation coefficient of 0 means there is no linear relationship. The p-value is used to determine the probability as to whether the difference between two data sets is due to chance. The smaller the p-value, the more likely the differences are not due to chance alone. In general, if the p-value is less than or equal to 0.05, the outcome is considered statistically significant. (Source: Vinel et al. 2018).

However, both basal levels of apelin and the degree of exercise-induced elevation of the peptide decline with age, coinciding with deterioration of fitness and muscle function.

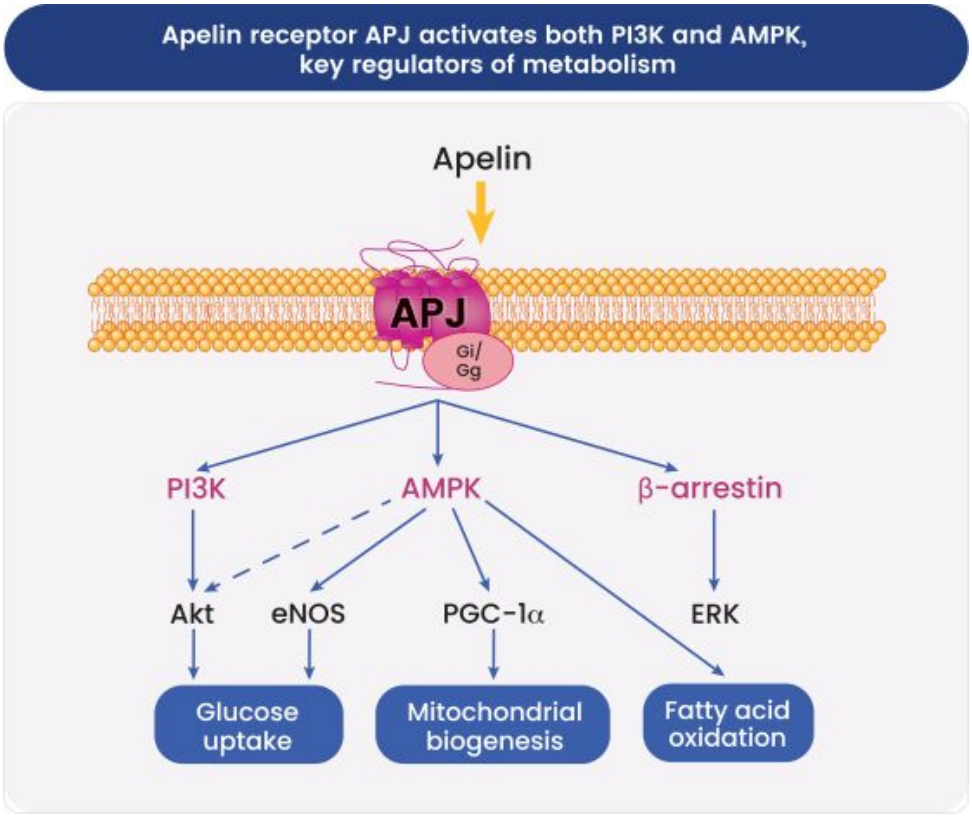


*In a third-party preclinical study, apelin expression in mice significantly decreased with age (n= 6 mice per group). There was also a lower magnitude increase in apelin expression in response to exercise with age, with no significant increase observed in the 24 month group. In mice, 12 months represents middle age and 24 months old age. #p< 0.05; *p< 0.05; ** p< 0.01. (Source: Vinel et al. 2018).*

The relationship between apelin, exercise and function over the lifespan, taken together with the correlation between apelin levels and muscle-related health parameters observed in our longitudinal cohorts, suggest that apelin may help mediate the beneficial anti-aging effects of exercise.

Apelin activates key metabolic regulators AMPK, PI3K, and ERK

The molecular mechanisms of apelin pathway signaling are well characterized. As depicted in the figure below, the physiological effects of apelin in target cells are mediated by the apelin receptor (APJ/APLNR), a G protein-coupled receptor that activates multiple intracellular signaling pathways including AMP-activated protein kinase (AMPK) and PI3K. In parallel, via recruitment of ß-arrestin upon apelin binding, APJ activates extracellular signal regulated kinase (ERK). These pathways are involved in metabolic processes consistent with apelin's role as an exerkine, including glucose uptake, mitochondrial biogenesis, and fatty acid oxidation.



APJ is a G protein-coupled receptor that signals through AMPK and PI3K. AMPK and PI3K activate downstream effectors Akt and endothelial nitric oxide synthase (eNOS), which increase cellular glucose uptake. AMPK activates transcriptional coactivator PCG1-a, which increases mitochondrial biogenesis. AMPK directly increases fatty acid oxidation. APJ also activates ERK signaling through ß-arrestin. (Source: Bertrand et al. 2015).

Azelaprag: an oral small molecule apelin receptor agonist

The data supporting the importance of apelin in metabolism suggests that apelin signaling has strong potential to be targeted for therapeutic purposes. However, the most common form of apelin peptide, apelin-13, has poor drug-like properties. Azelaprag, previously known as AMG 986 and BGE-105, is an investigational oral small molecule apelin receptor agonist designed with improved pharmacokinetic properties, including high potency and half-life that enables once daily dosing. Azelaprag also has a favorable preclinical safety profile: the no observed adverse effect level (NOAEL) in good laboratory practice (GLP) toxicology studies was the highest dose tested in both species (i.e., no dose-limiting toxicity was observed in preclinical studies). These findings are consistent with its clinical tolerability profile, as no treatment-related trends in adverse events have been observed.

We obtained an exclusive worldwide license from Amgen in 2021 to develop azelaprag—as well as Amgen's patent estate of APJ agonists—for all indications. We generated human clinical data where we observed the ability of azelaprag to maintain metabolism and preserve muscle in a bed rest trial. We have demonstrated in preclinical studies the potential of azelaprag to improve weight loss and restore both body composition and muscle function when administered in combination with tirzepatide or semaglutide. We are now in a position to assess the efficacy and tolerability of azelaprag in combination with these GLP-1R agonists in Phase 2 clinical trials in obese adults with the first of these trials anticipated to .

Completed clinical trials

In the seven Phase 1 clinical trials of azelaprag completed to date by us and Amgen, azelaprag was well-tolerated in over 240 individuals who received a daily dose of up to 1,440 mg for up to 21 days. Below is a summary of clinical trials completed to date:

Azelaprag has been studied in seven Phase 1 trials

Sponsor	Study goal	Participants	Years conducted	Admin	Azelaprag dosing	Primary endpoint	Secondary endpoints	Publication (PMID)
BioAge	Characterize safety & pharmacokinetics (PK) after oral administration	Older HVs	2023 - 2024	Oral	Part 1: Single dose crossover (N=16) • 300 mg, 600 mg Part 2: Multiple dose (N=9 – all subjects also participated in Part 1) • 300 mg oral BID x 14 days	PK	Safety & tolerability	-
	Characterize safety & pharmacokinetics (PK) after oral administration		2022	IV	Part A: Single ascending dose • 60 mg LD + 360 mg MD (N=6) • 120 mg LD + 720 mg MD (N=6) • 240 mg LD + 1440 mg MD (N=6) Part B: Multiple Dose • 240 mg x 10 days (N=11)	Safety & tolerability	PK, PD	-
Amgen	Characterize safety, PK, PD	HVs Heart failure patients	2016 - 2019	Oral, IV	Part A: Single ascending dose in healthy volunteers • Oral: 5, 30, 100, 200, 400, or 650 mg (N=36) • IV: 0.5 mg LD, 3 mg LD, 6 mg LD + 36 mg MD, 20 mg LD + 120 mg MD, 60 mg LD + 360 mg MD (N=30) Part B: Multiple dose in healthy volunteers • Oral: 5, 30, 100, 200, 400, or 650 mg x 7 days (N=37) • IV: 6 mg LD + 36/38 mg MD or 60 mg LD + 360/376 mg MD (N=13) Part C: Subjects with heart failure • 21 days of PO QD treatment: 10 mg × 7 days ›› 30 mg × 7 days ›› 100 mg × 7 days (N=19)	Safety & tolerability	PK, PD	35460392
	Compare oral tablet and capsule formulations	HVs	2018	Oral	200 mg (N=12)	PK	Safety & tolerability	35412220
	Characterize PK with renal impairment	HVs Subjects with severe renal impairment	2017 - 2018		200 mg (N=12)			35092583
	Characterize safety, tolerability, and PK in Japanese subjects	HVs	2017 - 2018		200 mg (N=6) 400 mg (N=6)			35279815
	Characterize effect of food and itraconazole on PK	HVs	2017		Food effect crossover (N=12) • 2x 200 mg itraconazole (N=15) • 2x 10 mg			35279815

Azelaprag has been studied in seven Phase 1 trials to date, conducted by BioAge and Amgen. HVs = healthy volunteers. LD = loading dose & MD = maintenance dose, used in the IV administration setting. In all trials, primary and secondary objectives were met.

The overall adverse event profile of azelaprag was comparable to placebo, with no treatment-related trends in adverse events observed, with the exception of mild, self-limited headaches. No serious adverse events have been reported. Furthermore, no adverse cardiac effects have been observed in any clinical or preclinical setting.

The figure below summarizes treatment-emergent adverse events reported in >3% of subjects: headache, dizziness and back pain. Dizziness and back pain were both reported at a higher rate in placebo than active groups. All events were mild except for a single moderate headache event reported in both the active and placebo groups. All events were self-limited.

Azelaprag has a favorable tolerability profile in over 240 subjects
Adverse events with >3% incidence

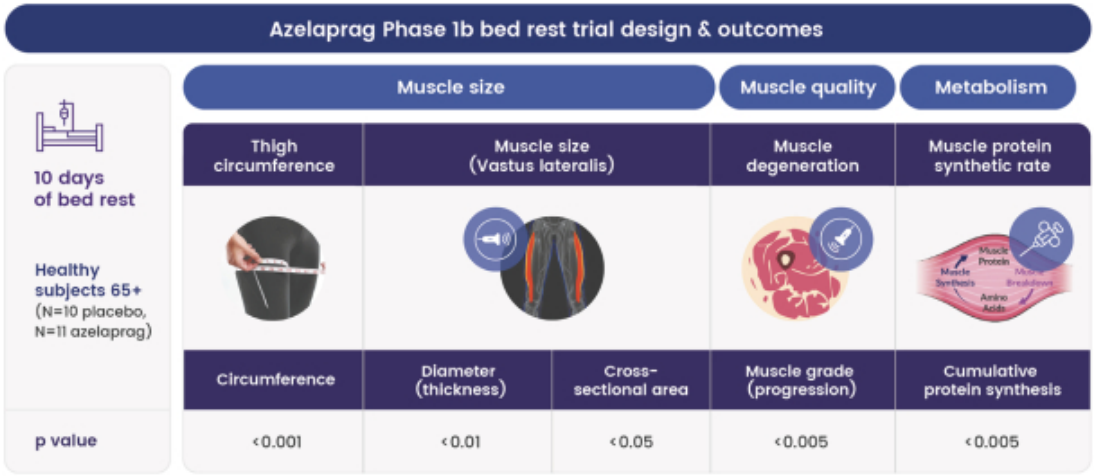
Event	Placebo (N=62)	Azelaprag (N=243)
Severe treatment-emergent adverse events: None have been reported		
Headache	0	0
Dizziness	0	0
Back Pain	0	0
Moderate treatment-emergent adverse events: Only headaches observed in both active and placebo groups		
Headache	1 (1.6%)	1 (0.4%)
Dizziness	0	0
Back Pain	0	0
Mild treatment-emergent adverse events		
Headache	2 (3.2%)	20 (8.2%)
Dizziness	2 (3.2%)	5 (2.1%)
Back Pain	2 (3.2%)	2 (0.8%)

Azelaprag has been well-tolerated in over 240 individuals in Phase 1 clinical trials, with no serious treatment-emergent adverse events reported.

We completed a double-blind, non-randomized Phase 1b bed rest atrophy trial of azelaprag in 21 healthy individuals 65 years of age or older. Bed rest studies are a well-established method to model muscle and functional aging on a compressed timeline. For example, a prior trial conducted by Amgen reported that 10 days of bed rest in older volunteers reduced protein synthesis and lean mass in lower extremities. Another trial reported that 10 days of bed rest in older volunteers substantially lowers oxidative metabolism.

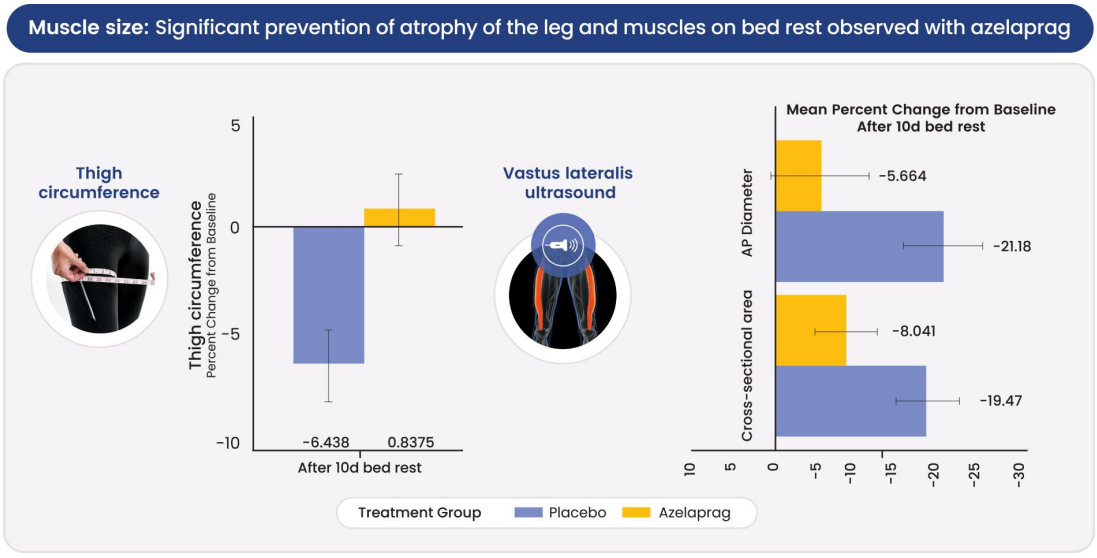
In our Phase 1b clinical trial, subjects on bed rest for 10 days received daily doses of 240 mg azelaprag or placebo delivered by intravenous infusion. The primary objective of the trial was to assess the tolerability of azelaprag. We also selected secondary endpoints to examine the effects of azelaprag on muscle size, muscle quality and metabolism.

We observed that treatment with azelaprag significantly decreased ($p<0.05$) bed-rest-induced muscle atrophy across endpoints in the figure below.



Overview endpoints and significance of results from the azelaprag bed rest atrophy Phase 1b trial.

Bed rest often results in rapid muscle atrophy, especially in older people. In our Phase 1b clinical trial, 10 days of bed rest led to a mean decrease of 6.4% in thigh circumference in subjects that received placebo. By contrast, we observed no significant decrease in thigh circumference in subjects dosed with azelaprag. We also measured the size of the vastus lateralis, the largest and most powerful part of the quadriceps femoris, a muscle in the thigh. 10 days of bed rest led to a decrease in the diameter and cross-sectional area of this muscle of approximately 20% as measured by ultrasound in the placebo treatment group. In contrast, treatment with azelaprag resulted in significantly less muscle loss, with observed decreases of 6-8%.

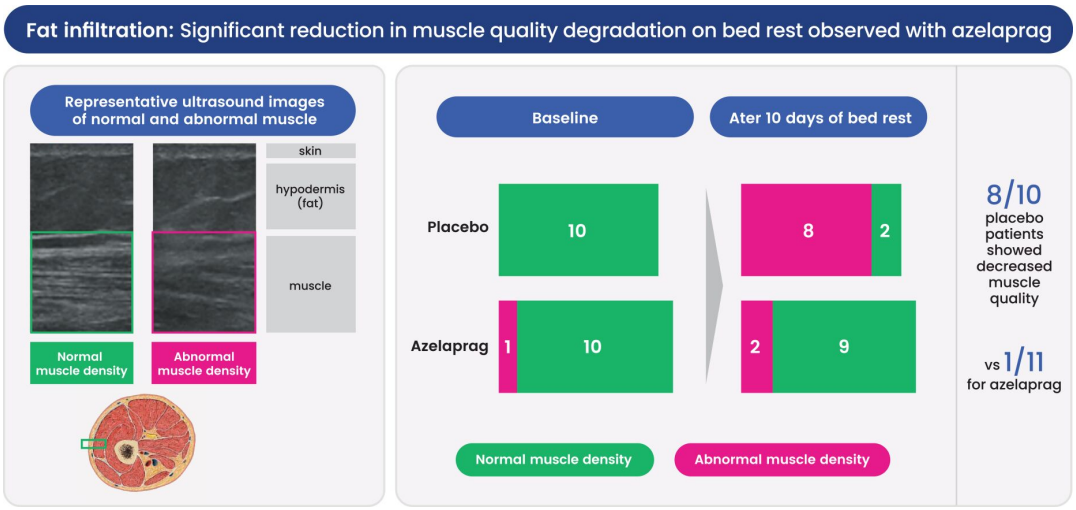


A decrease in thigh circumference ($p<0.001$), as well as in muscle diameter and thickness ($p<0.01$) and cross-sectional area ($p<0.05$) of the vastus lateralis muscle was observed in subjects on bed rest with azelaprag.

Muscle function and metabolism are determined not only by muscle size but also by muscle quality. On bed rest, muscle quality often deteriorates as muscle fibers experience degeneration and infiltration with fat. Collectively, this results in:

- Reduced contractile fibers and force generation potential. As a result, muscle quality is highly correlated to muscle function.
- Decreased energy expenditure of the muscle tissue. As a result, worsened muscle quality is linked to a lower basal metabolic rate and impaired insulin sensitivity.

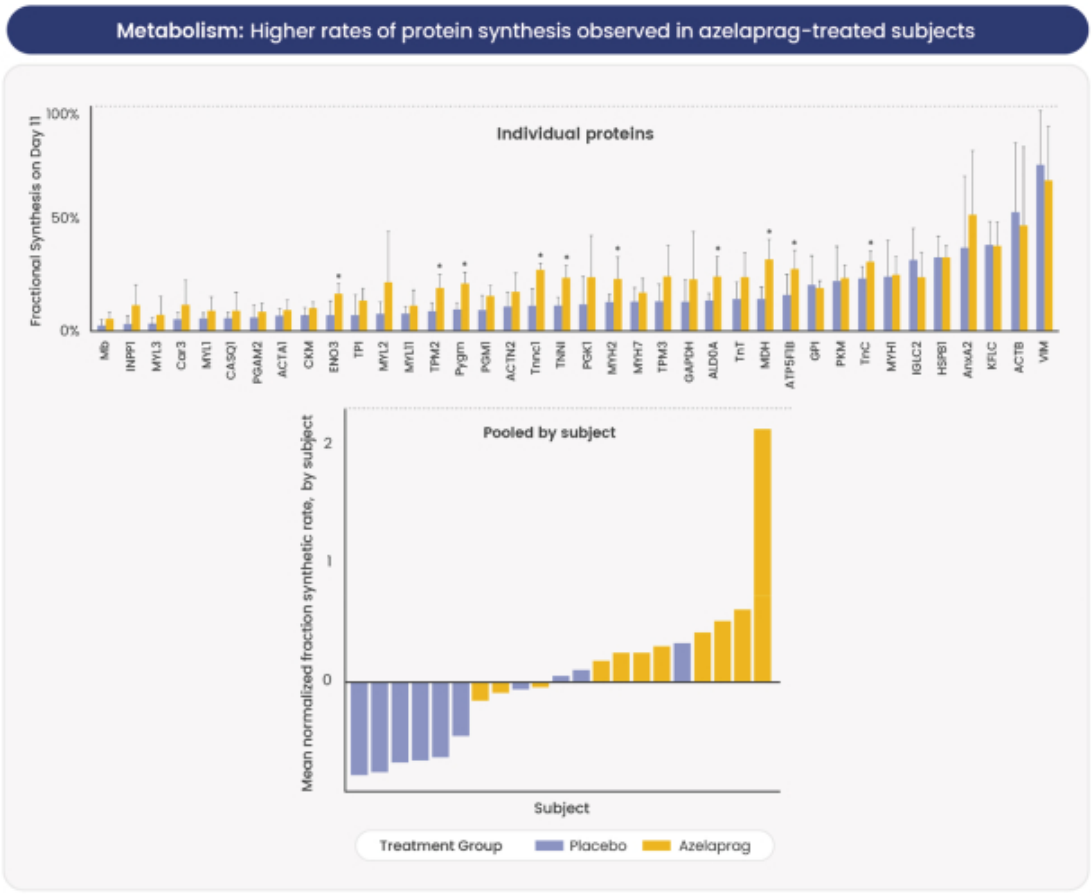
In our Phase 1b clinical trial, we measured the density of muscle tissue via ultrasound (i.e., echo density). Muscle echo density is a proxy measurement for muscle quality: fat infiltration and fibrosis reduce the density of muscle as measured with ultrasound (see representative images in the figure below). At baseline, all but one subject in the azelaprag treatment group showed normal muscle quality, as measured by echo density. Over 10 days of bed rest, eight of 10 placebo-treated subjects showed reduced muscle quality, consistent with previous reports describing fat infiltration of the muscle in acute bed rest. In contrast, this worsening of muscle quality was seen in only one of 11 azelaprag-treated subjects, representing a highly statistically significant difference ($p < 0.005$).



Representative muscle ultrasound images representing normal and abnormal echo density / muscle quality, as well as the anatomical location where the images were captured (left). Azelaprag was shown to significantly reduce worsening of muscle quality that is a hallmark of bed rest (right). p<0.005.

Muscle protein synthesis is a metabolically expensive process that supports maintenance of muscle mass. On bed rest, protein synthesis can drop up to 40%. Treatment with azelaprag resulted in higher muscle protein synthesis rates compared to placebo, whether analyzed by protein or by subject. Synthesis rates during the trial were measured directly in biopsies of the vastus lateralis muscle.

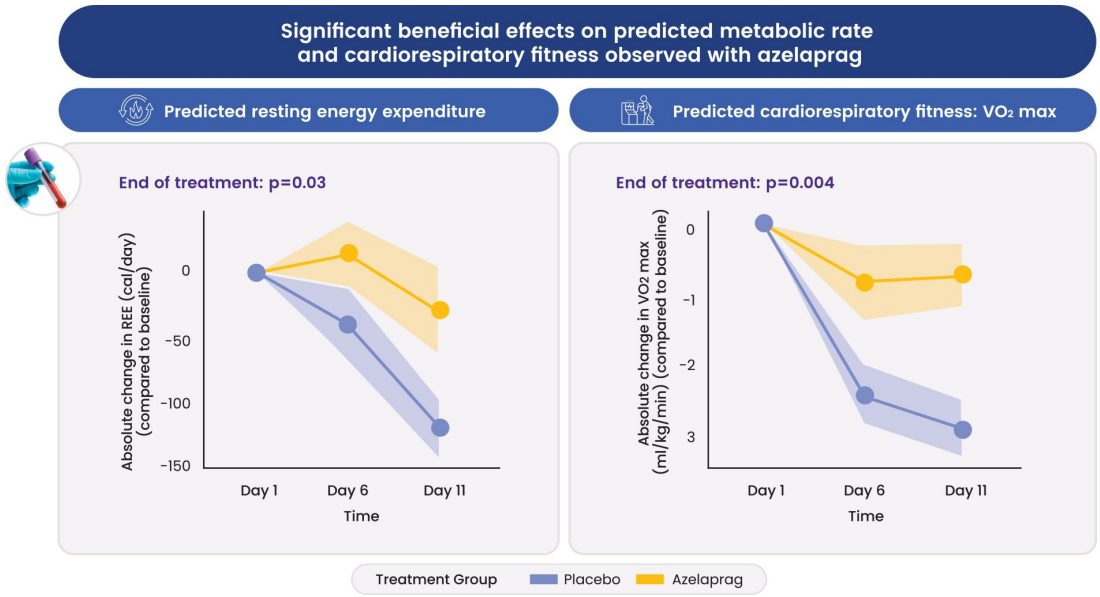
- *Protein-level analysis*: Across the 38 proteins measured in all subjects, the rate of synthesis for each protein was almost always higher in azelaprag-treated subjects, including for all of the nine proteins with statistically significant differences between treatment groups.
- *Subject-level analysis*: We calculated a pooled score representing the synthesis rate across all detected proteins for a given subject. This showed a strong and statistically significant difference between treatment groups, highlighting the higher protein synthesis scores in azelaprag-treated subjects relative to placebo treated subjects.



*Azelaprag treatment led to a significant relative increase in muscle protein synthesis, both in individual proteins measured (top) and when proteins are pooled by subject (bottom). p<0.005 based on a t-test comparing per-patient normalized FSR values across all common proteins (N=38). * p < 0.05 for individual proteins.*

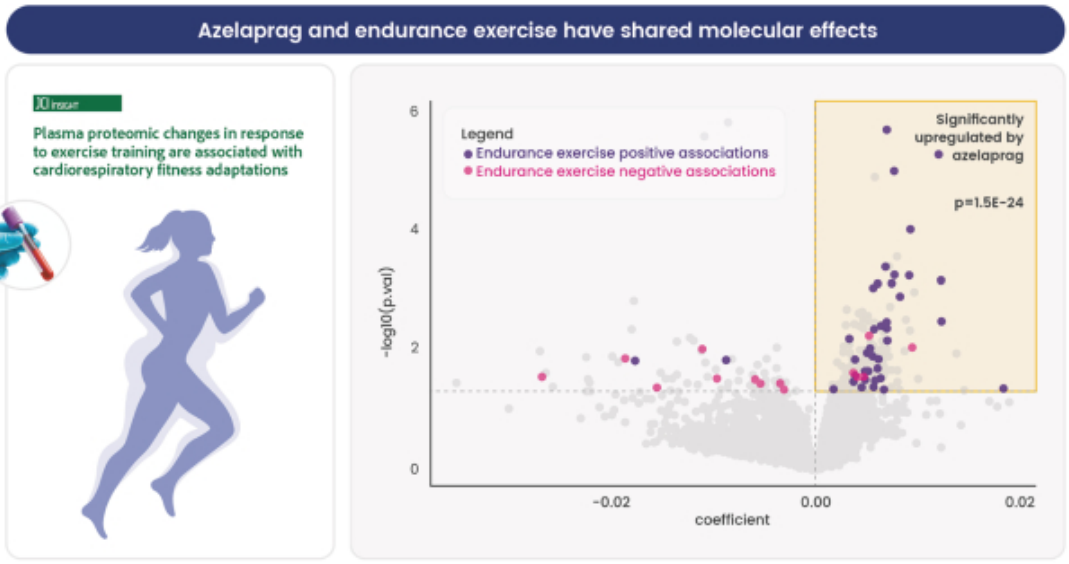
We also performed deep profiling of circulating proteins in subjects in our Phase 1b clinical trial. Proteomic profiling was performed using the SomaLogic SomaScan platform, which measures levels of >7,000 circulating proteins. The resulting protein profiles enabled us to predict potential benefits of azelaprag beyond those directly measured in the trial, by assessing protein biomarker models of specific functional outcomes.

- Predictive modeling identified several metabolic benefits following treatment with azelaprag, including increased energy expenditure and improved physical performance. We used SomaSignal predictive models to estimate resting energy expenditure (REE) and cardiorespiratory fitness (VO_2 max) for each subject at multiple time points during the study based on their biomarker profile. These SomaSignal models were previously trained and tested by Somalogic in participants where both biomarkers and clinical measurements were collected in the same individuals. In the placebo group, both predicted REE and VO_2 max declined dramatically, whereas azelaprag-treated subjects were largely protected from these declines.



Azelaprag had significant and beneficial effects on predicted REE and VO_2 max, protecting against the detrimental effects of bedrest-associated decline. These predictions were made using SomaLogic SomaSignal models. The REE model was trained on N=9,022 adults with an r^2=0.46. The VO_2 max model was trained on N=743 adults with an r^2 of 0.75.

- Azelaprag treatment recapitulated the molecular effects of exercise. We compared azelaprag treatment and exercise based on the changes they induce in circulating protein levels. We found that azelaprag recapitulated many previously observed protein changes induced by exercise: many of the proteins increased by endurance exercise were also increased by azelaprag, with four times substantially more overlap than would be expected by chance alone ($p=1.5x10^{-24}$) in an enrichment analysis.

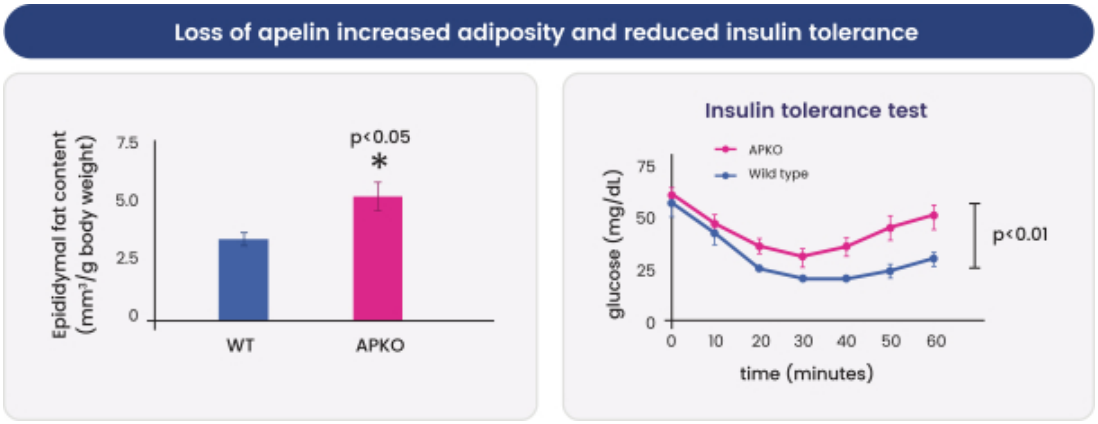


Consistent with azelaprag having the ability to potentially mimic certain biological effects of exercise, there was a strong and statistically significant overlap between circulating proteins increased in azelaprag-treated subjects in our Phase 1b bed rest trial and those increased by endurance exercise.

- Azelaprag treatment recapitulated molecular effects associated with health outcomes in our longitudinal human aging cohorts. Changes in circulating proteins with azelaprag treatment were associated with healthier function across several dimensions in our human aging cohorts, including tolerance of strenuous activity ($p=3.3x10^{-24}$) and greater longevity ($p=9.7x10^{-20}$).

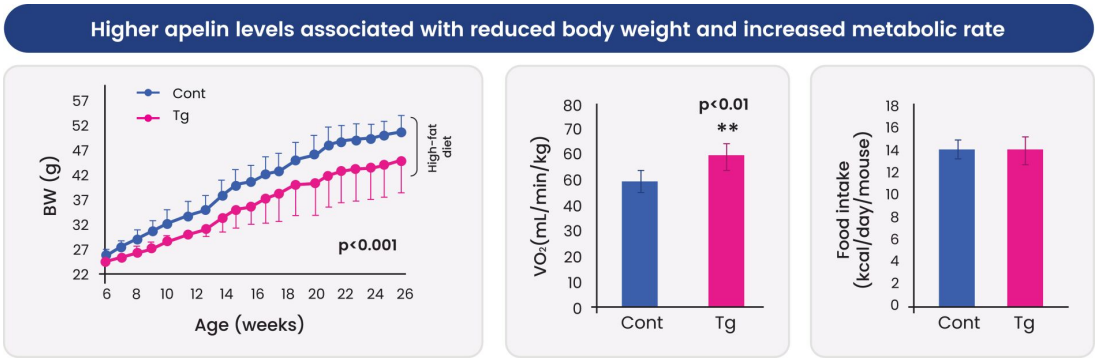
Azelaprag for obesity: Genetic evidence supports the potential of azelaprag to improve metabolism

Consistent with the metabolic benefits of azelaprag observed in our Phase 1b clinical trial, genetic studies of apelin in mice published by other groups provide support for the potential role of azelaprag in the treatment of obesity. Inactivation of the gene for apelin was shown to result in mice with a statistically significant increase in fat content compared to similarly treated wild-type mice. Apelin knockout mice fed a high fat diet for three weeks also had significantly decreased sensitivity to insulin than similarly treated wild-type mice.



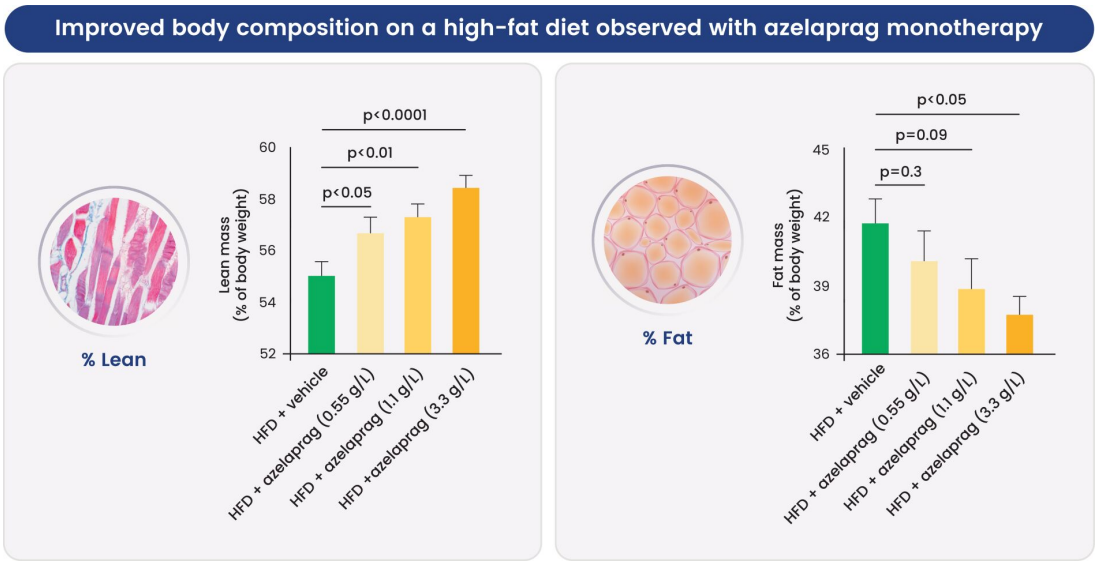
In a third-party preclinical study, inactivation of the gene for apelin (APKO) in mice led to a significant increase in fat content compared to wild-type counterparts ($p<0.05$) (n =10–15 mice per group). In a separate third-party preclinical study, APKO mice had significantly worse performance on an insulin tolerance test ($p<0.01$) (n= 6 –7 mice per group). (Source: Yue et al. 2010, Yue et al. 2011).

In contrast, transgenic mice with overexpressed apelin showed several metabolic benefits. Animals were significantly protected from weight gain when placed on a high fat diet. This was not due to a decrease in food intake, but instead to an increased metabolic rate. Consistent with apelin's role as an exerkine, transgenic apelin mice also had increased skeletal muscle mitochondrial biogenesis and increased oxygen intake compared to wild-type counterparts.



In a third-party preclinical study, overexpression of apelin in a transgenic mouse (Tg) resulted in significantly reduced weight when fed a high fat diet compared to wild-type control mice (Cont) ($p<0.001$) (n= 19–24 mice per group). Tg mice had a significantly higher basal metabolic rate than their wild-type counterparts on a high fat diet ($p<0.01$) (n= 7-9 mice per group) with no significant difference in food intake (n= 19–24 mice per group). (Source: Yamamoto et al. 2011).

Similar to observations in animals transgenically modified to overexpress apelin, we found that azelaprag monotherapy resulted in significantly improved body composition as measured both by an increased percentage of lean mass as well as by a decreased percentage of fat mass, in mice challenged with a high-fat diet.



Azelaprag monotherapy treatment resulted in significantly improved body composition (% lean, % fat) in mice challenged with a high-fat diet, similar to transgenic mice overexpressing apelin. Mice were treated with azelaprag for 22 weeks, starting at 5 weeks of age. Mice treated with the highest dose of azelaprag (3.3g/L) showed a 3.5% increase in lean mass and a 3.9% decrease in fat mass. For reference, lean controls mice were 73.6% lean mass and 22.9% fat mass.

Human genetics are consistent with findings in interventional genetic studies in mice. Significant genome-wide associations have been reported at the apelin receptor, APJ, and body mass index, lean body mass and serum lipid levels across diverse populations.

Human genetics connects apelin signaling to BMI, body composition, and metabolism

Reported trait	p-Value	Cohort	Author	PMID
Apolipoprotein A1 levels	9.00E-13			
HDL cholesterol levels	5.00E-10	UK	Richardson TG	32203549
Triglyceride levels	8.00E-10			
Low high density lipoprotein cholesterol levels	4.00E-10	Middle East	Wakil SM	26879886
Body mass index	4.00E-09	UK & GIANT consortium	Pulit SL	30239722
Body mass index	2.00E-8	Japan, UK, & Finland	Sakaue S	34594039
Appendicular lean mass	6.81E-9	UK	Pei YF	33097823

The apelin receptor APJ (APLNR) has human genome-wide associations with serum lipids, body mass index, and lean mass.

Obesity disease overview: A growing driver of both morbidity and healthcare spending

Obesity is a complex medical disorder that has been described as an accelerated aging condition, as it increases the risk of both morbidity and mortality from age-related chronic disease. It involves both appetite dysregulation and altered lipid and energy metabolism, which in turn result in excessive accumulation of fat

tissue. Globally, over 875 million adults age 20+ are living with obesity, defined as a body mass index (BMI) of 30 or greater. Furthermore, the worldwide prevalence of obesity in adults 20+ more than doubled from under 7% in 1990 to over 16% in 2022. The global estimated cost of overweight and obesity is in the trillions of dollars, representing more than 2% of the global gross domestic product.

Obesity is associated with over 200 health comorbidities and complications, including many cardiometabolic disorders. Among obese patients, the prevalence of these conditions is high: 19-23% have type 2 diabetes, (19-23%), dyslipidemia (66-70%), hypertension (51-61%), metabolic dysfunction-associated steatohepatitis, (30-36%), and (32% heart disease 3.5% congestive heart failure, 8% ischemic heart disease, 21% myocardial infarction). Obesity is also associated with an increased risk of developing infertility and certain cancers. Weight loss leads to improvements across many comorbidities associated with obesity.

Obesity treatment landscape: incretin drugs are transforming care, creating an important clinical and commercial opportunity

Current treatments for patients who are overweight or obese begin with lifestyle modification, such as diet and exercise. If this course of treatment fails to produce the desired results, as is often the case, physicians may prescribe pharmaceutical therapies, and in patients with more severe obesity, physicians may pursue aggressive bariatric surgical treatments, such as gastric bypass and sleeve gastrectomy. However, adoption of surgical approaches has been limited by concerns around safety, lifestyle impact, ease of use, cost, compliance, and the significant weight regain that is often observed.

Until recently, pharmaceutical treatments for obesity had limited efficacy and were associated with side effects that led to poor tolerability. The development of a class of drugs that target hormones known as incretins has dramatically changed the treatment landscape. Incretins are peptides released by the gut in response to ingestion of food. The two primary incretins glucagon-like peptide-1 (GLP-1), and glucose-dependent insulinotropic polypeptide (GIP) increase insulin response and lower blood glucose levels. GLP-1 also serves to reduce appetite and food intake. Peptide agonists of GLP-1R and of the GIP receptor and inhibitors of the degradation of incretins have been approved as treatments for type 2 diabetes, where they have been shown to improve glycemic control.

GLP-1R agonists and GLP-1R/GIP receptor dual agonists have since been shown to lead to significant reductions in body weight, partly by decreasing dietary intake. In 2021, the GLP-1R agonist Wegovy was the first incretin receptor agonist to be approved by the FDA for the treatment of obesity. In Phase 3 trials with Zepbound, a dual GLP-1R and GIP receptor agonist, obese adults lost a mean of between 15-20% of their body weight at one year depending on dose.

Weight loss treatment leads to improvements across various comorbidities associated with obesity, with outcomes proportional to the amount of weight lost. Diabetic patients treated with these drugs have improved glycemic control through increased pancreatic function and insulin sensitivity. These drugs lead to reduced frequencies of major adverse cardiovascular events including stroke, myocardial infarction and cardiovascular death. Patients taking these drugs experience a reduction in hospitalizations due to heart failure. Older diabetic patients have reduced risk of progression to chronic kidney disease, and early reports suggest that GLP-1R agonists decrease the risk of developing neurodegenerative disease.

The market for GLP-1R agonists, including those used to treat diabetes, was $35 billion in 2023. According to third-party estimates, the global market is expected to grow to $150 billion by 2031, driven by:

- Continued adoption of approved products
- Improved reimbursement of approved products as trials demonstrates the ability to not only improve weight loss but also reduce the burden of comorbidities like heart disease, kidney disease, and obstructive sleep apnea
- The potential of product candidates in development to address critical unmet needs

Anticipated evolution of obesity treatment: oral and combination approaches

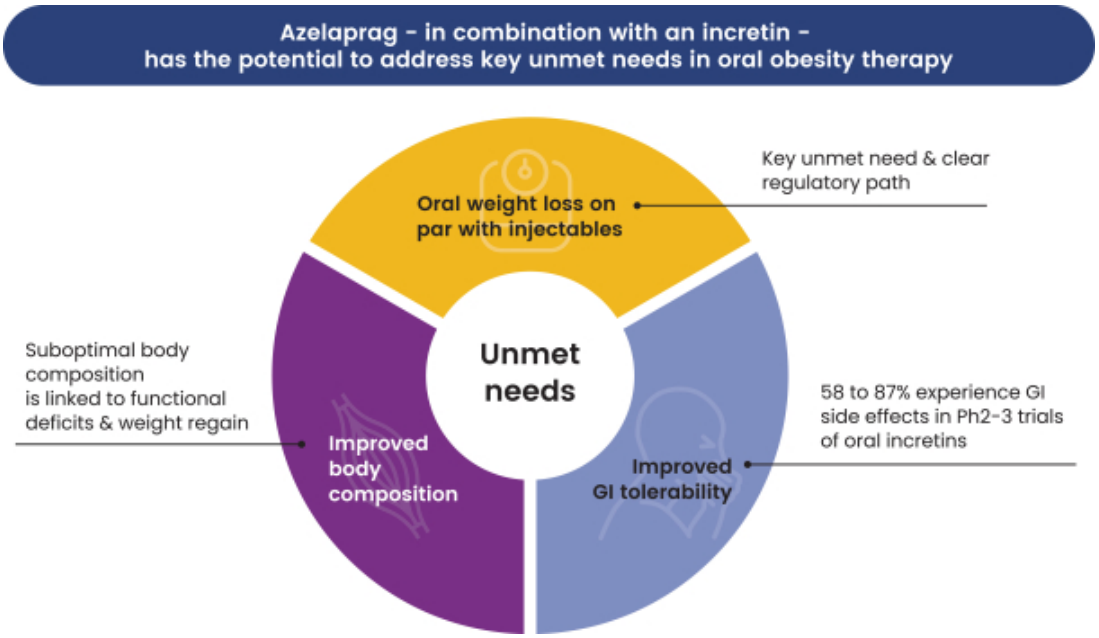
Several factors have spurred the biopharmaceutical industry to develop new product candidates for obesity. These include the large and rapidly growing market created by injectable GLP-1R agonists in treating obesity; the high prevalence of the disease; the impact of obesity on overall health and healthcare spending; and the limitations of currently prescribed drugs.

There are two important new trends in obesity drug development, both of which support the development potential of azelaprag in obesity:

- *Oral small molecule for weight loss.* Significant pharmaceutical development activity in this area is driven by:
  - *Patient preference.* 77% of patients strongly prefer the convenience of once-daily oral GLP-1Rs vs. once-weekly self-administering injections.
  - *Manufacturing and supply chain advantages*. Oral small molecules can alleviate cold-chain requirements and higher manufacturing costs associated with injectables.
  - *Dose titration*. Daily oral dosing enables more flexible titration compared to weekly administered injectables.
- *Combination therapies.* Combining multiple therapeutics with different mechanisms of action has the potential to improve weight loss while reducing side effects, improving body composition, and / or improving comorbidities.

Azelaprag has the potential to address critical unmet needs

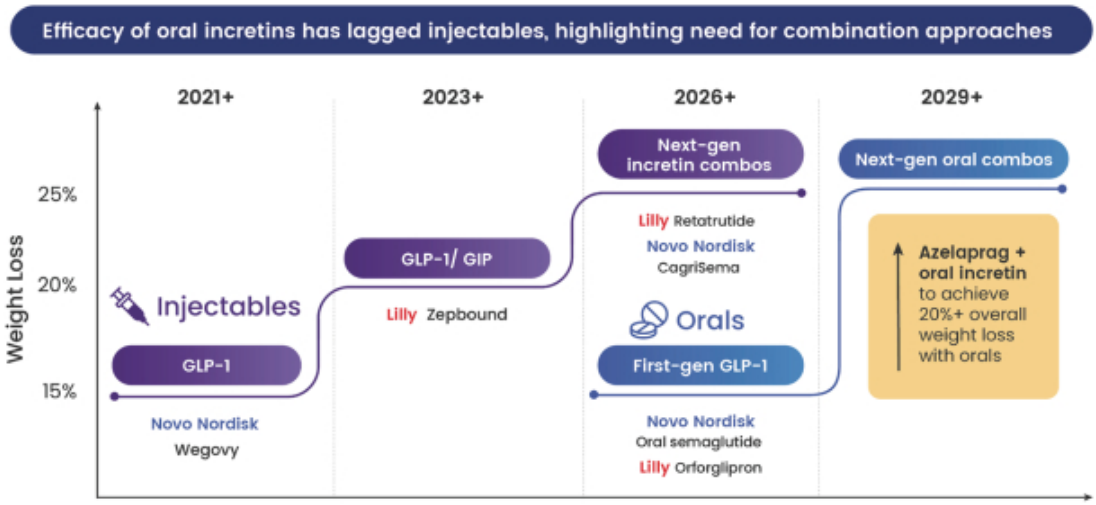
Azelaprag is an oral small molecule that showed synergistic benefits in combination with incretins in preclinical obesity studies. Importantly, azelaprag has the potential to address several key unmet needs in an all-oral combination.



Key unmet needs for oral weight loss regimens include increased weight loss, improved tolerability and improved body composition.

Goal: Overall oral weight loss on par with injectables

A highly competitive oral product would achieve weight loss of approximately 20% after one year of treatment. Weight loss with oral incretins in development has lagged injectables, potentially because the most advanced orals have a single target, GLP-1R, whereas some injectables have combined multiple mechanisms. Late-stage oral incretins have been observed to achieve up to approximately 15% weight loss in clinical trials: oral semaglutide reached 15.1% (50 mg, week 68); orforglipron reached 14.7% (45 mg, week 36). By contrast, in a separate clinical trial, Zepbound (tirzepatide 15 mg), which is a dual GLP-1R and GIP agonist and has the highest percentage of weight loss among approved injectables, reached 20.9% at week 72. Next-generation injectables in late-stage development may achieve or exceed 25% weight loss (e.g., Lilly's triple incretin agonist retatrutide 12 mg, 24.2% at week 48).



Current late-stage oral incretins have lower levels of weight loss compared to leading injectable products.

Goal: Improved body composition and weight loss quality

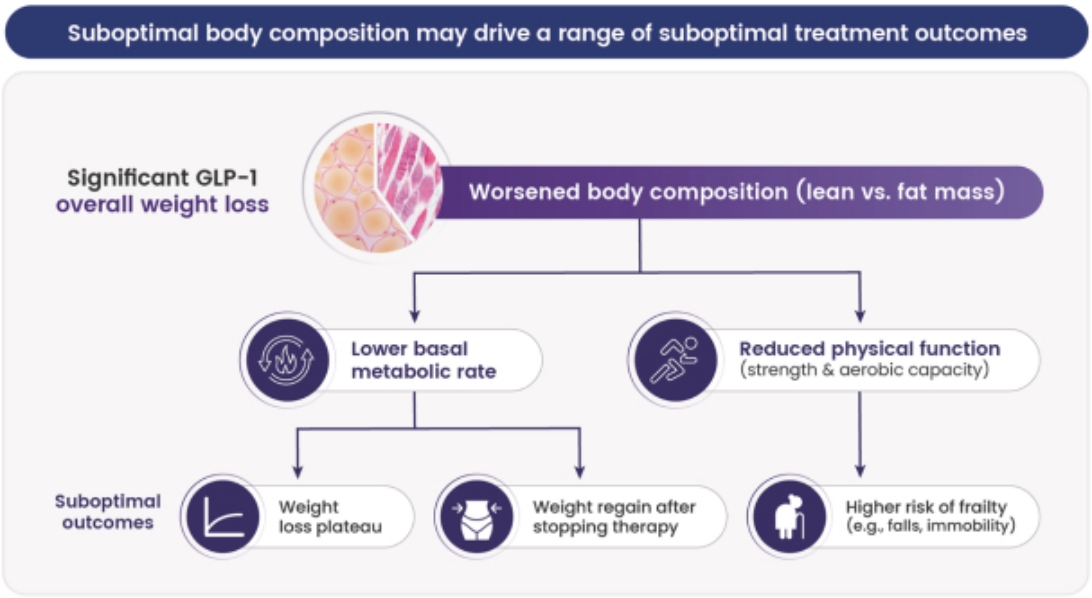
Up to 50% of the weight loss on GLP-1R agonist therapy is due to reduction in lean body mass. Loss of lean mass can result in suboptimal body composition (% fat vs. % lean mass). This effect is more pronounced in older adults who are less able to conserve lean mass in the presence of weight loss interventions than are younger adults.

Excessive loss of lean body mass, which is predominantly composed of skeletal muscle, can be a serious drawback for obesity treatments because skeletal muscle has several crucial functions. Skeletal muscle acts as a primary site of glucose disposal, and reductions in skeletal muscle contribute to poor glycemic control. Lean mass is a strong determinant of resting metabolic rate, helping the body to expend excess calories. A suboptimal proportion of lean mass following weight loss may therefore predispose individuals to a greater chance of rebound weight gain after stopping therapy.

Worsened body composition in older adults may also result in reduced physical function, including reduced mobility, hospitalization and physical frailty, especially in older patients. For example, Wegovy treatment resulted in a five times increased risk of hip and pelvis fractures in female patients, as reported in the SELECT cardiovascular outcomes trial.

It is important to note that the impact of weight loss on lean body mass is not limited to a single type of weight loss therapy. Indeed, this undesired impact is commonly observed after treatment with multiple classes of therapeutics, as well as in patients who undergo bariatric surgery.

Ultimately, the treatment goal for patients is to achieve not just weight loss – but also a healthy body composition and physical function. As a result, there is substantial interest from both physicians and pharmaceutical companies in mechanisms that improve the quality of body composition in connection with weight loss in addition to the quantity of weight loss.



Suboptimal body composition can be a key limitation of incretins currently used to treat obesity.

Goal: Improved tolerability with potential to improve titration, compliance and discontinuation

Injectable GLP-1R agonists are peptides that are associated with a high rate of gastrointestinal side effects such as nausea, diarrhea, vomiting, constipation, and abdominal pain. For example, in the STEP-1 and SURMOUNT-1 clinical trials, 44% of patients treated with semaglutide (2.4 mg) and 31% of patients treated with tirzepatide (15 mg) experienced nausea, respectively. These side effects contributed to discontinuation rates of 17% for patients on semaglutide (2.4 mg) and 15% for patients on tirzepatide (15 mg) in these clinical trials. In the real world, discontinuation has been reported at up to 68% at one year, of which up to 64% has been ascribed to tolerability based on patient reports. The frequency of these side effects is reduced with lower doses; however, lowering the dose results in lower weight loss. Titration to a maintenance dose is used to minimize treatment-associated side effects, but this is a slow process with approved products that occurs over months.

Oral GLP-1R agonists in development have generally reported an equivalent or inferior tolerability profile compared to injectable agonists, with higher rates of gastrointestinal side effects and subsequent trial discontinuation. In Phase 2–3 obesity trials of oral GLP-1R agonists, 58% (orforglipron, 24 mg) to 87% (GSBR-1290, 120 mg) of patients reported gastrointestinal side effects such as nausea, diarrhea, vomiting, constipation, and abdominal pain; by contrast, 31% (tirzepatide, 15 mg) to 44% (semaglutide, 2.4 mg) reported such adverse events with approved injectable agonists.

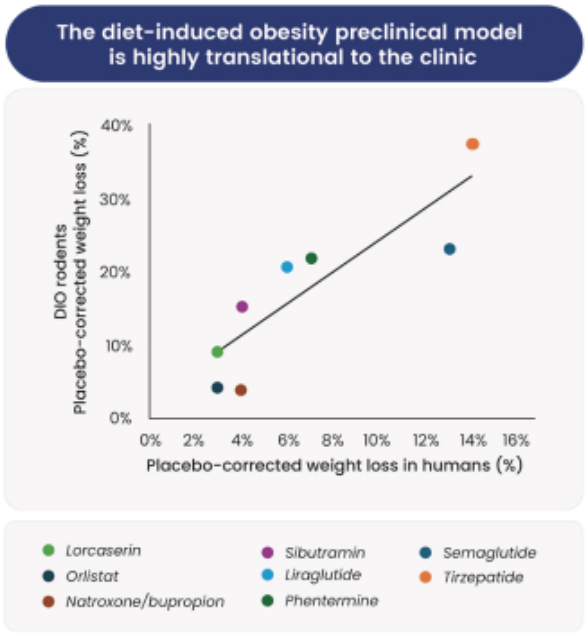
Combination approaches that limit incretin doses required to achieve target weight loss have the potential to substantially improve tolerability, which has clear potential downstream benefits, including:

- Improved patient compliance and reduced discontinuation, the majority of which is currently ascribed to tolerability in the real-world setting

- Shorter titration schedules, given fewer tolerability challenges that extend the time to reach a maintenance dose

Preclinical results in a diet-induced obesity model demonstrate the potential of azelaprag to increase weight loss quantity and quality

We evaluated the effects of azelaprag, both individually and in combination with incretin drugs, to improve weight loss and other outcomes in a diet-induced obesity mouse model. This model is considered the gold standard and is highly translational to the clinic: there is a linear relationship between weight loss in this preclinical model and weight loss observed in human patients, across multiple mechanisms of action.

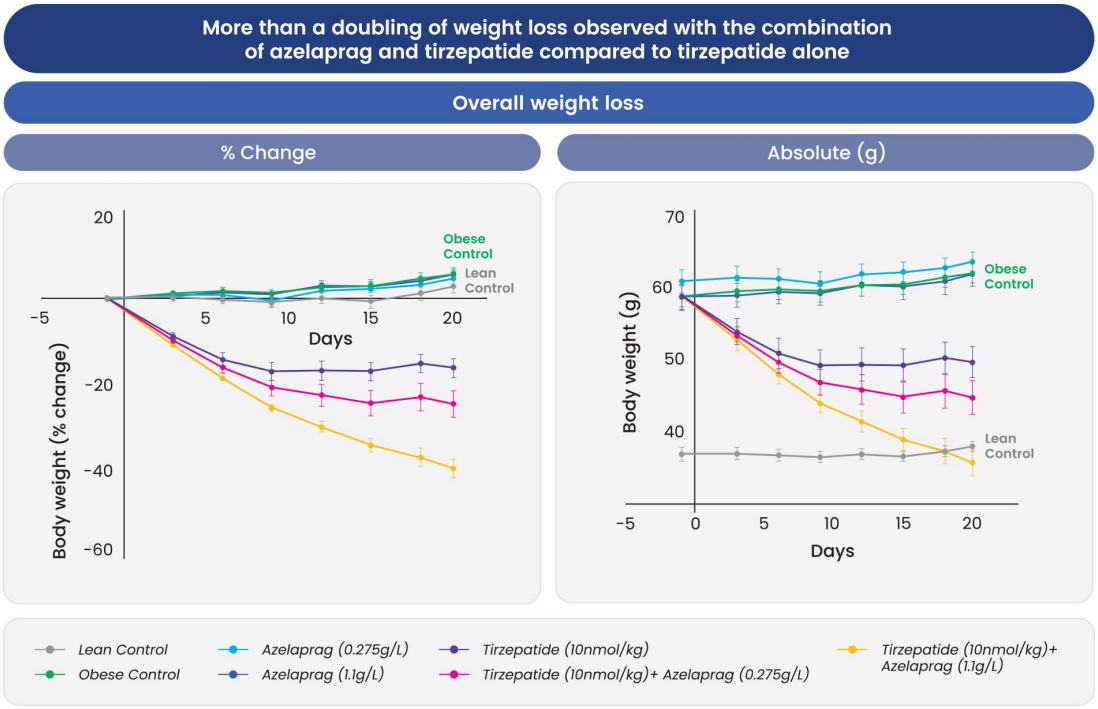


There is a linear relationship between weight loss achieved in the diet-induced obesity preclinical model and weight loss achieved in clinical trials in various obese populations. (Source: Müller et al. 2021).

Azelaprag, in combination with tirzepatide, restored body weight and body composition of obese mice to lean control levels. In our experiments, mice were fed a high fat diet, then treated with tirzepatide, azelaprag or a combination of both agents for three weeks while maintaining the same diet. All treatments were well-tolerated, with normal serum chemistries and normal behaviors observed in all animal groups.

As expected in this well-validated model, tirzepatide monotherapy led to a reduction in body weight of approximately 15% at the dose tested. The addition of azelaprag to tirzepatide treatment led to further significant, dose-dependent decreases in body weight, with 40% weight reduction by three weeks in the highest dose group. Importantly, at the highest dose of azelaprag, the weight of mice receiving the combination of azelaprag and tirzepatide was restored to that of lean controls (mice fed a regular diet, not a high fat diet).

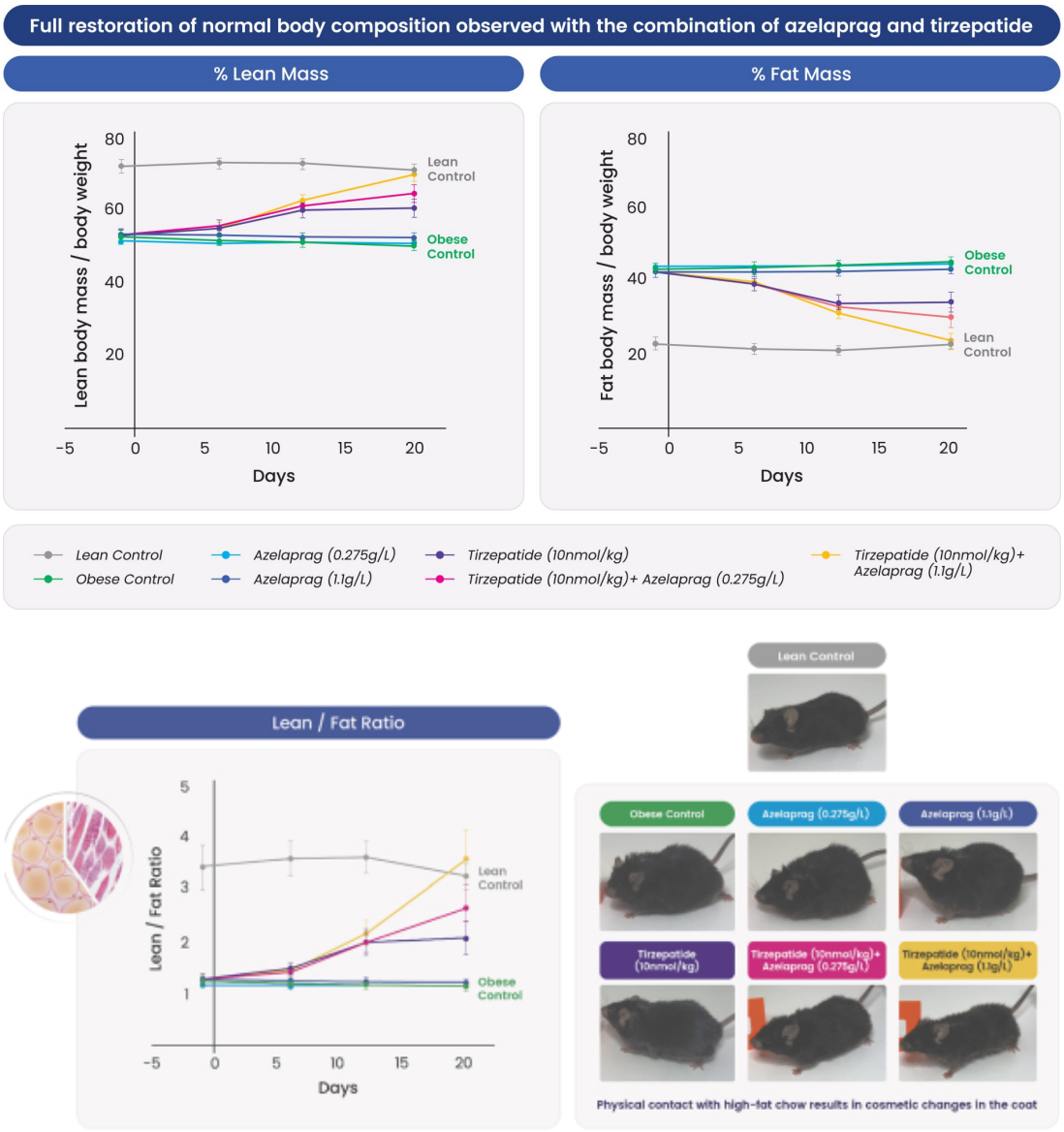
Monotherapy azelaprag had no notable effect on body weight in this study, a finding consistent with other efficacious combination mechanisms in obesity. For example, tirzepatide is a dual agonist of GLP-1R and the GIP receptor. In preclinical models, GIP agonism did not show a monotherapy weight loss benefit but showed a substantial weight loss increase in combination with a GLP-1R agonist.



The combination of azelaprag and tirzepatide resulted in significant, dose-dependent increases in overall weight loss compared to tirzepatide monotherapy in diet-induced obesity mouse model (left). High dose azelaprag in combination with tirzepatide resulted in weight loss that corrected obese mouse weight back to lean control levels (right). Group size: n=6-14 per group. Tirzepatide (10nmol/kg) vs. tirzepatide (10nmol/kg) + azelaprag (1.1g/l) on day 20: p<0.0001.

In addition to correcting total weight back to lean control levels, the addition of azelaprag in combination with tirzepatide also restored the body composition of obese mice to that of lean controls in a significant, dose-dependent fashion. The proportion of lean body mass increased while that of fat decreased over the three-week dosing period.

In the context of clinical care, body composition—and specifically the proportion of lean mass—is highly predictive of multiple health outcomes including physical function, metabolic health and cardiovascular outcomes (and more predictive than absolute levels of lean or fat mass).

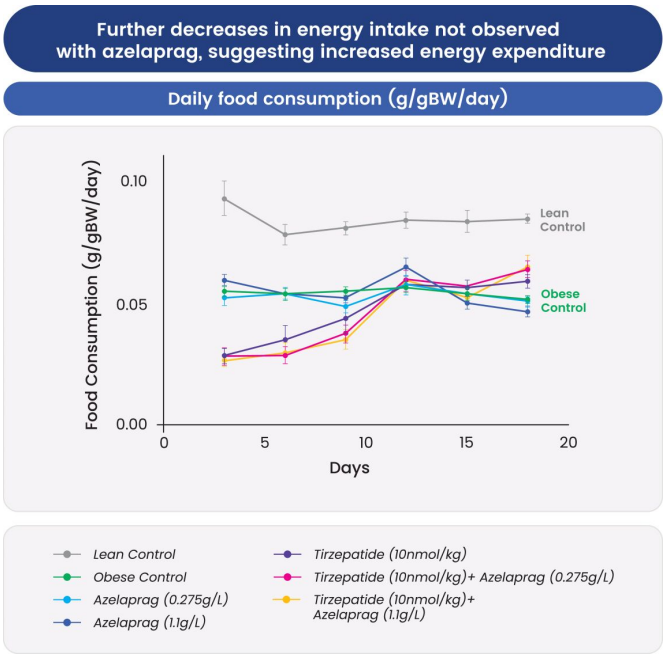


Azelaprag resulted in full restoration of body composition (% lean, % fat, lean / fat ratio) of obese mice to that of lean controls (top and bottom left). Representative images of mice in each treatment group are shown (bottom right). Lean and fat mass were measured by EchoMRI. Group size: n=6-14 per group. Tirzepatide (10nmol/kg) vs. tirzepatide (10nmol/kg) + azelaprag (1.1g/l) on day 20: p<0.0001 for both % lean and % fat.

Azelaprag did not further suppress energy intake, suggesting increased energy expenditure.

In contrast with incretins that show an appetite suppression mechanism, the incremental weight loss observed in the azelaprag combination therapy groups was not due to reduced food consumption (normalized for body weight). While food consumption was reduced with tirzepatide monotherapy, it was not decreased further

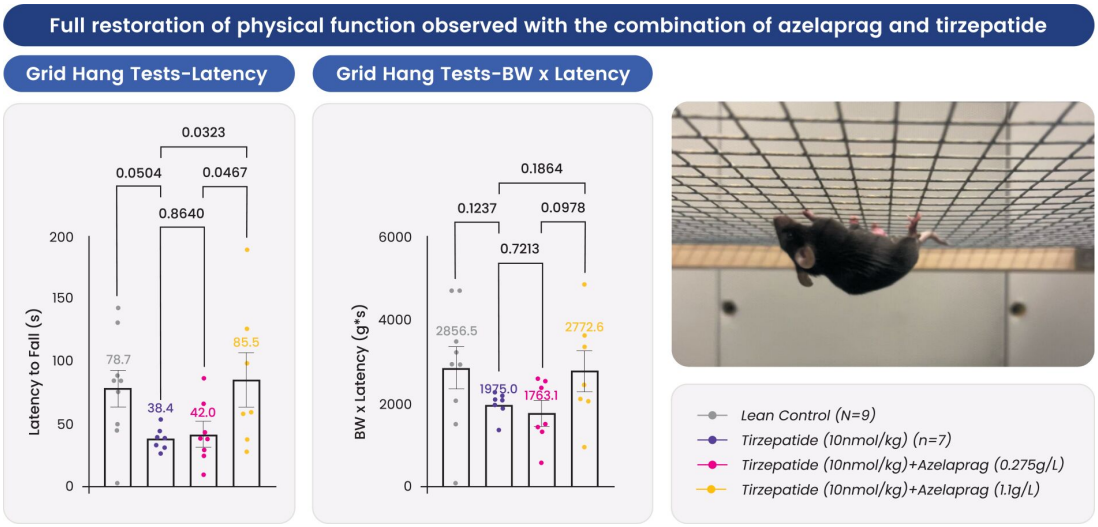
by the addition of azelaprag, suggesting a mechanism related to energy expenditure rather than further appetite suppression. This is consistent with apelin's role as an exerkine, and with the metabolic benefits previously observed in mice that transgenically overexpress apelin, as well as in our Phase 1b clinical trial.



Azelaprag in combination with tirzepatide did not result in lower food consumption than tirzepatide monotherapy in obese mice. Chow consumption was measured every 3 days and normalized to body weight. Group size: n=6-14 per group. Tirzepatide (10nmol/kg) vs. tirzepatide (10nmol/kg) + azelaprag (1.1g/l) on day 18: p=0.22.

Azelaprag, in combination with tirzepatide, fully restored physical function to lean control levels

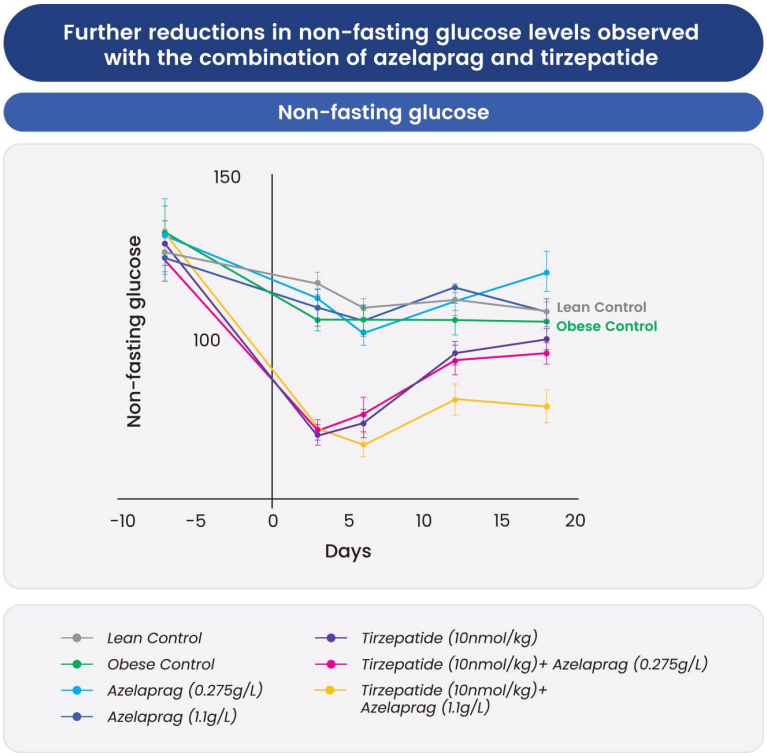
In addition to restoring obese animal weight and body composition to healthy control levels, we also observed the combination of azelaprag and tirzepatide to significantly restore normal physical function. Mice that received tirzepatide monotherapy showed worse functional performance compared to compared to lean controls as measured by a grid hang test. However, those that also received azelaprag showed restored physical function, as measured by grid hang times, roughly equivalent to those of lean controls.



The combination of azelaprag and tirzepatide restored muscle function to that of lean controls in obese mice. Latency to fall in the grid hang test is shown in seconds on the left panel and normalized to body weight (BW) on the right panel. Group size: n=7-9 per group.

Azelaprag, when administered in combination with tirzepatide, further decreased blood glucose level.

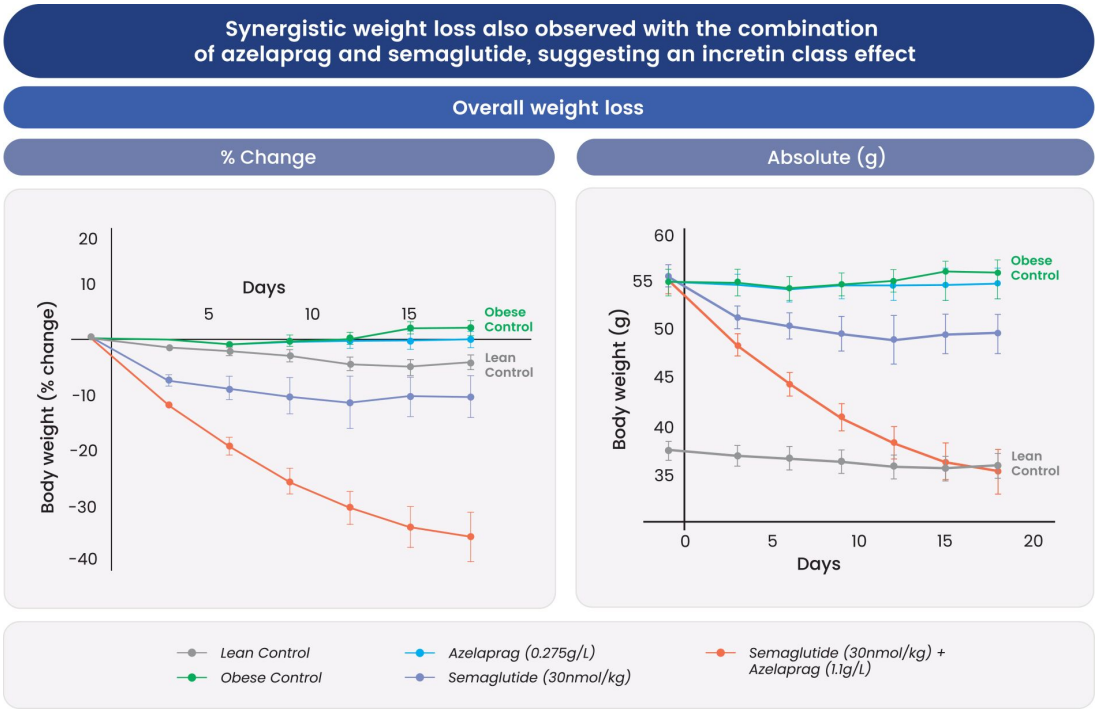
Administration with azelaprag in combination with tirzepatide also led to further improvements in glycemic control over that of tirzepatide monotherapy. Lowering blood glucose levels is one of the primary benefits of incretins such as tirzepatide. This effect of tirzepatide was also observed in this mouse model. While azelaprag monotherapy did not result in a further reduction in blood glucose levels, the combination of azelaprag and tirzepatide resulted in a significant and sustained decrease in non-fasting glucose levels. This observation is consistent with a small hyper insulinemic-euglycemic clamp trial of apelin-13 peptide in overweight men, where infusion of the peptide significantly improved insulin sensitivity.



Azelaprag combination with tirzepatide led to significant and prolonged suppression of non-fasting serum glucose levels in obese mice. Levels were measured between 9-11 AM. Baseline levels were captured on day -7 and treatment was initiated at day 0. Group size: n=6-14 per group. Tirzepatide (10nmol/kg) vs. tirzepatide (10nmol/kg) + azelaprag (1.1g/l) on day 18: p=0.0005.

A class effect: we observed similar weight loss synergy when azelaprag was combined with semaglutide.

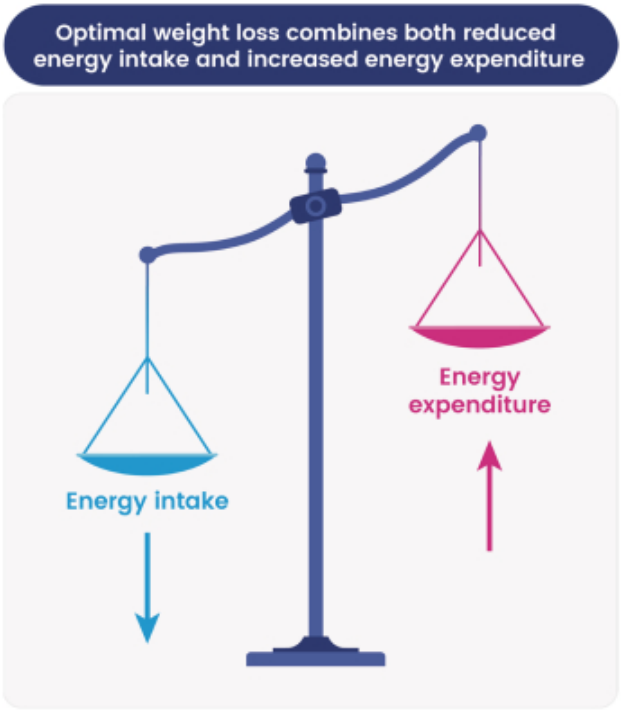
Mechanistically, azelaprag should show similar benefits in preclinical models when combined with other similar incretins that are GLP-1R agonists, beyond tirzepatide. In the same diet-induced obesity mouse model as our tirzepatide experiments, we observed comparable weight loss and other benefits when we administered azelaprag in combination with semaglutide, suggesting a class effect in incretins, as well as the potential for additivity with other appetite-suppressing weight loss therapies.



Azelaprag led to significantly increased weight loss in combination with semaglutide in obese mice, suggesting an incretin class synergy. Group size: n=7 lean controls; n=8 in all other groups. Semaglutide (30nmol/kg) vs. semaglutide (30nmol/kg) + azelaprag (1.1g/l) on day 18: p<0.0001.

We believe the totality of these preclinical results reinforce the potential benefits of an exercise mimetic as a complement to incretin obesity therapy. Exercise has been shown to significantly improve outcomes—including overall weight loss, body composition, and glucose control—when performed in combination with GLP-1R therapy. Azelaprag may recapitulate these benefits in incretin weight loss therapy, leading to increased weight loss quantity and quality.

We believe combination of azelaprag and an incretin is a pharmacological parallel to diet and exercise: one mechanism relies largely on reducing energy intake, the other on increasing energy expenditure.



Azelaprag Phase 2 clinical development in obesity

We are planning to conduct two Phase 2 clinical trials of azelaprag in combination with GLP-1R therapies in patients with obesity.

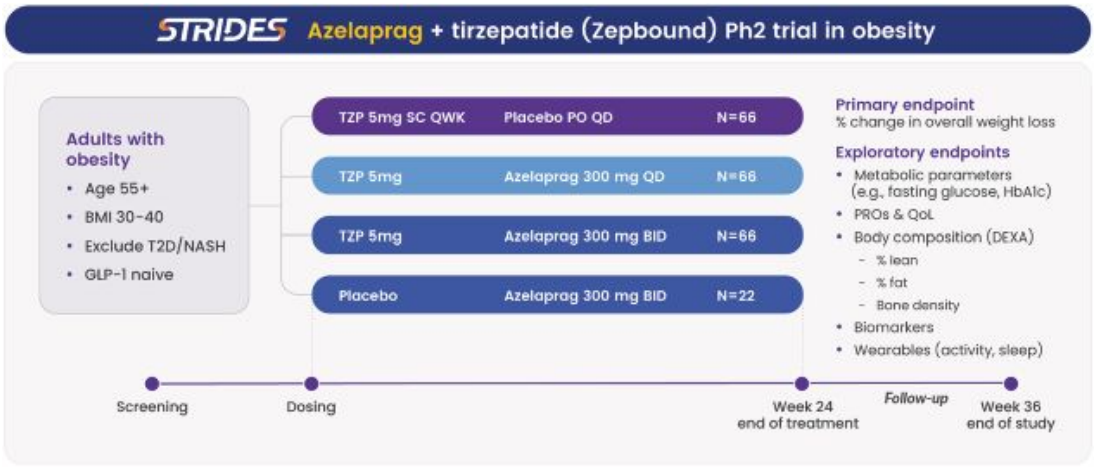
The ongoing STRIDES clinical trial is the first of these and aims to establish proof of concept in obesity and evaluate the ability of azelaprag to enhance weight loss in combination with tirzepatide in adults aged 55 and above with obesity, an age group that represents 35-40% of the adult obese population in the U.S. We chose to initially establish proof of concept in these older patients given the strong muscle and metabolic benefits of azelaprag observed in our Phase 1b clinical trial in older patients.

We have selected a 5 mg dose of tirzepatide in the STRIDES clinical trial given it approximates oral efficacy. Our ultimate goal is to develop azelaprag as part of an all-oral obesity combination therapy. The 5 mg dose of tirzepatide achieves similar weight loss as the most advanced oral in development, oral semaglutide. Tirzepatide 5 mg achieved 15.0% overall weight loss at 72 weeks; oral semaglutide 50 mg, achieved 15.1% weight loss after 68 weeks.

We plan to investigate two doses of azelaprag, 300 mg QD and 300 mg BID (which has potential for 600 mg QD dose formulation) in combination with tirzepatide as compared to tirzepatide alone. The doses were selected based on a completed Phase 1 oral pharmacokinetic trial; they are intended to result in azelaprag exposures (area under the curve) that bracket the similar exposure achieved in the Phase 1b bed rest trial and diet-induced obesity preclinical studies. These doses will be administered orally in combination with weekly subcutaneous tirzepatide. We are collaborating with Lilly's Chorus clinical development organization, which will provide clinical trial design and execution expertise, and Lilly, which is supplying tirzepatide. We retain all rights to azelaprag.

The primary endpoint of the STRIDES clinical trial is mean percent weight loss at 24 weeks with exploratory endpoints focused on body composition, glycemic control, patient-reported outcomes / quality of life, biomarkers, and rebound weight gain. We set the primary endpoint at 24 weeks because there is lower variability in tirzepatide monotherapy weight loss compared to later time points in clinical trials, and because Lilly has found weight loss at 24 weeks to be predictive for weight loss at 72 weeks (one year of treatment once the maintenance dose is reached). The trial has 90% power to detect a 3.3% difference between treatment groups (azelaprag plus tirzepatide versus tirzepatide alone) in weight loss at 24 weeks of treatment, which is expected to correspond to 5% at one year of treatment. FDA's 2007 draft guidance for development of weight management products states that a 5% treatment difference compared to placebo can be evidence of effectiveness in Phase 3 trials. A 5%+ benefit in weight loss for azelaprag could also translate into potential 20%+ overall weight loss in an oral combination, a competitive efficacy benchmark; for reference, the most advanced oral incretin in development, oral semaglutide, achieves 15.1% overall weight loss at 68 weeks.

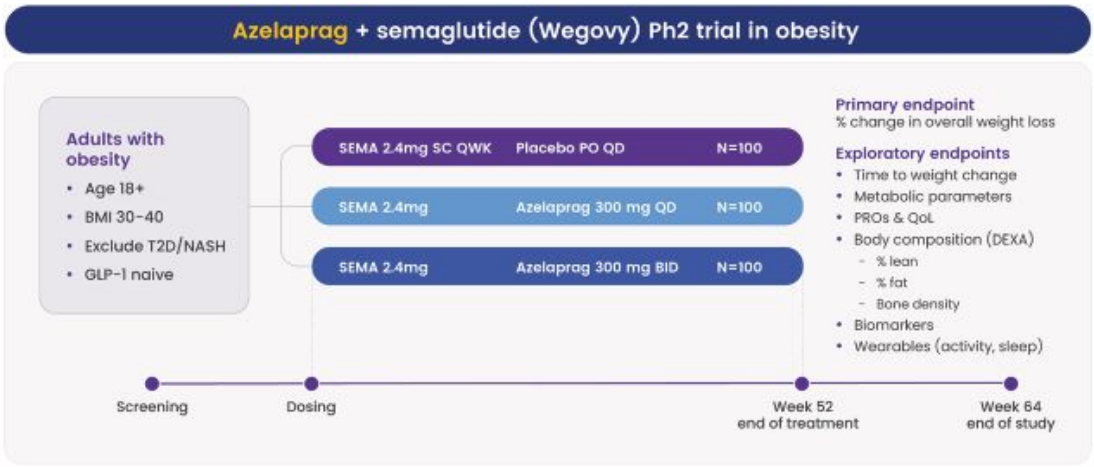
We anticipate topline results from this trial in .



Design of Phase 2 STRIDES clinical trial of azelaprag in combination with tirzepatide.

We intend to initiate an additional Phase 2 clinical trial in that will evaluate the potential of azelaprag to stimulate increased weight loss when administered in combination with semaglutide. The incremental goals of the trial are to support an incretin class effect and age-agnostic benefits over a year of treatment. The trial will enroll younger obese individuals, ages 18 and above. We intend to use the approved 2.4 mg dose of semaglutide in this trial, delivered weekly with subcutaneous injection, in combination with the same azelaprag doses used in the STRIDES clinical trial. This dose achieved 14.9% overall weight loss at 68 weeks, similar to the 5 mg tirzepatide dose in the STRIDES clinical trial.

The primary endpoint will be percent weight loss at 52 weeks, with similar exploratory endpoints as the STRIDES clinical trial. The study has 90% power to detect a 5% improvement in weight loss after one year of treatment, the difference stated in FDA guidance as providing evidence of effectiveness in Phase 3 trials.



Design of Phase 2 clinical trial of azelaprag in combination with semaglutide.

Indication expansion opportunities

Incretins have many potential applications in indications driven by obesity, where weight loss improves or resolves disease symptoms. We intend to focus azelaprag indication expansion on two indications where the apelin mechanism, in combination with an incretin, has the potential to provide therapeutic benefits beyond those driven by increased weight loss:

Type 2 diabetes.

According to the CDC, 90% of people with type 2 diabetes are overweight or obese. While incretins improve glucose control, efficacy currently lags with oral medications: Rybelsus (oral semaglutide 14mg), the only oral GLP-1R approved by the FDA for type 2 diabetes, led to 64% of T2D patients achieving hemoglobin A1c < 6.5% (target range for T2D at which disease is well-controlled) vs.79% with tirzepatide.

There is evidence indicating apelin has the potential to directly improve insulin sensitivity and glucose control. In a small randomized, double-blind, placebo-controlled, third-party cross-over trial of overweight men, infusion of apelin-13 peptide (30 nmol/kg) significantly improved insulin sensitivity in eight participants using a hyperinsulinemic-euglycemic clamp technique ($p<0.05$). In the third-party preclinical literature, apelin knockout mice experienced impaired performance on an insulin tolerance test ($p<0.01$, n=6-7 mice per group). By contrast, intravenous administration of apelin peptide (200 pmol/kg) to obese, insulin-resistant mice improved performance on an oral glucose tolerance test ($p<0.05$, n=6 mice per group).

We intend to initiate an insulin sensitivity proof-of-concept trial of azelaprag monotherapy in . The goal of the trial is to assess the potential direct benefits of azelaprag that are independent of weight loss, informing potential subsequent development for treatment of obesity with comorbid type 2 diabetes in combination with a GLP-1R agonist.

Heart failure with preserved ejection fraction (HFpEF).

HFpEF represents nearly half of all heart failure cases in the U.S. with prevalence of more than 3 million. Obesity is a significant risk factor for HFpEF: at least 80% of patients with HFpEF are overweight or obese. Unmet need is very high as there are very few effective therapies, resulting in high morbidity and mortality, and poor quality of life. There are several ongoing clinical trials in HFpEF with incretins and other weight loss

interventions. A recent trial of semaglutide 2.4 mg delivered weekly via injection showed significant improvements in symptoms and exercise function, in addition to greater weight loss, after 52 weeks of treatment.

Amgen demonstrated the specific therapeutic potential of azelaprag in preclinical heart failure models. In ZSF1 obese rats, a model of HFpEF, acute administration of azelaprag increased left ventricular pressure (dP/dtmax, p=0.004), cardiac output (p=0.004), stroke volume (p=0.036), and ejection fraction (p=0.014) (n=16-17 per group). In addition, azelaprag significantly improved cardiac reserve in these rats.

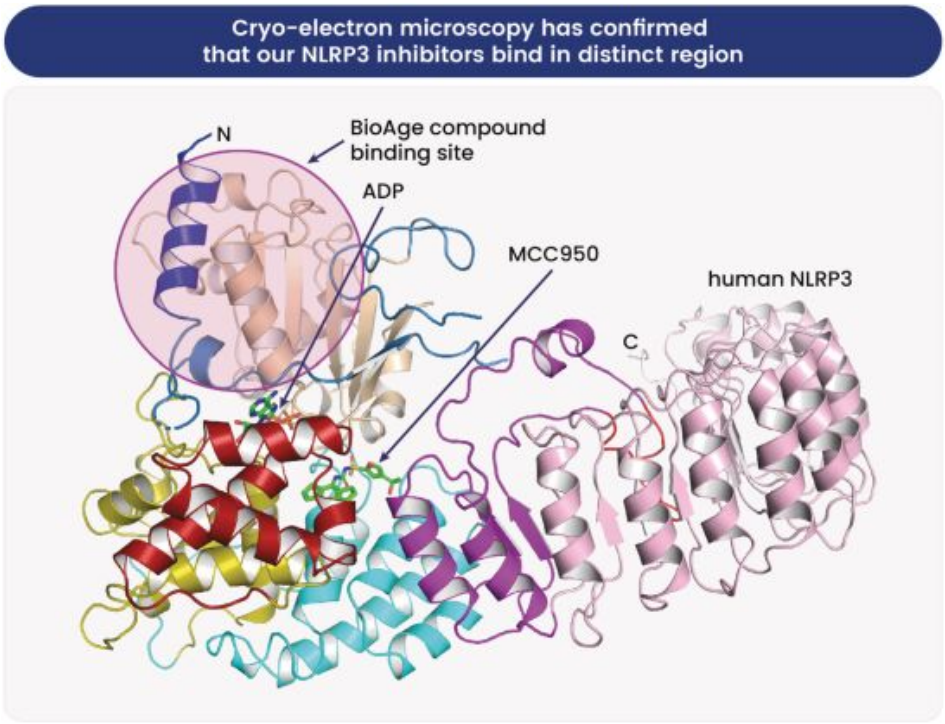
NLRP3 inhibitors for the treatment of neuroinflammation; IND submission anticipated in followed by Phase 1 initiation

We are developing potent, selective, and structurally novel penetrant NLRP3 inhibitors, for the treatment of neuroinflammation.

BGE-100, our most advanced compound, is designed with chemical properties (e.g., potency, brain penetration) and a binding site that distinguish it from other NLRP3 inhibitors in development.

We have demonstrated that BGE-100 is orally bioavailable and highly brain-penetrant in multiple species, and capable of potently inhibiting NLRP3 activity in mouse *in vivo* and human whole blood *ex vivo* assays. BGE-100 was discovered by BioAge chemists by screening a HitGen DNA-encoded chemical library.

Through a collaboration with Dr. Matthias Geyer at the University of Bonn, we identified the specific binding site of BGE-100 on NLRP3. This enabled the discovery of next-generation NLRP3 inhibitors with superior binding affinity, 50 to 100 times more potent than BGE-100.

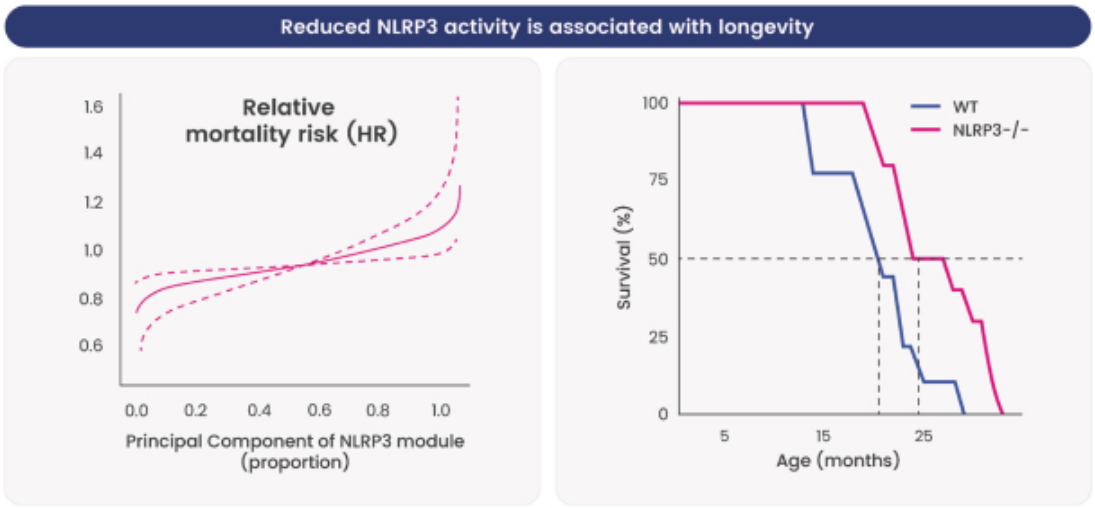


BGE-100, and other NLRP3 inhibitors in the chemical series discovered by BioAge, bind in a region of NLRP3 that is distinct from other NLRP3 inhibitors described to date (e.g., MCC950). Collaboration with Dr. Matthias Geyer, Institute of Structural Biology, University of Bonn.

We intend to submit an IND for an NLRP3 inhibitor to the FDA in and, if cleared, initiate a Phase 1 trial to evaluate safety, tolerability, pharmacokinetics and pharmacodynamics in .

NLRP3 and inflammation—a predictor of decreased longevity

NLRP3 is a component of a multi-protein complex referred to as the inflammasome, part of the innate immune system that activates inflammation upon recognition of pathogens. Activation of the NLRP3 inflammasome leads to the secretion of inflammatory cytokines interleukin 1 beta (IL-1ß) and interleukin 18 (IL-18). We found that increased transcription of genes for all three of these proteins in our human aging cohorts was associated with significantly increased all-cause mortality risk. Consistent with our findings that NLRP3 can have detrimental effects on human longevity, previous studies have shown that genetic deletion of NLRP3 significantly extended mouse lifespan and healthspan as measured by parameters such as muscle strength (e.g., muscle size, wire hang latency to fall) and cognitive function (e.g., preserved contextual memory).



Levels of NLRP3-associated proteins (principal component) are inversely related to mortality risk in our human aging cohorts (left). Consistently, in a third-party preclinical study, knockout of the NLRP3 gene in mice significantly extends lifespan (n = 10 mice per group) (right). (Source: Marín-Aguilar et al. 2020).

Targeting NLRP3 in the brain—therapeutic applications

NLRP3-driven neuroinflammation has been implicated in a variety of diseases including:

- Obesity. Studies have suggested that activation of inflammatory responses in the hypothalamus is associated with diet-induced obesity and may be a key mechanism driving its development. Recent data showed that a brain-penetrant NLRP3 inhibitor unrelated to BGE-100 led to weight loss in a diet-induced obesity mouse model that was similar in magnitude to that of semaglutide. In a third-party 28-day Phase 1b/2a trial in obese adults with cardiovascular risk factors, this inhibitor showed a statistically and clinically meaningful reduction in C-reactive protein.
- Neurodegeneration. Studies have increasingly shown that the activation of the NLRP3 inflammasome may play a role in the pathogenesis of both Parkinson's disease (PD) and Alzheimer's disease (AD). In a mouse model of PD, inhibition of NLRP3 reduced motor dysfunction and neurodegeneration. In AD, NLRP3 is substantially elevated in the brain, and activation of the NLRP3 inflammasome enhances aggregation or amyloid ß.

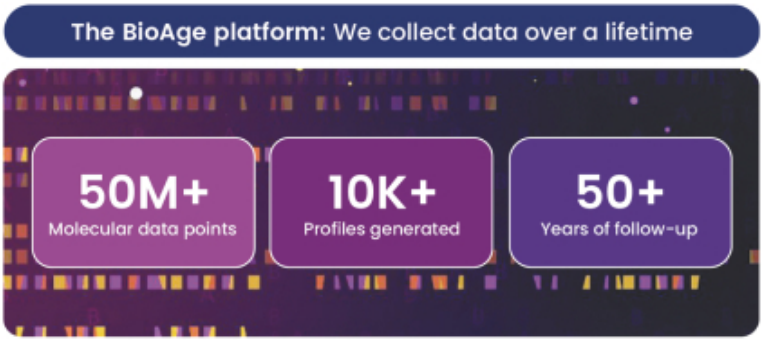
Development plans for our NLRP3 Inhibitor Program

We intend to submit an IND for an NLRP3 inhibitor to the FDA in and, if cleared, initiate a Phase 1 trial to evaluate safety, tolerability, pharmacokinetics and pharmacodynamics in .

Our platform for discovery of novel targets that drive human metabolic aging

We have built a target discovery capability specifically designed to identify and validate drug targets that drive metabolic aging and age-related diseases in humans. Our approach combines:

- **Long-term longitudinal cohorts of naturally aging individuals.** We have generated proprietary datasets based on serial biological samples from cohort studies that satisfy a set of unusual and valuable requirements for the study of aging biology: (1) being composed of healthy aging adults originally recruited decades in the past, (2) having followed subject outcomes and collected deep healthspan data continuously to the present day, and (3) having collected longitudinal biosamples that have also been maintained to the present day.
- **Serial multi-omic molecular profiling**. Through partnerships with companies using state-of-the-art molecular profiling techniques, we quantified thousands of components from these samples, such as proteins and metabolites, with high sensitivity.
- **Data science analysis.** We have developed a suite of analytic approaches allowing us to integrate longitudinal molecular profiles with clinical and health outcome data to directly decode the biology that drive disparate aging trajectories and metabolic aging and related health outcomes and identify novel drug targets for treating metabolic disease.
- **Expertise in aging biology**. We apply our knowledge of the aging process, including our own large colony of naturally aged rodents, to validate potential drug targets in relevant *in vitro* and *in vivo* models of age-related metabolic disorders.
- **Technology-forward approach to clinical trials.** We aim to maximize the value of our clinical trials by leveraging advanced analytic approaches to quantify participants' biology and health, derive mechanistic insights, and link trial observations back to long-term healthspan outcomes from our natural aging cohorts. Examples from prior and ongoing trials include plasma proteomic profiling, wearable devices, protein synthetic rate analysis, and single-nucleus RNA sequencing of biopsy samples.



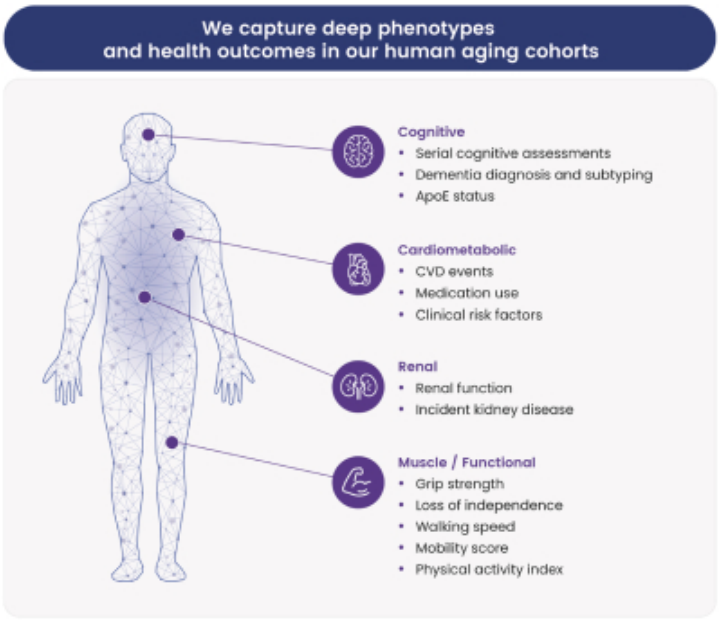
The BioAge platform encompasses over 50 million molecular data points spanning over 10 thousand individual participant profiles and over 50 years of follow-up.

Approach for identifying novel targets based on unique insights into human aging biology

We have negotiated favorable agreements with biobanks to access long-term longitudinal cohorts of individuals with serially biobanked samples who were enrolled as healthy adults and followed for over 50 years.

In these cohorts, we have detailed medical records and physiological measurements systematically collected over the course of these studies, including lifespan outcomes, such as all-cause and disease-specific mortality; functional healthspan outcomes such as grip strength and walking speed; and disease outcomes such as cognitive scores and dementia diagnoses, cardiovascular disease progression, BMI and skinfold thickness.

The biobanks to which we have secured access are from distinct geographical regions and include samples from individuals whose demographics are representative of those regions, enabling us to identify aging processes that are conserved across populations and environmental backgrounds.

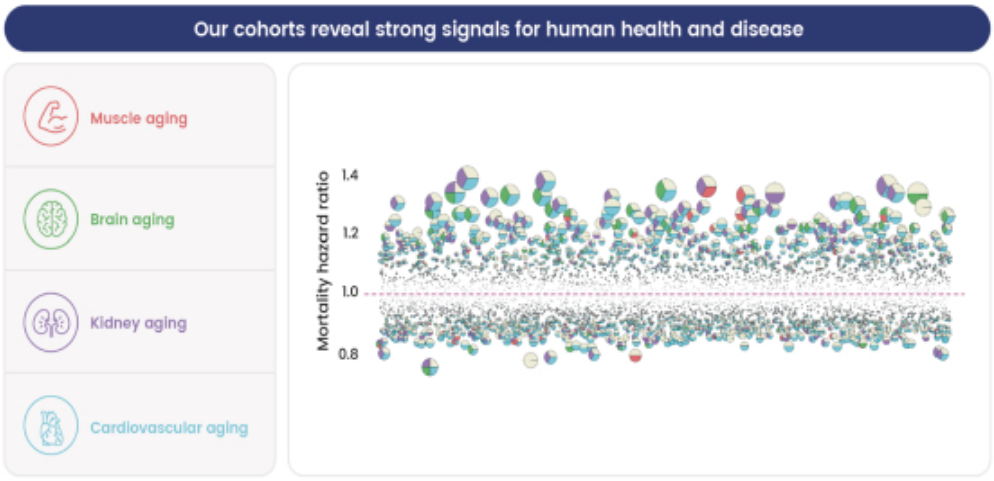


Example of longitudinal lifespan and health outcomes captured in human aging cohorts. CVD: Cardiovascular. ApoE: Apolipoprotein E.

We partner with organizations and companies leading the development of highly sensitive multi-omic molecular profiling technologies, including SomaLogic and Metabolon, to identify and quantify components of longitudinally biobanked serum and plasma specimens from our aging cohorts. The capabilities that these organizations and companies bring allow us to generate molecular profiles with more detail than had previously been possible.

We combine proteomics and metabolomics with orthogonal data such as clinical outcomes and healthspan phenotypes to obtain insights into the underlying pathways and potential targets that predispose individuals to age more quickly or be more resistant to developing multi-morbidity. Our goal as a company is to use these insights to develop pharmaceuticals that can treat a range of metabolic diseases driven by aging.

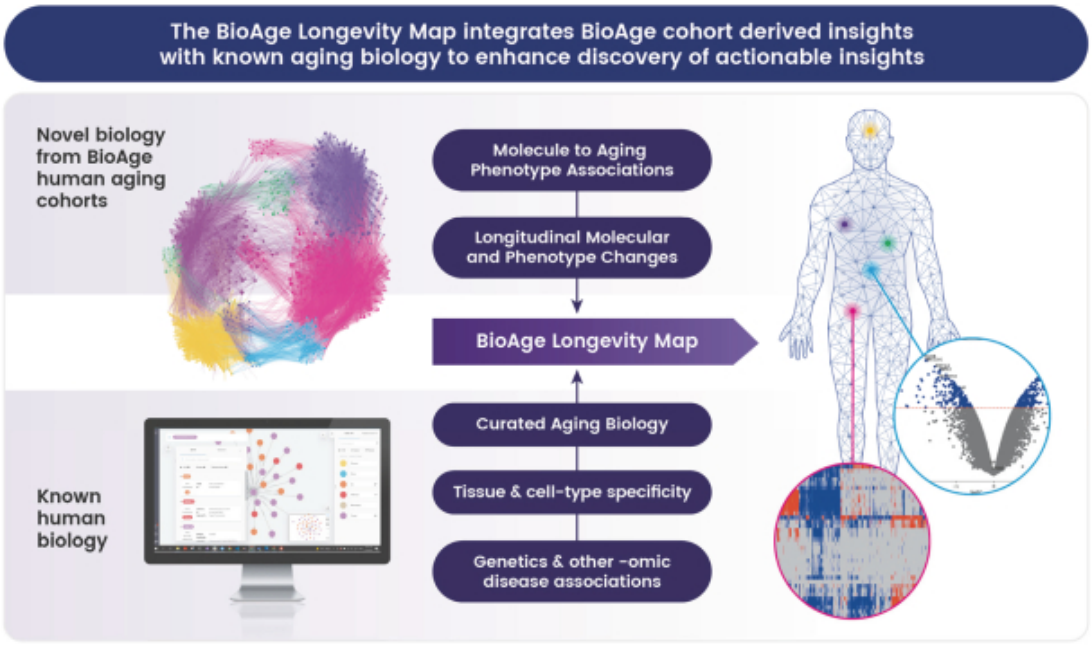
We have previously shared the identification of apelin and NLRP3 from our platform. Beyond these targets, there are many promising targets emerging from our data sets. The figure below highlights the many proteins that have significant signals for both longevity as well as multiple health outcomes in our cohort data.



Circulating proteins are shown based on their magnitude of association with mortality (hazard ratio) in the BioAge human aging cohorts. Proteins are color coded based on significant associations (p<0.05) with future healthspan outcomes representing different organ systems, including grip strength (muscle aging), cognitive scores (brain aging), renal function quantified with cystatin C (kidney aging), and cardiovascular aging. A protein was considered significant for cardiovascular aging if significantly associated with ≥2+ of the following risk factors: total cholesterol, HDL, LDL, systolic or diastolic BP, fasting glucose, CRP, MCP-1 and ICAM-1.

Our Longevity Map is the result of applying an aging-biology-focused analytic approach that integrates proprietary data originating from our human aging cohorts with public data on aging and target biology to generate powerful insights into human aging mechanisms and targets. Our core analytical pipeline leverages (among other approaches):

- longitudinal multi-omic and clinical data,
- relationships across multiple datasets and data modalities,
- network based propagation of biological signals, and
- causal evidence from genetic signals via a bespoke mendelian randomization analysis.



The BioAge Longevity Map integrates novel aging biology and public data to derive insights into aging biology and resulting therapeutic targets.

The apelin and NLRP3 pathways were identified in our platform due to strong associations of pathway activation with long-term health outcomes. It provides strong validation of the platform that in our clinical trials, azelaprag not only showed the acute muscle and metabolic benefits suggested by the platform, but also induced molecular changes independently predictive of the same positive long-term health outcomes that originally distinguished apelin as an attractive therapeutic target.

We are advancing several additional platform targets, currently in discovery stage, which we believe have the potential to transform treatment of metabolic disease. We plan to expand this pipeline over time, both internally and potentially through partnerships with pharmaceutical companies that have complementary datasets and capabilities.

Material Agreements

Exclusive License Agreement with Amgen Inc.

On April 5, 2021, we entered into an exclusive license agreement (the Amgen Agreement) with Amgen Inc. (Amgen) pursuant to which Amgen granted us an exclusive, worldwide license, with the right to sublicense (subject to certain conditions), under Amgen's rights in specified patents relating to Amgen's proprietary compound, AMG 986, a novel apelin J receptor agonist, to research, develop and commercialize AMG 986 in all diagnostic, preventative or therapeutic uses. Amgen also granted us a non-exclusive, worldwide license, with the right to sublicense (subject to certain conditions), under Amgen's rights in specified know-how relating to AMG 986, including research reports, clinical data, manufacturing processes, regulatory documents and other information pertaining to AMG 986, to research, develop and commercialize AMG 986 in all diagnostic, preventative or therapeutic uses. Although we maintain the exclusive rights described above with respect to the specified patents, Amgen retains research-only rights solely for Amgen's internal research. All right, title and interest to inventions conceived or created by a party under the Amgen Agreement that are exclusively related to AMG 986 will be owned exclusively by us, regardless of inventorship.

Under the Amgen Agreement, we are obligated to use commercially reasonable efforts to develop and commercialize at least one licensed product in each of the United States, European Union, Japan and the rest of the world (ROW). If we fail to materially develop or commercialize such products for twelve months in the United States, European Union, Japan or ROW, and such failure is not due to reasons out of our control, in addition to other available remedies, Amgen may terminate our agreement with respect to the failing region, subject to a cure period.

In consideration for the rights granted under the Amgen Agreement, we paid an upfront fee of $1.0 million and issued Amgen 846,152 shares of our Series C redeemable convertible preferred stock, which will automatically convert into shares of our common stock in connection with the completion of this offering. Additionally, we may also be required to pay up to an additional $120.0 million in the aggregate for future development, regulatory and commercial milestone payments, as well as tiered royalties at percentages ranging in the low- to upper-single digits on future net sales by us and our sublicensees of licensed products, if any. Royalties are paid on a product-by-product basis and commence with respect to a particular country upon the first commercial sale in such country and terminate in such country on the latest to occur of the date on which such product is no longer covered by a valid claim in such country, the loss of regulatory exclusivity for such product in such country, and for a specified time period after the first commercial sale of such product in such country. Such royalties may be decreased if, among other reasons, we are required to pay a third party for rights to intellectual property for the exploitation of a licensed product in a given country, but in no event be reduced in aggregate by a specified percentage.

The term of the Amgen Agreement will end on a licensed product-by-licensed product basis and country-by-country basis upon the expiration of our obligation to pay royalties to Amgen with respect to such licensed products in such countries. We may terminate the Amgen Agreement in its entirety for convenience upon a specified written notice period. Amgen has the right to terminate the agreement if we, or one of our affiliates or sublicensees, challenges the patentability, enforceability or validity of a licensed patent, subject to a cure period. Additionally, either party will be able to terminate the Amgen Agreement for the other party's uncured material breach or bankruptcy.

Material Transfer Agreement with Eli Lilly and Company

On October 25, 2023, we entered into a material transfer agreement (the Lilly Agreement) with Lilly. Under the Lilly Agreement, Lilly has agreed to manufacture and supply us with a certain quantity (which may be increased by mutual consent) of tirzepatide so we can sponsor a clinical trial in which azelaprag and tirzepatide are co-administered concomitantly or sequentially. Such trial is expected to be conducted pursuant to a protocol developed in accordance with a development services agreement between us and Lilly dated as of October 25, 2023. The Lilly Agreement is a non-exclusive agreement, with specific carveouts as set forth in the Lilly Agreement allowing Lilly limited exclusive rights if we desire to conduct any additional clinical trials utilizing certain specified compounds, as outlined in the Lilly Agreement.

Additionally, Lilly has an exclusive right of first negotiation for a limited period after we complete or terminate our clinical trial, or, if earlier, after we provide notice of our intent to initiate certain significant corporate or licensing transaction processes (a Significant Transaction). If Lilly declines, or fails to pursue, the right of first negotiation or if the parties fail to mutually agree upon a non-binding term sheet during such period, then we shall thereafter have the right to (i) commence discussions with any other third party regarding a Significant Transaction and (ii) enter into an exclusive arrangement or execute a binding agreement with any other third party regarding a Significant Transaction. In addition, prior to completing our planned Phase 2 clinical trial, other Significant Transactions outlined in the Lilly Agreement require us to grant Lilly a non-exclusive right of negotiation for a limited period of time.

We are responsible for the conduct of the planned Phase 2 clinical trial in accordance with all applicable laws and regulations, will hold the IND and will own the clinical data. In exchange, we must provide Lilly with information relating to the Phase 2 clinical trial (including, without limitation, all clinical data and communications with regulatory authorities) and grant Lilly certain rights with respect to the clinical data derived from the Phase 2 clinical trial.

Inventions generated under the Phase 2 clinical trial or conceived through the use of the tirzepatide or Lilly's confidential information (Inventions) and relating to or covering the combined use of azelaprag and tirzepatide are jointly owned by us and Lilly. Inventions primarily relating to azelaprag and not materially to tirzepatide are our exclusive property. Inventions primarily relating to tirzepatide and not materially to azelaprag are the exclusive property of Lilly. Pursuant to the terms of the Lilly Agreement, each party has granted the other party a non-exclusive license under its intellectual property which covers an invention and claims the combination of azelaprag and tirzepatide in order to practice the combination of azelaprag and tirzepatide for all purposes. Neither party has granted the other any rights to their respective background intellectual property that does not claim the combination of azelaprag and tirzepatide except as necessary to conduct the combination trial.

The term of the Lilly Agreement will expire four years after the effective date. However, if our development service agreement with Lilly terminates for any reason, the Lilly Agreement will automatically terminate simultaneously. Additionally, either party may terminate the Lilly Agreement for any uncured material breach that continues for a certain period after notice and reasonable opportunity to cure. Lilly can terminate with prior notice in the event of a Significant Transaction if certain conditions pursuant to the Lilly Agreement are met. In the event that the Lilly Agreement is terminated, we have the right to continue with the conduct of the planned Phase 2 clinical trial.

Manufacturing

We oversee and manage CDMOs to support development and manufacture of product candidates for our clinical trials. We expect our strategy to use CDMOs will enable us to maintain a more efficient infrastructure, avoiding the necessity to acquire our own manufacturing facility and equipment, while simultaneously enabling us to focus our expertise on the clinical development and the potential future commercialization of our products. Currently, we rely on and have agreements with multiple third-party CDMOs to manufacture and supply active pharmaceutical ingredients (APIs) and drug products (DPs) for our clinical trials. To prepare for advancement of our drug candidates to Phase 3 clinical trials, we anticipate the need to enter into a manufacture and supply agreement with, and transfer API and DP manufacture to, one or more additional third-party CDMOs with whom we would also likely enter into commercial supply agreements prior to any potential regulatory approval if any of our drug candidates are commercialized. The DP for our drug candidates is manufactured via conventional pharmaceutical processing procedures, employing commonly used and commercially available excipients and packaging materials. The procedure and equipment employed for manufacture and analysis are consistent with standard organic synthesis or pharmaceutical production, and are transferable to a range of manufacturing facilities, if needed.

Competition

The biotechnology and pharmaceutical industries are characterized by rapid evolution of technologies, fierce competition and strong defense of intellectual property. While we believe that our platform, knowledge, experience and scientific resources provide us with competitive advantages, we face competition from major pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions, among others.

If any of our product candidates are approved for the indications for which we expect to conduct clinical trials, they will compete with existing therapies and currently marketed drugs, as well as any drugs products currently or in the future in development that are ultimately approved, that are potential treatments for metabolic diseases, such as obesity. It is also possible that we will face competition from other pharmaceutical approaches as well as other types of therapies. The key competitive factors affecting the success of all our programs, if approved, are likely to be their efficacy, safety, convenience, price, level of generic competition, and availability of reimbursement.

Many of our current or potential competitors, either alone or with their collaboration 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.

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. Mergers and acquisitions in the biopharmaceutical 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. Our competitors for azelaprag include Structure Therapeutics, Bristol Myers Squibb, APIE Therapeutics and Sanofi, S.A. who have or had small molecule APJ agonists in preclinical or clinical development. With respect to BGE-100, direct competition is currently limited as there are no approved NLRP3 inhibitors or other inflammasome-targeted therapeutics for neuroinflammation. However, we are aware of NLRP3 inhibitor pipeline programs with reported CNS activity, which is a key feature of BGE-100, including those from NodThera, Ventyx Biosciences, Roche and Ventus Therapeutics.

We anticipate that we will continue to face increasing competition as new therapies and combinations thereof, and related data emerge. Competitors, independently or through collaboration, are developing products that potentially directly compete with our current or future product candidates and which may (i) be a longer lasting or a more efficacious treatment, or better tolerated or (ii) receive FDA or other applicable regulatory approval more rapidly than our current or future product candidates. 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. Our competitors also may obtain FDA or other applicable regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

Intellectual Property

Intellectual property is of vital importance in our field and in biotechnology generally. We seek to protect and enhance proprietary technology, inventions, and improvements that are commercially important to the development of our business by seeking, maintaining and defending patent rights, whether developed internally or licensed from third parties. We will also seek to rely on regulatory protection afforded through inclusion in expedited development and review, data exclusivity, market exclusivity and patent term extensions where available.

We have sought patent protection in the United States and internationally related to our novel drugs, including compositions of matter directed both specifically and generically to our leads and backup compounds and corresponding methods of use directed to various clinical indications of the same, and other inventions and improvements that are central to our research and development efforts. In addition, we intend to seek additional patent protection which may enhance commercial success to the extent warranted by future developments.

As of June 30, 2024, our intellectual property portfolio contained owned and in-licensed cases and contains several issued U.S. and foreign national patents, and multiple pending U.S., Patent Cooperation Treaty (PCT) and foreign national applications. These patent families are expected to expire between 2036 and 2045, excluding patent term adjustments, extensions or terminal disclaimers, and assuming payment of all appropriate maintenance fees.

Azelaprag Program

As of June 30, 2024, we had exclusively in-licensed 10 patent families from Amgen Inc. relating to apelin receptor agonists and related methods. One patent family specifically and generically claims azelaprag, and 9 patent families are directed to various structural analogs. These 10 patent families collectively include 20 issued U.S. patents, no pending U.S. patent applications, 99 issued foreign national patents, including patents in

Australia, Brazil, Canada, China, Europe (with validation in 40 European states), India, Japan, Korea Mexico, Singapore, Taiwan and 23 other jurisdictions, and nine pending foreign national applications, including applications in Argentina, Egypt, Europe, Gulf Cooperation Council (GCC), Libya and Thailand. With respect to the 1 patent family that specifically and generically claims azelaprag, there are 10 issued U.S. patents, 77 issued foreign patents, and five pending foreign applications. U.S. Patent No. 9,573,936, U.S. Patent No. 9,868,721 and U.S. Patent No. 10,221,162 generically and specifically claim the drug substance azelaprag and each expires in 2036, without taking into account patent term adjustments, terminal disclaimers, or potential future extensions, and assuming payment of all appropriate maintenance fees. Foreign patents in this family expire and pending foreign applications are expected to expire in 2036, without taking into account potential future supplementary protection certificates and assuming payment of all appropriate annuity fees. The nine patent families that are directed to various structural analogs all expire between 2037 and 2039, without taking into account patent term adjustments, terminal disclaimers, or potential future extensions and assuming payment of all appropriate maintenance fees for the U.S. patents and without taking into account potential future supplementary protection certificates and assuming payment of all appropriate annuities for foreign patents in these families.

As of June 30, 2024, we had also in-licensed one patent family from Institut National De La Sante Et De La Recherche Medicale (INSERM) relating to use of the class of apelin receptor agonists for treating sarcopenia. This patent family includes one U.S. Patent, and foreign national patents in Japan and Europe (with validation in 5 European states), which patents are expected to expire in 2032, without taking into account any patent term adjustments, or extensions, and assuming payment of all appropriate maintenance fees.

As of June 30, 2024, we owned seven patent families relating to methods of using azelaprag, including therapeutic uses for frailty, muscle atrophy, or obesity. These patent families include 14 pending U.S. provisional applications, seven pending U.S. and PCT non-provisional applications, and 14 pending foreign national applications, including applications in Australia, Brazil, Canada, China, Europe, Israel, Japan, Korea, Mexico, New Zealand, Singapore and Taiwan. Any patents that may issue from our pending patent applications or claim priority to pending provisional applications are expected to expire between 2042 and 2045, without taking into account any patent term adjustments, extensions or terminal disclaimers, and assuming payment of all appropriate maintenance fees.

NLRP3 Inhibitor Program

As of June 30, 2024, we owned six patent families relating to novel NLRP3 (nucleotide binding oligomerization domain-like receptor family pyrin domain-containing 3) inhibitors and related methods. One of these patent families is co-owned with HitGen, Inc. The six patent families include 3 issued U.S. patents (one co-owned with HitGen, that is under our exclusive control, and two solely-owned by BioAge), four pending U.S. provisional applications, eight pending U.S. and PCT non-provisional applications, and 28 pending foreign national applications, including applications in 24 jurisdictions, including Argentina, Australia, Canada, China, Europe, Eurasia, Japan, Korea and Taiwan. Patent term is based on the effective filing date of each family. Of the 3 issued patents, two will expire on March 23, 2042, and one will expire on January 27, 2043, without taking into account any patent term adjustments, extensions or terminal disclaimers, and assuming payment of all appropriate maintenance fees. Future patents that result from pending applications in these families are projected to expire on one of March 23, 2042; January 27, 2043; June 9, 2044; September 12, 2044; October 4, 2044; or March 26, 2045, without taking into account any patent term adjustments, extensions, or terminal disclaimers, and assuming payment of all appropriate maintenance fees.

Platform Technology and Discovery Program

As of June 30, 2024, we owned 3 patent families relating to platform technology for identifying pathways for healthy aging and druggable targets, and 1 patent family relating to a class of therapeutic fusion proteins that bind endogenous RAGE ligands. These patent families include 4 issued U. S. patents, one issued Japanese patent, 3 pending U.S. applications, and 3 pending foreign national applications, including applications in Canada, and Europe. U.S. Patent No. 11,881,311 expires September 23, 2041, inclusive of patent term adjustment, and without taking into account any potential future extension. U.S. Patent No. 11,445,981 expires August 11, 2039, inclusive of patent term adjustment, and without taking into account any potential future extension. U.S. Patent

No. 10,913,784 expires September 13, 2039, without taking into account any potential future extension. U.S. Patent No. 11,535,661, expires September 13, 2039, inclusive of a terminal disclaimer, and without taking into account any potential future extension. Japanese Patent No. 7,307,178 B2 expires in September 2039, without taking into account any potential future extension. The 3 pending U.S. applications are expected to expire respectively in February 2038, July 2038, and October 2038, without taking into account any potential patent term adjustment, terminal disclaimer, or future extension. The 3 pending foreign national applications are expected to expire in October 2038 or September 2039, without taking into account any potential future supplementary protection certificate or extension.

We expect to file additional patent applications in support of current and future clinical candidates as well as new platform and core technologies.

Our commercial success will depend in part on obtaining and maintaining patent protection on our current and future product candidates and their related methods of use, as well as successfully defending any such patents against third-party challenges and operating without infringing on the proprietary rights of others. Our ability to stop third parties from making, using, selling, offering to sell or importing our product candidates will depend, in part, on the extent to which we have rights under valid and enforceable patents that cover these activities. We cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any patents that may be granted to us in the future will be commercially useful in protecting our product candidates, discovery programs and processes. For this and more comprehensive risks related to intellectual property, see “Risk Factors—Risks Related to Intellectual Property.”

The terms of individual patents depend upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, including the United States, the patent term is 20 years from the earliest date of filing a non-provisional patent application. In the United States, a patent’s term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the U.S. Patent and Trademark Office (USPTO) in examining and granting a patent, or may be shortened if a patent is terminally disclaimed over an earlier filed patent. In the United States, the term of a patent that covers a drug approved by the FDA may also be eligible for extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Hatch-Waxman Act permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the subject drug candidate is under regulatory review. Patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent applicable to an approved drug may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. Similar provisions to extend the term of a patent that covers an approved drug are available in Europe and other foreign jurisdictions. In the future, if and when our products receive FDA approval, we expect to apply for patent term extensions on patents covering those products. We plan to seek patent term extensions to any issued patents we may obtain in any jurisdiction where such patent term extensions are available, however there is no guarantee that the applicable authorities, including the FDA in the United States, will agree with our assessment that such extensions should be granted, and if granted, the length of such extensions. For more information regarding the risks related to intellectual property, see “Risk Factors—Risks Related to Intellectual Property.”

In most instances, we have submitted and expect to submit patent applications directly to the USPTO as provisional patent applications. Corresponding non-provisional patent applications must be filed not later than 12 months after the provisional application filing date. While we intend to timely file non-provisional patent applications relating to our provisional patent applications, we cannot predict whether any such patent applications will result in the issuance of patents that provide us with any competitive advantage.

We file U.S. non-provisional applications, PCT applications and non-PCT foreign national applications that claim the benefit of the priority date of earlier filed provisional applications, when applicable. The PCT system

allows a single application to be filed within 12 months of the original priority date of the patent application, and to designate all of the PCT member states in which national patent applications can later be pursued based on the international patent application filed under the PCT. The PCT searching authority performs a patentability search and issues a non-binding patentability opinion which can be used to evaluate the chances of success for the national applications in foreign countries prior to having to incur the filing fees. Although a PCT application does not issue as a patent, it allows the applicant to seek protection in any of the member states through national-phase applications. Before the end of the period of approximately two and a half years from the first priority date of the patent application, separate patent applications can be pursued in any of the PCT member states either by direct national filing or, in some cases, by filing through a regional patent organization, such as the European Patent Office. The PCT system delays expenses, allows a limited evaluation of the chances of success for national/regional patent applications, and enables substantial savings where applications are abandoned within the first two and a half years of filing.

For all patent applications, we determine claiming strategy on a case-by-case basis. Advice of counsel and our business model and needs are always considered. We seek to file patents containing claims for protection of all useful applications of our proprietary technologies and any products, as well as all new applications and/or uses we discover for existing technologies and products, assuming these are strategically valuable. We continuously reassess the number and type of patent applications, as well as the pending and issued patent claims to pursue maximum coverage and value for our processes, and compositions, given existing patent office rules and regulations. Further, claims may be modified during patent prosecution to meet our intellectual property and business needs.

We recognize that the ability to obtain patent protection and the degree of such protection depends on a number of factors, including the extent of the prior art, the novelty and non-obviousness of the invention, and the ability to satisfy the enablement requirement of the patent laws. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted or further altered even after patent issuance. Consequently, we may not obtain or maintain adequate patent protection for any of our future product candidates or for our technology platform. 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 issued patents will provide sufficient proprietary protection from competitors. Any patents that we hold may be challenged, circumvented or invalidated by third parties.

In addition to patent protection, we also rely on trademark registration, trade secrets, know how, other proprietary information and continuing technological innovation to develop and maintain our competitive position. We seek to protect and maintain the confidentiality of proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. Our agreements with employees also provide that all inventions conceived by the employee in the course of employment with us or from the employee's use of our confidential information are our exclusive property. However, such confidentiality agreements and invention assignment agreements can be breached and we may not have adequate remedies for any such breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our consultants, contractors or collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting trade secrets, know-how and inventions. For more information regarding the risks related to our intellectual property, see "Risk Factors—Risks Related to Intellectual Property."

The patent positions of biotechnology companies like ours are generally uncertain and involve complex legal, scientific and factual questions. Our commercial success will also depend in part on not infringing upon the proprietary rights of third parties. Third-party patents could require us to alter our development or commercial strategies, or our products or processes, obtain licenses or cease certain activities. Our breach of any license agreements or our failure to obtain a license to proprietary rights required to develop or commercialize our future products may have a material adverse impact on us. If third parties prepare and file patent applications in the United States that also claim technology to which we have rights, we may have to participate in interference or derivation proceedings in the USPTO to determine priority, or rights in, an invention. For more information, see "Risk Factors—Risks Related to Intellectual Property."

When available to expand market exclusivity, our strategy is to obtain or license additional intellectual property related to current or contemplated development platforms, core elements of technology and/or clinical candidates.

Government Regulation

Pharmaceutical products are subject to extensive regulation by government authorities in the United States, at the federal, state and local level, and in other countries and jurisdictions. The processes for obtaining regulatory approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources.

FDA Approval Process

In the United States, pharmaceutical products are subject to extensive regulation by the U. S. Food and Drug Administration (the FDA). The Federal Food, Drug, and Cosmetic Act (the FD&C Act) and other federal and state statutes and regulations govern, among other things, the research, development, testing, manufacture, quality control, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling and import and export of pharmaceutical products. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as a clinical hold, FDA refusal to approve pending new drug applications (NDAs), warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties and criminal prosecution.

Pharmaceutical product development for a new product or certain changes to an approved product in the U.S. typically involves preclinical laboratory and animal tests, the submission to the FDA of an IND, which must become effective before clinical testing may commence, and adequate and well-controlled clinical trials to establish the safety and effectiveness of the drug for each indication for which FDA approval is sought. Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease.

Preclinical tests include laboratory evaluation of product chemistry, formulation and toxicity, as well as animal studies to assess the characteristics and potential safety and efficacy of the product, as well as in some cases to establish a rationale for therapeutic use. The conduct of the preclinical tests must comply with federal regulations and requirements, including good laboratory practices for safety/toxicology studies. The results of preclinical testing are submitted to the FDA as part of an IND along with other information, including information about product chemistry, manufacturing and controls, and a proposed clinical trial protocol. Long-term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted. An IND automatically becomes effective and the proposed clinical trial may commence 30 days after receipt of the IND 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 must resolve the issues to the FDA's satisfaction before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence.

Clinical trials involve the administration of the investigational new drug to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted: (i) in compliance with federal regulations; (ii) in compliance with good clinical practices (GCP), an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators and monitors; as well as (iii) under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The study protocol and informed consent information for patients in clinical trials must also be submitted to an institutional review board (IRB), and ethics committee for approval. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions.

Clinical trials to support NDAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap. In Phase 1, the initial introduction of the drug into healthy human subjects or patients, the drug is tested to assess metabolism, pharmacokinetics, pharmacological actions, side effects associated with increasing doses, and, if possible, early evidence of effectiveness. Phase 2 usually involves trials in a limited patient population to determine the effectiveness of the drug for a particular indication, dosage tolerance and optimum dosage, and to identify common adverse effects and safety risks. If a drug demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 trials are undertaken to obtain the additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit the FDA to evaluate the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug. In most cases, the FDA requires two adequate and well-controlled Phase 3 clinical trials to demonstrate the efficacy of the drug. A single Phase 3 trial may be sufficient in rare instances, including (1) where the study is a large multicenter trial demonstrating internal consistency and a statistically very persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible or (2) when in conjunction with confirmatory evidence.

The manufacturer of an investigational new drug in a Phase 2 or 3 clinical trial for a serious or life-threatening disease is required to make available, such as by posting on its website, its policy on evaluating and responding to requests for expanded access.

After completion of the required clinical testing, an NDA is prepared and submitted to the FDA. FDA approval of the NDA is required before marketing of the product may begin in the U.S. The NDA must include the results of all preclinical, clinical and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture and controls, as well as any proposed labeling. The cost of preparing and submitting an NDA is substantial and includes an application user fee (unless a waiver applies) as well as an annual program fee, and the fees are typically increased annually.

The FDA has 60 days from its receipt of an NDA to determine whether the application will be filed based on the agency's threshold determination that it is sufficiently complete to permit substantive review. Once the submission is filed, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of NDAs to encourage timeliness. Applications for new molecular entity (NME) standard review drug products are reviewed within twelve months of the date of submission of the NDA to the FDA; applications for priority review NMEs are reviewed within eight months of the date of submission of the NDA to the FDA. Priority review can be applied to drugs that the FDA determines offer major advances in treatment or provide a treatment where no adequate therapy exists. The review process for both standard and priority review may be extended by the FDA for three additional months to consider certain late-submitted information, or information intended to clarify information already provided in the submission.

The FDA may also refer applications for novel drug products, or drug products that present difficult questions of safety or efficacy, to an outside 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. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations.

Before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. The FDA will not approve the product unless compliance with current good manufacturing practices (cGMPs) is satisfactory and the NDA contains data that provide substantial evidence that the drug is safe and effective in the indication studied.

After the FDA evaluates the NDA and the manufacturing facilities, it issues either an approval letter or a complete response letter (CRL). A CRL generally outlines the deficiencies in the submission and may require substantial additional testing, or information, in order for the FDA to reconsider the application. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included.

An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of NDA approval, the FDA may require a risk evaluation and mitigation strategy (REMS) to help ensure that the benefits of the drug outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use (ETASU). ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring and the use of patient registries. The requirement for a REMS can materially affect the potential market and profitability of the drug. Moreover, product approval may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy.

Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing. Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or NDA supplement before the change can be implemented. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing NDAs.

Disclosure of Clinical Trial Information

Sponsors of clinical trials of FDA regulated products, including drugs, are required to register and disclose certain clinical trial information on ClinicalTrials.gov. Information related to the product, patient population, phase of investigation, study sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to disclose the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed in certain circumstances for up to two years after the date of completion of the trial. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs.

Pediatric Information

Under the Pediatric Research Equity Act (PREA), NDAs or supplements to NDAs must contain data to assess the safety and effectiveness 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 drug is safe and

effective. The FD&C Act requires that a sponsor who is planning to submit a marketing application for a product that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial Pediatric Study Plan (PSP), within 60 days of an end-of-Phase 2 meeting or as may be agreed between the sponsor and FDA. The FDA and the sponsor must reach agreement on the PSP. The FDA may grant full or partial waivers, or deferrals, for submission of data.

The Best Pharmaceuticals for Children Act (BPCA) provides NDA holders a six-month extension of any exclusivity—patent or nonpatent—for a drug if certain conditions are met. Conditions for exclusivity include the FDA's determination that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, the FDA making a written request for pediatric studies, and the applicant agreeing to perform, and reporting on, the requested studies within the statutory timeframe. Applications under the BPCA are treated as priority applications, with all of the benefits that designation confers.

Post-Approval Requirements

Once an NDA is approved, a product will be subject to certain post-approval requirements. For instance, the FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved labeling. 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.

Adverse event reporting and submission of periodic reports are required following FDA approval of an NDA. The FDA also may require post-marketing testing, sometimes referred to as Phase 4 testing, REMS, and surveillance to monitor the effects of an approved product, or the FDA may place conditions on an approval that could restrict the distribution or use of the product. In addition, quality control, drug manufacture, packaging and labeling procedures must continue to conform to cGMPs after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies. Registration with the FDA subjects entities to periodic unannounced inspections by the FDA, during which the Agency inspects manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality-control to maintain compliance with cGMPs. FDA may withdraw product approvals or request product recalls if a company fails to comply with regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered.

The Hatch-Waxman Amendments

Orange Book Listing

Under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch Waxman Amendments, NDA applicants are required to list with the FDA each patent whose claims cover the applicant's product or approved method of using the product. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential generic competitors in support of approval of an abbreviated new drug application (ANDA). An ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown through bioequivalence testing to be therapeutically equivalent to the listed drug. Other than the requirement for bioequivalence testing, ANDA applicants are not required to conduct, or submit results of, preclinical or clinical tests to prove the safety or effectiveness of their drug product. Drugs approved in this way are commonly referred to as "generic equivalents" to the listed drug and can often be substituted by pharmacists under prescriptions written for the original listed drug.

The ANDA applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA's Orange Book. Specifically, the applicant must certify that (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. The ANDA applicant may also elect to submit a Section VIII statement certifying that its proposed ANDA label does not contain (or carve out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent. If the applicant does not challenge the listed patents, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired.

A certification that the new product will not infringe the already approved product's listed patents, or that such patents are invalid, is called a Paragraph IV certification. If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit, or a decision in the infringement case that is favorable to the ANDA applicant.

Exclusivity

Market exclusivity provisions under the FD&C Act also can delay the submission or the approval of certain applications. An ANDA application will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the referenced product has expired. Upon NDA approval of a new chemical entity (NCE), which is a drug that contains no active moiety that has been approved by the FDA in any other NDA, that drug receives five years of marketing exclusivity during which the FDA cannot receive any ANDA seeking approval of a generic version of that drug. An ANDA may be submitted one year before NCE exclusivity expires if a Paragraph IV certification is filed. If there is no listed patent in the Orange Book, there may not be a Paragraph IV certification, and, thus, no ANDA may be filed before the expiration of the exclusivity period. Certain changes to a drug, such as the approval of a new indication, new strength, or new condition of use, can be the subject of a three-year period of exclusivity from the date of approval if the application contains reports of new clinical investigations (other than bioavailability studies) conducted or sponsored by the sponsor that were essential to the approval of the application. The FDA cannot approve an ANDA for a generic drug that includes the change during the exclusivity period. In some instances, an ANDA applicant may receive approval prior to expiration of certain non-patent exclusivity if the applicant seeks, and FDA permits, the omission of such exclusivity-protected information from the ANDA prescribing information.

Patent Term Restoration

After NDA approval, the owner of a relevant drug patent may apply for up to a five-year patent extension. Only one patent may be extended for each regulatory review period, which is composed of two parts: a testing phase and an approval phase. The allowable patent term extension is generally calculated as half of the drug's testing phase (the time between IND application and NDA submission) and all of the review phase (the time between NDA submission and approval) up to a maximum of five years. If the extended patent was issued during the development or review period, the calculation begins from the date of patent issuance. The review period can be shortened if the FDA determines that the applicant did not pursue approval with due diligence. The total patent term after the extension may not exceed 14 years.

For patents that might expire during the application phase, the patent owner may request an interim patent extension. An interim patent extension increases the patent term by one year and may be renewed up to four times. For each interim patent extension granted, the post-approval patent extension is reduced by one year. The director of the United States Patent and Trademark Office must determine that approval of the drug covered by

the patent for which a patent extension is being sought is likely. Interim patent extensions are not available for a drug for which an NDA has not been submitted.

Coverage and Reimbursement

Sales of a product in the U.S. will depend, in part, on the extent to which such products will be covered by third-party payors, such as government health care programs, commercial insurance and managed healthcare organizations. These third-party payors are increasingly limiting coverage and/or reducing reimbursements for medical products and services. The process for determining whether a payor will provide coverage for a drug product may be separate from the process for setting the reimbursement rate that the payor will pay for the drug. Third-party payors may limit coverage to specific drug products on an approved list, or formulary, which might not include all of FDA-approved drugs for a particular indication. Further, one payor's determination to provide coverage for a drug product does not ensure that other payors will also provide coverage for the drug product. Coverage policies and third-party payor reimbursement rates may change at any time and can differ significantly from payor to payor.

In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Third-party payors are increasingly challenging the prices charged for medical products and services, examining the medical necessity, and reviewing the cost effectiveness of pharmaceutical or biological products, medical devices, and medical services, in addition to questioning safety and efficacy. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit sales of any product that receives approval. Decreases in third-party payor reimbursement or a decision by a third-party payor to not cover a product could reduce physician usage and patient demand for the product.

Other Healthcare Laws

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal laws have been applied to restrict certain general business and marketing practices in the pharmaceutical industry in recent years. These laws include anti-kickback statutes, false claims statutes, price transparency and reporting, privacy and cybersecurity laws, and other healthcare laws and regulations.

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid, or other federally financed healthcare programs. The Patient Protection and Affordable Care Act as amended by the Health Care and Education Reconciliation Act (collectively, the ACA) amended the intent element of the federal statute so that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to commit a violation. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers, among others, on the other. Violations of the federal Anti-Kickback Statute are punishable by imprisonment, criminal fines, civil monetary penalties, and exclusion from participation in federal healthcare programs. Although there are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, the exceptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Additionally, a violation of the federal Anti-Kickback Statute can serve as a basis for liability under the federal civil False Claims Act.

Federal civil and criminal false claims laws, including the federal civil False Claims Act, prohibit any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to have a false claim paid. This includes claims made to programs where the federal government reimburses, such as Medicare and Medicaid, as

well as programs where the federal government is a direct purchaser, such as when it purchases off the Federal Supply Schedule. Pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. Additionally, the ACA amended the federal Anti-Kickback Statute such that a violation of that statute can serve as a basis for liability under the federal civil False Claims Act. Most states also have statutes or regulations similar to the federal Anti-Kickback Statute and civil False Claims Act, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

Other federal statutes pertaining to healthcare fraud and abuse include the civil monetary penalties statute, which prohibits, among other things, the offer or payment of remuneration to a Medicaid or Medicare beneficiary that the offeror or payor knows or should know is likely to influence the beneficiary to order a receive a reimbursable item or service from a particular supplier, and the additional federal criminal statutes created by the Health Insurance Portability and Accountability Act of 1996 (HIPAA), which prohibits, among other things, knowingly and willfully executing or attempting to execute a scheme to defraud any healthcare benefit program or obtain by means of false or fraudulent pretenses, representations or promises any money or property owned by or under the control of any healthcare benefit program in connection with the delivery of or payment for healthcare benefits, items or services.

In addition, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH), and their respective implementing regulations, including the Final Omnibus Rule published on January 25, 2013, impose obligations on certain healthcare providers, health plans, and healthcare clearinghouses, known as covered entities, as well as their business associates and subcontractors that perform certain services involving the storage, use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security, and transmission of individually identifiable health information, and require notification to affected individuals and regulatory authorities of certain breaches of security of individually identifiable health information. HITECH increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, 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 attorney's fees and costs associated with pursuing federal civil actions. In addition, many state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, and often are not pre-empted by HIPAA. For example, the California Consumer Privacy Act of 2018 (CCPA), imposes obligations on businesses to which it applies, including, but not limited to, providing specific disclosures in privacy notices and affording California residents certain rights related to their personal data, although it exempts some data processed in the context of clinical trials. In addition, the California Privacy Rights Act of 2020 (CPRA), which went into effect on January 1, 2023, imposes additional obligations on companies covered by the legislation and significantly modifies the CCPA, including by expanding consumers' rights with respect to certain sensitive personal information. The CPRA also creates a new state agency that is vested with authority to implement and enforce the CCPA and CPRA. Virginia's Consumer Data Protection Act, which took effect on January 1, 2023, requires businesses subject to the legislation to conduct data protection assessments in certain circumstances and requires opt-in consent from consumers to acquire and process their sensitive personal information, which includes information revealing a consumer's physical and mental health diagnosis and genetic and biometric information that can identify a consumer. In addition, Colorado enacted the Colorado Privacy Act, and Connecticut enacted the Connecticut Data Privacy Act, each of which took effect on July 1, 2023, and Utah enacted the Consumer Privacy Act, which became effective on December 31, 2023, and each of these laws may increase the complexity, variation in requirements, restrictions and potential legal risks, and could require increased compliance costs and changes in business practices and policies. Other states have also enacted, proposed, or are considering proposing, data privacy laws, which could further complicate compliance efforts, increase our potential liability and adversely affect our business.

Further, pursuant to the federal Physician Payments Sunshine Act, enacted as part of the ACA, the Centers for Medicare & Medicaid Services (CMS), has issued a final rule that requires manufacturers of approved prescription drugs that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program, with certain exceptions, to collect and report information on certain payments or transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician practitioners (such as physician assistants and nurse practitioners) and teaching hospitals, as well as investment interests held by physicians and their immediate family members. The reports must be submitted on an annual basis. The reported data is made available in searchable form on a public website on an annual basis. Failure to submit required information may result in civil monetary penalties.

In addition, several states now require prescription drug companies to report certain expenses relating to the marketing and promotion of drug products and to report gifts and payments to individual healthcare practitioners in these states. Other states prohibit various marketing-related activities, such as the provision of certain kinds of gifts or meals. Several states, including California, Connecticut, Nevada, and Massachusetts, require pharmaceutical companies to implement compliance programs and/or marketing codes. Still other states require the posting of information relating to clinical studies and their outcomes. A growing number of states require the reporting of certain drug pricing information, including information pertaining to and justifying price increases and the prices of newly launched drugs, or prohibit prescription drug price gouging. In addition, certain states require pharmaceutical companies to implement compliance programs and/or marketing codes. Certain states and local jurisdictions also require the registration of pharmaceutical sales and medical representatives. Compliance with these laws is difficult and time consuming, and companies that do not comply with these state laws face civil penalties.

Efforts to ensure that business arrangements with third parties comply with applicable healthcare laws and regulations involve substantial costs. If a drug company's operations are found to be in violation of any such requirements, it may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, the curtailment or restructuring of its operations, loss of eligibility to obtain approvals from the FDA, exclusion from participation in government contracting, healthcare reimbursement or other federal or state government healthcare programs, including Medicare and Medicaid, integrity oversight and reporting obligations, imprisonment, and reputational harm. Any action for an alleged or suspected violation can cause a drug company to incur significant legal expenses and divert management's attention from the operation of the business, even if such action is successfully defended.

U.S. Healthcare Reform

In the United States there have been, and continue to be, proposals by the federal government, state governments, regulators and third-party payors to control or manage the increased costs of health care and, more generally, to reform the U.S. healthcare system. The pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. For example, in March 2010, the ACA was enacted, which was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms.

Several healthcare reform proposals culminated in the enactment of the Inflation Reduction Act (IRA) in August 2022, which will eliminate, beginning in 2025, the coverage gap under Medicare Part D by significantly lowering the enrollee maximum out-of-pocket cost and requiring manufacturers to subsidize, through a newly established manufacturer discount program, 10% of Part D enrollees' prescription costs for brand drugs below the out-of-pocket maximum, and 20% once the out-of-pocket maximum has been reached. Among other things, the IRA also requires HHS to negotiate the selling price of a statutorily specified number of drugs and biologics each year that CMS reimburses under Medicare Part B and Part D. Only high-expenditure single-source drugs that have been approved for at least 7 years (11 years for biologics) are eligible to be selected by CMS for

negotiation, with the negotiated price taking effect two years after the selection year. Negotiations for Medicare Part D products began in 2024 with the negotiated price taking effect in 2026, and negotiations for Medicare Part B products begin in 2026 with the negotiated price taking effect in 2028. In August 2023, HHS announced the ten Medicare Part D drugs and biologics that it selected for negotiations. HHS will announce the negotiated maximum fair prices by September 1, 2024. This price cap, which cannot exceed a statutory ceiling price, will come into effect on January 1, 2026, and will represent a significant discount from average prices to wholesalers and direct purchasers. The IRA also imposes rebates on Medicare Part B and Part D drugs whose prices have increased at a rate greater than the rate of inflation. The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Manufacturers that fail to comply with the IRA may be subject to various penalties, including civil monetary penalties. These provisions may be subject to legal challenges. For example, the provisions related to the negotiation of selling prices of high-expenditure single-source drugs and biologics have been challenged in multiple lawsuits brought by pharmaceutical manufacturers. The outcome of these lawsuits is uncertain. Thus, while it is unclear how the IRA will be implemented, it will likely have a significant impact on the pharmaceutical industry and the pricing of prescription drug products.

Employees and Human Capital Resources

As of June 30, 2024, we had 60 employees, 58 of whom were full-time and 41 of whom were engaged in research and development activities. Approximately 48% of our employees hold Ph.D. or M.D. or other advanced degrees. Women comprise approximately 45% of our employees, and individuals from underrepresented ethnic groups comprise approximately 30%. Women comprise approximately 33% of our senior leadership team and 25% of our board of directors. None of our employees are represented by a labor union or covered under a collective bargaining agreement. We consider our relationship with our employees to be good.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and new employees, advisors and consultants. It is important that we not only attract and retain the best and brightest diverse talent, but also ensure they remain engaged and can thrive in an environment that is committed to helping them grow, succeed and contribute directly to achieving our purpose. The principal purposes of our equity and cash incentive plans are to attract, retain and reward personnel through the granting of stock-based and cash-based compensation awards, in order to increase the success of our Company by motivating such individuals to perform to the best of their abilities and achieve our objectives. We also strive to foster career growth and internal mobility by providing a broad range of training, mentoring and other development opportunities.

Facilities

Our headquarters are located in Richmond, California where we lease and occupy 18,829 square feet of office, and laboratory and warehouse space. The current term of our lease expires in August 2025.

We believe that our existing facilities are sufficient to meet our near-term needs and that suitable additional space will be available as and when needed.

Legal Proceedings

From time to time, we may be subject to legal proceedings. We are not currently a party to or aware of any proceedings that we believe will have, individually or in the aggregate, a material adverse effect on our business, financial condition or results of operations. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

MANAGEMENT

Executive Officers and Directors

The following table provides information, including ages as of June 30, 2024, regarding our executive officers and directors:

Executive Officers and Employee Directors:	Age	Position
Kristen Fortney, Ph.D.	41	Chief Executive Officer, President and Director
Dov Goldstein, M.D.	56	Chief Financial Officer
Eric Morgen, M.D.	42	Chief Operating Officer and Director
Paul Rubin, M.D.	70	Chief Medical Officer
Non-Employee Directors:		
James Healy, M.D., Ph.D.	59	Chairman of the Board
Jason Coloma, Ph.D.	48	Director
Michael Davidson, M.D.	67	Director
Patrick Enright	62	Director
Rekha Hemrajani	55	Director
Vijay Pande, Ph.D.	53	Director

(1) Member of the Compensation Committee.
(2) Member of the Audit Committee.
(3) Member of the Nominating and Governance Committee.

Executive Officers and Employee Directors

Kristen Fortney, Ph.D., is our co-founder and has served as our Chief Executive Officer, President, and a member of our board of directors since our inception in April 2015. She also currently serves as an Advisor to several biotechnology companies. Dr. Fortney received her Ph.D. in Medical Biophysics from the University of Toronto and completed postdoctoral training at Stanford University where she was a fellow of the Ellison Medical Foundation / American Federation for Aging Research. We believe Dr. Fortney is qualified to serve on our board of directors because of her extensive experience in the biopharmaceutical industry and leadership experience, including her role as our co-founder, Chief Executive Officer, and President.

Dov Goldstein, M.D., M.B.A., has served as our Chief Financial Officer since November 2021. Prior to joining us, from August 2020 to November 2021, he served as the Chief Financial Officer and Chief Business Officer of Indapta Therapeutics, Inc., a biotechnology company. From November 2019 to July 2020, Dr. Goldstein served as the Chief Executive Officer of RIGImmune Inc, a biopharmaceutical company. Prior to that, he served as the Chief Financial Officer at Schrödinger, LLC, a biotechnology company. Dr. Goldstein held various leadership roles of increasing responsibility at Aisling Capital, a private investment firm, from September 2006 to November 2019, serving as its Managing Partner from 2014 to 2019. Dr. Goldstein served as the Chief Financial Officer of Loxo Oncology, Inc., a biopharmaceutical company, between July 2014 and April 2015. Dr. Goldstein currently serves on the board of directors of NeuBase Therapeutics, Inc. since July 2019 and Gain Therapeutics, Inc. since December 2020. Dr. Goldstein previously served on the board of directors for ADMA Biologics, Inc. from May 2008 to November 2019, Loxo Oncology, Inc. from July 2013 to October 2014, Esperion Therapeutics, Inc. from May 2008 to May 2019, Durata Therapeutics, Inc. from 2009 to 2013, and Cempra Pharmaceuticals, Inc. from 2007 to 2017. Dr. Goldstein received a B.S. in Biological Sciences from Stanford University, an M.B.A. from Columbia Business School and an M.D. from Yale School of Medicine.

Eric Morgen, M.D., is our co-founder and has served as our Chief Operating Officer since May 2020 and as a member of our board of directors since June 2017. Previously, Dr. Morgen served as our Chief Medical

Officer from February 2018 to April 2020. From July 2016 to January 2018, Dr. Morgen served as an Assistant Professor at the University of Toronto, where his research focused on biomarker discovery and characterization in high-dimensional datasets from human cohorts. Prior to that, Dr. Morgen served from July 2014 to June 2016 as a Clinical Fellow and a Research Fellow in Computational Biology and Molecular Epidemiology at the University of Toronto, where he held a Canada Graduate Scholarship from the Canadian Institutes of Health Research, and was subsequently a CIHR research fellow. Dr. Morgen is a licentiate of the Medical Council of Canada, a fellow of the Royal College of Physicians and Surgeons of Canada, and previously practiced medicine at Mount Sinai Hospital in Toronto. Dr. Morgen received his Bachelor of Health Sciences from the University of Toronto, Innis College, his M.P.H. from the Dalla Lana School of Public Health at the University of Toronto and his M.D. from the Faculty of Medicine at the University of Toronto. We believe that Dr. Morgen's experience as our Chief Operating Officer and Chief Medical Officer, and his medical training and scientific expertise qualifies him to serve on our board of directors.

Paul Rubin, M.D., has served as our Chief Medical Officer since May 2018. Prior to joining us, Dr. Rubin was the Executive Vice President of Research and Development at miRagen Therapeutics, Inc., a biotechnology company, from November 2016 to December 2019. Prior to that, he also served as Senior Vice President of Research and Development and Chief Medical Officer at XOMA Corporation, a biopharmaceutical company, from June 2011 to November 2016. Prior to that, Dr. Rubin served as Chief Executive Officer of Resolvyx Pharmaceuticals, Inc., a biopharmaceutical company, from June 2007 to May 2009, and President and Chief Executive Officer of Critical Therapeutics, Inc., a biopharmaceutical company, from August 2002 to May 2007. Dr. Rubin received a B.A. from Occidental College and his M.D. from Rush Medical College. He is also board certified in internal medicine completing his post-graduate training at the University of Wisconsin Hospital and Clinics.

Non-Employee Directors

Jason Coloma, Ph.D., has served as a member of our board of directors since April 2021. Since June 2019, Dr. Coloma has served as Chief Executive Officer of Maze Therapeutics, Inc., a biotechnology company. He served as a Venture Partner at Third Rock Ventures, LLC from June 2017 to June 2019. While at Third Rock Ventures, LLC, Dr. Coloma also held the role of Business Officer at insitro, Inc., a biotechnology company, from August 2018 to August 2019, and at Celsius Therapeutics, Inc., a biopharmaceutical company, from July 2017 to November 2018. Dr. Coloma also served as Senior Vice President and Chief Business Officer at Corvus Pharmaceuticals, Inc., a biotechnology company, from July 2016 to July 2017. Previously, he held a number of roles at biopharmaceutical companies, Genentech, Inc. and Roche, between February 2008 and July 2016, including Vice President & Global Therapeutic Area Head of Oncology and Cancer Immunotherapy Partnering. Before joining Genentech, Inc. and Roche, Dr. Coloma was a consultant in the life sciences practice at L.E.K. Consulting LLC. He also worked as a scientist at Cytokinetics, Incorporated, from June 2002 to July 2005. Dr. Coloma holds a B.S. in Biology from the University of San Francisco, an M.B.A. from the Tuck School of Business at Dartmouth, and a Ph.D. and M.P.H. from the University of California, Berkeley. We believe Dr. Coloma is qualified to serve on our board of directors due to his extensive experience as an executive in the biotechnology sector.

Michael Davidson, M.D., has served as a member of our board of directors since March of 2024. Since August of 2020, Dr. Davidson has served as Chief Executive Officer and Executive Director at NewAmsterdam Pharma Company B.V., a pharmaceutical company. Prior to joining NewAmsterdam Pharma B.V., Dr. Davidson was the founder and Chief Executive Officer of Corvidia Therapeutics, Inc., a cardio-renal disease therapy company, from January 2016 to April 2018 and the Chief Science and Medical Officer from April 2018 to July 2020, when Corvidia Therapeutics, Inc. was acquired by Novo Nordisk A/S. Dr. Davidson is board-certified in internal medicine, cardiology, and clinical lipidology and served as President of the National Lipid Association from May 2010 to May 2011. Dr. Davidson currently serves on the board of directors of Tenax Therapeutics, Inc., a biopharmaceutical company, since April 2021 and Silence Therapeutics plc since January 2022. Dr. Davidson also serves on the boards of two private biotechnology companies, SonoThera, Inc. and NanoPhoria Bioscience. Dr. Davidson received his B.A. and M.S. from Northwestern University and his M.D.

from The Ohio State University School of Medicine. We believe Dr. Davidson is qualified to serve on our board of directors because of his medical training and extensive leadership experience in the industry.

Patrick Enright, M.B.A., has served on our board of directors since February 2024. Mr. Enright co-founded Longitude Capital, a healthcare venture capital firm, where he has served as a Managing Director since 2006. Previously, Mr. Enright was a Managing Director of Pequot Ventures from 2002 to 2007, where he co-led the life sciences investment practice. Mr. Enright also has significant life sciences operations experience, including senior executive positions at Valentis, Inc., Boehringer Mannheim Pharmaceuticals Corp. (acquired by Roche) and Sandoz, Inc. (now known as Novartis). Mr. Enright currently serves on the boards of directors of Vera Therapeutics, Inc., Jazz Pharmaceuticals plc, and other privately held healthcare companies. Mr. Enright previously served on the boards of directors of over twenty companies, including Aimmune Therapeutics, Inc. (acquired by Nestlé) from 2013 to 2020, Corcept Therapeutics, Inc. from 2008 to 2017, and Vaxcyte, Inc. from 2015 to 2020. Mr. Enright received a B.S. in Biological Sciences from Stanford University and an M.B.A. from The Wharton School of the University of Pennsylvania. We believe that Mr. Enright is qualified to serve on our board of directors due to his experience serving on the board of directors of clinical-stage biotechnology companies and his investment experience in the life sciences industry.

James Healy, M.D., Ph.D., has served on our board of directors since February 2024. Dr. Healy has been a general partner at Sofinnova Investments, Inc. (formerly Sofinnova Ventures), a biotechnology investment firm, since June 2000. Dr. Healy currently serves on the board of directors of Natera, Inc. since November 2014, Bolt Biotherapeutics, Inc. since January 2021, ArriVent Biopharma, Inc. since 2022; Y-mAbs, Inc. and several private companies. Dr. Healy has previously served on the boards of directors of Ascendis Pharma A/S, Amarin Corporation, Auris Medical Holding AG, CinCor Pharma Inc., Coherus BioSciences, Inc., Edge Therapeutics, Inc., Hyperion Therapeutics, Inc., InterMune, Inc., Iterum Therapeutics plc, Anthera Pharmaceuticals, Inc., Karuna Therapeutics, Inc., Durata Therapeutics, Inc., CoTherix, Inc., Movetis NV, NuCana plc, ObsEva SA and several private companies, as well as on the board of the National Venture Capital Association and the board of the Biotechnology Industry Organization. Dr. Healy holds a B.A. in Molecular Biology and in Scandinavian Studies from the University of California, Berkeley, and an M.D. and Ph.D. in Immunology from Stanford University School of Medicine. We believe that Dr. Healy is qualified to serve on our board of directors due to his extensive scientific expertise, investment experience, and experience in venture capital and the life sciences industry.

Rekha Hemrajani, M.B.A., has served as a member of our board of directors since August 2021. Previously, Ms. Hemrajani served as Chief Executive Officer and a Director of Jiya Acquisition Corporation, a special purpose acquisition company, from its inception in August 2020 to November 2022. Ms. Hemrajani also served as President and Chief Executive Officer and a Director of Aravive, Inc., a clinical-stage biotechnology company, from January 2020 to April 2020. From March 2019 to September 2019, Ms. Hemrajani served as the Chief Operating Officer and Chief Financial Officer of Arcus Biosciences, Inc., a biotechnology company. From March 2016 to March 2019, she served as Chief Operating Officer of FLX Bio, Inc. (now RAPT Therapeutics, Inc.), a biotechnology company. From March 2015 to March 2016, Ms. Hemrajani served as Chief Financial Officer and Senior Vice President of Business and Financial Operations at 3-V Biosciences, Inc. (now Sagimet Biosciences, Inc.), a biotechnology company. From 2013 to March 2015, Ms. Hemrajani advised privately held companies on strategic corporate development and financing activities at Ravinia Consulting, a consulting firm she founded. Ms. Hemrajani currently serves on the board of directors for ALX Oncology Holdings Inc., a biotechnology company, since May 2020. From May 2019 to May 2021, she served on the board of directors at Adverum Biotechologies, Inc., a biopharmaceutical company. She holds a B.S. in Economics and Computer Science from the University of Michigan and an M.B.A. from the Kellogg Graduate School of Management at Northwestern University. We believe Ms. Hemrajani is qualified to serve on our board of directors due to her extensive executive and financial experience in the biopharmaceutical and biotechnology industries.

Vijay Pande, Ph.D., has served as a member of our board of directors since June 2017. Since September 2014, Dr. Pande has served in various roles of increasing responsibility at Andreessen Horowitz, a venture capital

fund, including most recently as a General Partner since September 2015. Dr. Pande co-founded Globavir Biosciences, Inc., an infectious disease company, in April 2014, where he continues to serve on the Scientific Advisory Board. Prior to Globavir Biosciences, Inc., Dr. Pande served at Stanford University between July 1999 and October 2015, including as the Henry Dreyfus Professor of Chemistry, Structural Biology and Computer Science and most recently as the Director, Program in Biophysics between September 2008 and October 2015. Dr. Pande has also served as a member of the board of directors of Nautilus Biotechnology, Inc., a biotechnology company, since May 2018, and currently serves on various private company boards. Dr. Pande holds a B.S. in Physics from Princeton University and a Ph.D. in Physics from the Massachusetts Institute of Technology. We believe Dr. Pande is qualified to serve on our board of directors because of his extensive scientific expertise, operational experience and his role in leadership positions.

Election of Executive Officers

Our executive officers are appointed by, and serve at the discretion of, our board of directors.

Family Relationships

There are no family relationships among any of our executive officers or directors.

Board Composition

Our board of directors currently consists of eight members. Six of our directors are independent within the meaning of the independent director guidelines of Nasdaq Global Market (Nasdaq). Pursuant to our current certificate of incorporation and our amended and restated voting agreement, Dr. Fortney, Dr. Morgen, Dr. Coloma, Dr. Davidson, Mr. Enright, Dr. Healy, Ms. Hemrajani, and Dr. Pande have been designated to serve as members of our board of directors. The amended and restated voting agreement and the provisions of our current certificate of incorporation that govern the election and designation of our directors will terminate immediately prior to the completion of this offering, after which no contractual obligations will concern the election of our directors.

Classified Board of Directors

In accordance with the terms of our restated certificate of incorporation and restated bylaws that will become effective immediately before the completion of this offering, our board of directors will be divided into three staggered classes of directors. At each annual meeting of our stockholders, a class of directors will be subject to re-election for a three-year term. As a result, only one class of directors will be elected at each annual meeting of our stockholders, with the other classes continuing for the remainder of their respective three-year terms. Any increase or decrease in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors. This classification of our board of directors may have the effect of delaying or preventing changes in control of our company.

Our directors will be divided among the three classes as follows:

- the Class I directors will be , and , and their terms will expire at the first annual meeting of our stockholders held following the completion of this offering;
- the Class II directors will be , and , and their terms will expire at the second annual meeting of our stockholders held following the completion of this offering; and
- the Class III directors will be , and , and their terms will expire at the third annual meeting of our stockholders held following the completion of this offering.

Each director's term continues until the election and qualification of his or her successor, or his or her earlier death, resignation or removal. Our restated certificate of incorporation and restated bylaws that will be in

effect upon the completion of this offering authorize only our board of directors to fill vacancies on our board of directors. Any increase or decrease in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors. This classification of our board of directors may have the effect of delaying or preventing changes in control of our Company. See the section titled "Description of Capital Stock—Anti-Takeover Provisions—Restated Certificate of Incorporation and Restated Bylaw Provisions" for additional information.

Director Independence

In connection with this offering, we have applied to list our common stock on Nasdaq. Under the rules of Nasdaq, independent directors must comprise a majority of a listed company's board of directors within a specified period following the completion of this offering. In addition, the rules of Nasdaq require that, subject to specified exceptions, each member of a listed company's audit, compensation and nominating and governance committees be independent. Under the rules of Nasdaq, a director will only qualify as an "independent director" if, in the opinion of that company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

Audit committee members must also satisfy the independence criteria set forth in Rule 10A-3 under the Securities Exchange Act of 1934, as amended (Exchange Act). In order to be considered independent for purposes of Rule 10A-3, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors or any other board committee: (1) accept, directly or indirectly, any consulting, advisory or other compensatory fee from the listed company or any of its subsidiaries or (2) be an affiliated person of the listed company or any of its subsidiaries. We intend to satisfy the audit committee independence requirements of Rule 10A-3 as of the completion of this offering. Additionally, compensation committee members must not have a relationship with us that is material to the director's ability to be independent from management in connection with the duties of a compensation committee member.

Our board of directors has undertaken a review of the independence of each director and considered whether each director has a material relationship with us that could compromise his or her ability to exercise independent judgment in carrying out his or her responsibilities. As a result of this review, our board of directors determined that all of our directors, except for Drs. Fortney and Morgen, are "independent directors" as defined under the current Nasdaq listing standards and SEC rules and regulations. In making these determinations, our board of directors reviewed and discussed information provided by the directors and us with regard to each director's business and personal activities and relationships as they may relate to us and our management, including the beneficial ownership of our capital stock by each non-employee director and the transactions involving them as described in the section titled "Certain Relationships and Related Party Transactions."

Leadership Structure of the Board

Our corporate governance guidelines provide our board of directors with flexibility to combine or separate the positions of chair of the board of directors and Chief Executive Officer. Dr. Healy currently serves as the chair of our board of directors and Dr. Fortney currently serves as our Chief Executive Officer. This structure allows our Chief Executive Officer to focus on our day-to-day business while our chair leads our board of directors in its fundamental role of providing advice to, and independent oversight of, management. We believe Dr. Healy is especially qualified for this role based on his medical training and experience with building early-stage biotechnology and innovation-based companies for over twenty years. Further, our board of directors believes such separation is appropriate, as it enhances the accountability of the Chief Executive Officer to the board of directors and strengthens the independence of the board of directors from management. Any changes to the leadership structure of our board of directors, if made, will be promptly disclosed on the investor relations section of our website and in our proxy materials. Our board of directors, in its sole discretion, may seek input from our stockholders on the leadership structure of the board of directors.

Our board of directors has concluded that our current leadership structure is appropriate at this time. However, our board of directors will continue to periodically review our leadership structure and may make such changes in the future as it deems appropriate.

Role of Board in Risk Oversight Process

Risk assessment and oversight are an integral part of our governance and management processes. Our board of directors encourages management to promote a culture that incorporates risk management into our corporate strategy and day-to-day business operations. Management discusses strategic and operational risks at regular management meetings, and conducts specific strategic planning and review sessions during the year that include a focused discussion and analysis of the risks facing us. Throughout the year, senior management reviews these risks with the board of directors at regular board meetings as part of management presentations that focus on particular business functions, operations or strategies, and presents the steps taken by management to mitigate or eliminate such risks.

Our board of directors does not have a standing risk management committee, but rather administers this oversight function directly through our board of directors as a whole, as well as through various standing committees of our board of directors that address risks inherent in their respective areas of oversight. While our board of directors is responsible for monitoring and assessing strategic risk exposure, our audit committee is responsible for overseeing our major financial risk exposures and the steps our management has taken to monitor and control these exposures. The audit committee also approves or disapproves any related person transactions. Our nominating and corporate governance committee monitors the effectiveness of our corporate governance guidelines. Our compensation committee assesses and monitors whether any of our compensation policies and programs has the potential to encourage excessive risk-taking.

Cybersecurity Risk Oversight

Securing the information of participants in our studies, medical professionals, employees, service providers, and other third parties is important to us. We have adopted physical, technological, and administrative controls on data security, and have a defined procedure for data incident detection, containment, response, and remediation. While everyone at our Company plays a part in managing these risks, oversight responsibility is shared by our board of directors, our audit committee, and management. Our information technology team provides regular cybersecurity updates in the form of written reports and presentations to our audit committee. Additionally, we leverage industry standard frameworks to drive strategic direction and maturity improvement. We also engage third-party security experts for risk assessments and program enhancements and maintain information security risk insurance coverage.

Committees of the Board of Directors

Our board of directors will have an audit committee, a compensation committee and a nominating and governance committee, each of which will have the composition and responsibilities described below as of the completion of this offering. In addition, from time to time, special committees may be established under the direction of our board of directors when necessary to address specific issues. Each of the below committees has a written charter approved by our board of directors. Upon completion of this offering, copies of each charter will be posted on the investor relations page of our website. Members that serve on these committees will serve until their resignation or until otherwise determined by our board of directors.

Audit Committee

Effective upon the effectiveness of the registration statement of which this prospectus is a part, our audit committee will be composed of , and , with as the Chairperson of our

audit committee. Our board of directors has determined that the composition of our audit committee meets the requirements for independence under the current Nasdaq listing standards and SEC rules and regulations, and that each member of our audit committee is financially literate. In addition, our board of directors has determined that is an "audit committee financial expert" as defined in Item 407(d)(5)(ii) of Regulation S-K promulgated under the Securities Act.

Our audit committee is responsible for, among other things:

- selecting and hiring our independent registered public accounting firm;
- evaluating the qualifications, independence and performance of our independent registered public accounting firm;
- the preparation of the audit committee report to be included in our annual proxy statement;
- oversight of our compliance with legal and regulatory requirements;
- assisting our board of directors with risk assessment and management, including cybersecurity risk management;
- oversight of our accounting and financial reporting processes, including our financial statement audits and the integrity of our financial statements; and
- reviewing and approving related-person transactions.

Compensation Committee

Effective upon the effectiveness of the registration statement of which this prospectus is a part, our compensation committee will be composed of , and , with as the Chairperson of our compensation committee. Our board of directors has determined that each member of our compensation committee is a non-employee director, as defined by Rule 16b-3 promulgated under the Exchange Act, and meets the requirements for independence under the current Nasdaq listing standards and SEC rules and regulations.

Our compensation committee is responsible for, among other things:

- evaluating, recommending, approving and reviewing executive officer compensation arrangements, plans, policies and programs;
- evaluating and recommending non-employee director compensation arrangements for determination by our board of directors;
- administering our cash-based and equity-based compensation plans; and
- overseeing our compliance with regulatory requirements associated with the compensation of directors, executive officers and employees.

Nominating and Governance Committee

Effective upon the effectiveness of the registration statement of which this prospectus is a part, our nominating and governance committee will be composed of , and with as the Chairperson of our nominating and governance committee. Our board of directors has determined that each member of our nominating and governance committee meets the requirements for independence under the current Nasdaq listing standards.

Our nominating and governance committee is responsible for, among other things:

- identifying, considering and recommending candidates for membership on our board of directors;

- overseeing the process of evaluating the performance of our board of directors; and
- advising our board of directors on environmental, social and other corporate governance matters.

Compensation Committee Interlocks and Insider Participation

None of the members of our compensation committee has been an officer or employee of our Company. None of our executive officers currently serves, or in the past year has served, as a member of the board of directors or compensation committee (or other board committee performing equivalent functions or, in the absence of any such committee, the entire board of directors) of any entity that has one or more of its executive officers serving on our board of directors or compensation committee. Prior to establishing the compensation committee, our full board of directors made decisions relating to the compensation of our officers.

Code of Business Conduct and Ethics

Prior to the completion of this offering, our board of directors will adopt a code of business conduct and ethics that applies to all of our employees, officers and directors, including our Chief Executive Officer and President and other executive and senior officers. The full text of our code of business conduct and ethics will be posted on the investor relations page of our website. The reference to our website address in this prospectus does not include or incorporate by reference the information on our website into this prospectus. We intend to disclose future amendments to certain provisions of our code of business conduct and ethics, or waivers of these provisions, on our website or in public filings to the extent required by the applicable rules.

Non-Employee Director Compensation

Our employee directors have not received any compensation or reimbursement of any expenses (other than customary expenses in connection with the attendance of meetings of our board of directors) for their services as directors for the year ended December 31, 2023.

The following table sets forth information concerning the compensation paid to certain non-employee directors for the year ended December 31, 2023:

Name	Fees Earned or Paid in Cash ($)[1]	Option Awards ($)[2]	Total ($)
Jason Coloma, Ph.D.	40,000		40,000
Michael Davidson, M.D.[3]	—	—	—
James Healy, M.D., Ph.D.	—	—	—
Patrick Enright	—	—	—
Rekha Hemrajani	40,000		40,000
Vijay Pande, Ph.D.	—	—	—

(1) Dr. Coloma and. Ms. Hemrajani receive a cash fee of $40,000 annually for their service on our board of directors.
(2) As of December 31, 2023, Dr. Coloma held an aggregate of 127,600 options to purchase common stock and Ms. Hemrajani held an aggregate of 156,961 options to purchase common stock. None of our other non-employee directors held equity as of December 31, 2023.
(3) Dr. Davidson joined our board of directors on April 9, 2024.

Non-Employee Director Compensation Policy

Prior to this offering, we did not have a formal policy to provide any cash or equity compensation to our non-employee directors for their service as directors but Drs. Coloma and Davidson and Ms. Hemrajani receive a cash fee of $40,000 annually for their service on our board of directors. In connection with this offering, our board of directors expects to approve a non-employee director compensation policy, which will take effect following the completion of this offering.

EXECUTIVE COMPENSATION

The following tables and accompanying narrative disclosure set forth information about the compensation earned by our named executive officers during the year ended December 31, 2023. Our named executive officers, who are our principal executive officer and the two most highly compensated executive officers (other than our principal executive officer) serving as executive officers as of December 31, 2023, were:

- Kristen Fortney, Ph.D., *Chief Executive Officer and President;*
- Eric Morgen, M.D., *Chief Operating Officer; and*
- Paul Rubin, M.D., *Chief Medical Officer.*

Summary Compensation Table

The following table presents summary information regarding the compensation earned by our named executive officers for the year ended December 31, 2023.

Name and Principal Position	Salary ($)	Non-Equity Incentive Plan Compensation[1] ($)	Option Awards[1] ($)	All Other Compensation ($)	Total ($)
Kristen Fortney, Ph.D. Chief Executive Officer and President	493,271	246,635	626,169	16,645[2]	1,382,720
Eric Morgen, M.D. Chief Operating Officer	435,686	190,613	232,099	14,400[3]	872,798
Paul Rubin, M.D. Chief Medical Officer	468,939	205,161	148,262	18,463[4]	840,825

(1) For additional information regarding the non-equity incentive plan compensation, see the section titled "Annual performance-based bonuses." The amounts reported in this column represent the aggregate grant date fair value of the awards granted under our 2015 Plan to our officers during the year ended December 31, 2023 as computed in accordance with FASB ASC Topic 718. The assumptions used in calculating the grant date fair value of the awards reported in the Option Awards column are set forth in Note 7 to our financial statements included elsewhere in this prospectus. Note that the amounts reported in this column reflect the aggregate accounting cost for these awards, and do not necessarily correspond to the actual economic value that may be received by the executive from the awards.
(2) Represents a $15,445 matching contribution under our 401(k) plan and a $1,200 cell phone allowance.
(3) Represents a $13,200 matching contribution under our 401(k) plan and a $1,200 cell phone allowance.
(4) Represents a $17,263 matching contribution under our 401(k) plan and a $1,200 cell phone allowance.

Narrative to Summary Compensation Table

2023 Base Salaries

Base salary is the only fixed component of our named executive officers' total cash compensation and provides competitive and stable pay to attract and retain our executives. We make annual salary decisions by taking into account competitive data, the skills and experience that each executive brings to us, and the performance contributions of each executive. The base salaries paid to our named executive officers for the year ended December 31, 2023 are included in the Summary Compensation Table above.

Our board of directors, in conjunction with the compensation committee, set the compensation for each named executive officer, and the compensation is subject to periodic review and adjustment. Effective March 1, 2023, our board of directors approved the following salary increases for (i) Dr. Fortney's salary from $481,240 to $495,677, (ii) Dr. Morgen's salary from $425,060 to $437,811 and (iii) Dr. Rubin's salary from $475,501 to $471,226.

Annual Performance-Based Bonuses

A portion of the target compensation for each named executive officer is in the form of an annual cash bonus, which is based on the achievement of corporate and individual performance, as applicable. For the 2023 bonuses, the corporate performance objectives included certain development goals and milestones, including the advancement of our azelaprag program, as well as business development activities and budgetary goals. The 2023 target bonus amounts, expressed as a percentage of annual base salary, for Dr. Fortney, Dr. Morgen, and

Dr. Rubin were 40%, 35% and 35%, respectively. In March 2024, our board of directors met to review performance against the 2023 bonus goals and approved cash bonuses for the named executive officers in the amounts set forth in the "Non-Equity Incentive Plan Compensation" column of the "Summary Compensation Table" above.

Outstanding Equity Awards at Fiscal Year-End Table

The following table summarizes the outstanding equity awards for each of our named executive officers as of December 31, 2023.

		Option Award[1] [2]			
Name	Grant Date	Number of Securities Underlying Unexercised Options Exercisable	Number of Securities Underlying Unexercised Option Unexercisable	Option Exercise Price ($)	Option Expiration Date
Kristen Fortney Ph.D.					
Chief Executive Officer and President	04/30/2021[3]	815,700	271,900	2.30	04/29/2031
	05/29/2022[4]	225,793	290,307	1.62	05/28/2027
	03/16/2023[5]	96,768	419,332	2.43	03/15/2033
Eric Morgen, M.D.					
Chief Operating Officer	09/17/2018[6]	354,329	—	0.69	09/16/2028
	04/30/2021[7]	310,650	103,550	2.30	04/29/2031
	05/29/2022[8]	83,693	107,607	1.47	05/28/2032
	03/16/2023[9]	35,868	155,432	2.43	03/15/2033
Paul Rubin, M.D.					
Chief Medical Officer	07/01/2020[10]	362,331	42,132	0.92	06/30/2030
	04/30/2021[11]	133,787	60,813	2.30	04/29/2031
	05/29/2022[12]	53,462	68,738	1.47	05/28/2032
	03/16/2023[13]	22,912	99,288	2.43	03/15/2033

(1) All outstanding equity awards were granted under the 2015 Plan.
(2) There was no public market for our common stock as of December 31, 2023. The fair market value of our common stock as of December 31, 2023, was $2.43 per share.
(3) The option will vest over four years, with 1/48th of the total shares vesting and become exercisable on each monthly anniversary of the vesting commencement date of December 16, 2020 for so long as Dr. Fortney continues to provide services to the Company.
(4) The option will vest over four years, with 1/48th of the total shares vesting and become exercisable on each monthly anniversary of the vesting commencement date of March 1, 2021 for so long as Dr. Fortney continues to provide services to the Company.
(5) The option will vest over four years, with 1/48th of the total shares vesting and become exercisable on each monthly anniversary of the vesting commencement date of March 1, 2022 for so long as Dr. Fortney continues to provide services to the Company.
(6) The option will vest over four years, with 1/4th of the total shares vesting and becoming exercisable on February 21, 2019 and 1/48th of the total shares vesting and becoming exercisable monthly anniversary thereafter for so long as Dr. Morgen continues to provide services to the Company.
(7) The option will vest over four years, with 1/48th of the total shares vesting and become exercisable on each monthly anniversary of the vesting commencement date of December 16, 2020 for so long as Dr. Morgen continues to provide services to the Company.
(8) The option will vest over four years, with 1/48th of the total shares vesting and become exercisable on each monthly anniversary of the vesting commencement date of March 1, 2022 for so long as Dr. Morgen continues to provide services to the Company.
(9) The option will vest over four years, with 1/48th of the total shares vesting and become exercisable on each monthly anniversary of the vesting commencement date of March 1, 2023 for so long as Dr. Morgen continues to provide services to the Company.
(10) The option will vest over four years, 1/4th of the total shares vesting and becoming exercisable on May 11, 2021 and 1/48th of the total shares vesting and becoming exercisable on each monthly anniversary thereafter for so long as Dr. Rubin continues to provide services to the Company.
(11) The option will vest over four years, with 1/48th of the total shares vesting and become exercisable on each monthly anniversary of the vesting commencement date of March 1, 2021 for so long as Dr. Rubin continues to provide services to the Company.
(12) The option will vest over four years, with 1/48th of the total shares vesting and become exercisable on each monthly anniversary of the vesting commencement date of March 1, 2022 for so long as Dr. Rubin continues to provide services to the Company.

(13) The option will vest over four years, with 1/48th of the total shares vesting and become exercisable on each monthly anniversary of the vesting commencement date of March 1, 2023 for so long as Dr. Rubin continues to provide services to the Company.

Employment Agreements

We intend to enter into new employment agreements with certain senior management personnel in connection with this offering, including our named executive officers. We expect that each of these agreements will provide for at-will employment and include each officer's base salary, a discretionary annual incentive bonus opportunity and standard employee benefit plan participation.

Severance and Change of Control Agreements

We have entered into executive severance and change of control agreements, each effective January 1, 2023 (the Severance and CIC Agreements), with each of our named executive officers.

Pursuant to the Severance and CIC Agreements, if a named executive officer is terminated without "cause" or resigns for "good reason" (each as defined in the applicable Severance and CIC Agreement), subject to such executive's execution and non-revocation of a release of claims in favor of the Company, such executive will be entitled to receive (i) a lump sum cash amount equal to 9 months of executive's monthly base salary for Drs. Morgen and Rubin and 12 months in the case of Dr. Fortney and (ii) if executive timely elects continued coverage under the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA), reimbursement of the full amount of COBRA premiums for the executive's continued coverage under the Company's health, dental and vision plans, including coverage for such executive's eligible dependents, for 9 months following termination of or resignation from employment, in the case of Drs. Morgen and Rubin and 12 months in the case of Dr. Fortney ((i) and (ii) collectively, the Severance Benefits).

Pursuant to the Severance and CIC Agreements, if the executive is terminated without "cause" or resigns for "good reason" within three months prior to, upon or within 12 months following a change of control (as defined in the applicable Severance and CIC Agreement), subject to the executive's execution and non-revocation of a release of claims in favor of the Company, the executive will be entitled to receive (i) the Severance Benefits (as described above) and (ii) the full-vesting acceleration of executive's then outstanding and unvested equity awards, provided that equity awards that would otherwise vest upon satisfaction of performance criteria shall not be subject to this full vesting acceleration.

Equity Compensation Plans and Other Benefit Plans

We believe that our ability to grant equity-based awards is a valuable compensation tool that enables us to attract, retain and motivate our employees, consultants and directors by aligning their financial interests with those of our stockholders. The principal features of our equity plans are summarized below. These summaries are qualified in their entirety by reference to the actual text of the plans, which are filed as exhibits to the registration statement of which this prospectus is a part.

2015 Equity Incentive Plan

Our 2015 Plan was initially adopted by our board of directors, referred to as the Board, and approved by our stockholders in August 2015.

Share Reserve. As of June 30, 2024 we had 26,573,224 shares of our common stock reserved for issuance pursuant to grants under our 2015 Plan, of which 5,305,722 remained available for grant. As of June 30, 2024, options to purchase 333,582 shares of common stock had been exercised and options to purchase 20,183,532 shares remained outstanding, with a weighted-average exercise price of $1.89 per share. As of June 30, 2024,

no shares of restricted stock issued under the 2015 Plan remained outstanding. No other types of awards have been granted or are currently outstanding under the 2015 Plan. The 2015 Plan will terminate on the date that the 2024 Plan becomes effective (as described below) and no additional grants will be made pursuant to the 2015 Plan following its termination. However, any outstanding stock options and shares of restricted stock will remain outstanding and subject to the terms and conditions of the 2015 Plan until they are exercised, as applicable, or are terminated in accordance with the terms of the 2015 Plan and the applicable award agreements evidencing such awards.

Administration. Our board of directors, or a committee thereof appointed by our board of directors (collectively, the administrator), administers the 2015 Plan and the awards granted thereunder. Subject to the terms of the 2015 Plan, the administrator has the authority to, among other things, select the persons to whom awards will be granted, construe and interpret the 2015 Plan as well as amend the terms of any outstanding award under the 2015 Plan, provided that any amendment that would adversely affect a participant's rights under an outstanding award shall not be made without such participant's written consent. The 2015 Plan provides that the administrator may delegate the authority to grant awards under the 2015 Plan to one or more executive officers to the extent permitted by applicable law, provided that each such officer is a member of the Board.

Eligibility and Types of Awards. The 2015 Plan provides for the grant of both incentive stock options (ISOs), within the meaning of Section 422 of the Code, and nonqualified stock options (NSOs), as well as for the issuance or awards of Restricted Stock Units (RSUs), Stock Appreciation Rights (SARs) and Restricted Stock Awards (RSAs), (each as defined in the 2015 Plan) or other stock-based awards. We may grant ISOs only to our employees. We may grant NSOs, RSUs, SARs, RSAs, and other stock-based awards to our employees, outside directors and consultants. As of June 30, 2024, only stock options and RSAs have been granted under the 2015 Plan. We refer to employees, outside directors or consultants who receive an award under our 2015 Plan as participants.

Options. The 2015 Plan provides for the grant of both (1) ISOs, intended to qualify for tax treatment under Section 422 of the Code, which may be granted only to employees and (2) NSOs, which may be granted to our employees, outside directors and consultants, each at a stated exercise price and subject to certain vesting and other terms and conditions as set forth in the 2015 Plan. The 2015 Plan provides that the exercise price of each ISO and NSO must be at least equal to the fair market value of our common stock on the date of grant. In addition, the exercise price of any ISO granted to a participant who owns more than 10% of the total combined voting power of all classes of our capital stock must be at least equal to 110% of the fair market value of our common stock on the date of grant. The maximum permitted term of options granted under our 2015 Plan is ten years from the date of grant, except that the maximum permitted term of ISOs granted to a participant who owns more than 10% of the total combined voting power of all classes of our capital stock is five years from the date of grant. Our 2015 Plan allows for the "early exercise" of stock option grants in the administrator's discretion.

Restricted Stock Awards and RSUs. The 2015 Plan provides for the grant of RSAs and RSUs, with terms as generally determined by the administrator (in accordance with the 2015 Plan) and to be set forth in an award agreement. An RSA is an offer by us to sell shares of our common stock subject to restrictions, which may lapse based on the satisfaction of service or achievement of performance conditions. The price, if any, of an RSA will be determined by the administrator. Holders of RSAs, unlike holders of options, will have the right to vote and any dividends or stock distributions paid pursuant to RSAs will be accrued and paid when the restrictions on such shares lapse. RSUs represent the right to receive shares of our common stock at a specified date in the future and may be subject to vesting based on service or achievement of performance conditions. Vested RSUs may be settled in cash, shares of our common stock or a combination of both.

Stock Appreciation Rights. The 2015 Plan provides for the grant of SARs at a stated exercise price, which shall be at least equal to the fair market value of our common stock on the date of grant. A SAR provides for a payment, in cash or shares of our common stock (up to a specified maximum of shares, if determined by the administrator), to the holder based upon the difference between the fair market value of our common stock on the

date of exercise and the exercise price, multiplied by the number of shares subject to the SAR. The administrator will determine the vesting schedule applicable to each SAR. The maximum permitted term of SARs granted under the 2015 Plan is ten years from the date of grant.

Limited Transferability. During a participant's lifetime, the participant's options or SARs shall be exercisable only by the participant or by the participant's guardian or legal representatives and shall not be transferable other than by will or the laws of descent and distribution. To the extent permitted by our board of directors in its sole discretion, an NSO may be transferred by the participant to an inter vivos or testamentary trust in which the NSOs are to be passed to beneficiaries upon the death of the trustor (settlor) or by gift to family member as that term is defined in Rule 701. RSAs shall be non-transferable unless determined otherwise by the Board. Unless otherwise provided in the Award Agreement, Restricted Stock Units may not be transferred other than by will or the laws of descent and distribution.

Change in Control. In the event that we experience an Acquisition or Other Combination (each as defined in the 2015 Plan, and as described below), outstanding awards shall be treated as set forth in the agreement evidencing the Acquisition or Other Combination, in each case without the participant's consent. Subject to compliance with Section 409A of the Code, as applicable and as set forth in the 2015 Plan, such agreement may provide for one or more of the following: (i) the continuation of the outstanding awards by us, if we are a surviving corporation; (ii) the assumption, in whole or in part, of the outstanding awards by the surviving corporation or a successor entity or its parent; (iii) the substitution, in whole or in part, by the surviving corporation or a successor entity or its parent of equivalent awards with substantially the same terms for such outstanding awards; (iv) full or partial exercisability, or vesting and accelerated expiration of outstanding awards; (v) settlement of the full value of the outstanding awards, whether or not then vested or exercisable, with payment made in cash, cash equivalents or securities of the successor entity (or its parent if any) followed by the cancellation of such awards, provided however, that such award may be cancelled without consideration if such award has no value as determined by the administrator in its discretion. or (vi) the cancellation of outstanding awards in exchange for no consideration. We will have no obligation to treat all awards, all awards held by a participant, or all awards of the same type, similarly.

For purposes of the above provisions, an Acquisition is defined in the 2015 Plan as (a) any consolidation or merger in which the Company is a constituent entity or is a party in which the voting stock and other voting securities of the Company that are outstanding immediately prior to the consummation of such consolidation or merger represent, or are converted into, securities of the surviving entity of such consolidation or merger (or of any parent of such surviving entity) that, immediately after the consummation of such consolidation or merger, together possess less than fifty percent (50%) of the total voting power of all voting securities of such surviving entity (or of any of its parents, if any) that are outstanding immediately after the consummation of such consolidation or merger; (b) a sale or other transfer by the holders thereof of outstanding voting stock and/or other voting securities of the Company possessing more than fifty percent (50%) of the total voting power of all outstanding voting securities of the Company, whether in one transaction or in a series of related transactions, pursuant to an agreement or agreements to which the Company is a party and that has been approved by the Board, and pursuant to which such outstanding voting securities are sold or transferred to a single person or entity, to one or more persons or entities who are Affiliates of each other, or to one or more persons or entities acting in concert; or (c) the sale, lease, transfer or other disposition, in a single transaction or series of related transactions, by the Company and/or any subsidiary or subsidiaries of the Company, of all or substantially all the assets of the Company and its subsidiaries taken as a whole, (or, if substantially all of the assets of the Company and its Subsidiaries taken as a whole are held by one or more subsidiaries, the sale or disposition (whether by consolidation, merger, conversion or otherwise) of such subsidiaries of the Company), except where such sale, lease, transfer or other disposition is made to the Company or one or more wholly owned Subsidiaries of the Company. An Other Combination is defined in the 2015 Plan as any (a) consolidation or merger in which the Company is a constituent entity and is not the surviving entity of such consolidation or merger or (b) any conversion of the Company into another form of entity; provided that such consolidation, merger or conversion does not constitute an Acquisition.

In addition, the vesting and exercisability, as applicable, of equity awards granted to outside directors will automatically be accelerated in full in the event of a change in control of the company.

Modification, Extension and Renewal of Options. The administrator may modify, extend or renew outstanding stock options and authorize the grant of new options in substitution therefor, or reduce the exercise price of outstanding stock options, provided that, in each case, any such action may not, without the written consent of a participant, impair any of such participant's rights under any options previously granted.

Adjustments. In the event that the number of our outstanding common stock is changed by a declaration of a dividend payable in shares, a recapitalization, stock split, reverse stock split, subdivision, combination, reclassification or other change in the capital structure of the Company affecting shares without consideration, our board of directors shall make appropriate adjustments to the following: (i) the number of shares available for future awards, (ii) the number of shares covered by each outstanding award, (iii) the exercise price under each outstanding options and SARs and (iv) the purchase price of shares subject to other outstanding awards; provided, however, that fractions of a share will not be issued but will either be paid in cash at the fair market value of such fraction of a share or will be rounded down to the nearest whole share, as determined by the administrator.

Amendment and Termination. The administrator may amend, suspend or terminate the 2015 Plan at any time, provided that the administrator will not, without the approval of our stockholders amend the 2015 Plan in any manner that requires stockholder approval pursuant to Section 25102(o) or pursuant to the Code or the regulations promulgated under the Code as such provisions apply to ISO plans.

2024 Equity Incentive Plan

We intend to adopt our 2024 Plan that will become effective on the day prior to the date of the effectiveness of the registration statement for which this prospectus will form a part and will serve as the successor to our 2015 Plan. Our 2024 Plan authorizes the award of ISOs, which are intended to qualify for tax treatment under Section 422 of the Code, and NSOs, RSAs , SARs, RSUs, performance awards and stock bonus awards. We have initially reserved shares of our common stock, plus any reserved shares not issued or subject to outstanding grants under the 2015 Plan on the effective date of the 2024 Plan, for issuance pursuant to awards granted under our 2024 Plan. The number of shares reserved for issuance under our 2024 Plan will increase automatically on January 1 of each of 2024 through 2033 by the number of shares equal to the lesser of % of the aggregate number of shares of all classes of our common stock, plus the total number of shares of our common stock issuable upon conversion of any preferred stock (if any) or exercise of any pre-funded warrants, as issued and outstanding as of the immediately preceding December 31, or a number as may be determined by our board of directors. Pursuant to the 2024 Plan, ISOs may be granted only to our employees. We may grant all other types of awards to our employees, directors and consultants.

In addition, the following shares will again be available for issuance pursuant to awards granted under our 2024 Plan:

- shares subject to options or SARs granted under our 2024 Plan that cease to be subject to the option or SAR for any reason other than exercise of the option or SAR;
- shares subject to awards granted under our 2024 Plan that are subsequently forfeited or repurchased by us at the original issue price;
- shares subject to awards granted under our 2024 Plan that otherwise terminate without such shares being issued;
- shares subject to awards granted under our 2024 Plan that are surrendered, cancelled or exchanged for cash or a different award (or combination thereof);

- shares subject to options or other awards granted under our 2015 Plan that cease to be subject to such options or other awards, by forfeiture or otherwise, after the termination of the 2015 Plan;
- shares issued under the 2015 Plan before or after the effective date of the 2024 Plan pursuant to the exercise of stock options that are, after the effective date, forfeited;
- shares subject to awards granted under our 2015 Plan that are repurchased by us at the original price after the termination of the 2015 Plan; and
- shares subject to awards grant under either our 2015 Plan or our 2024 Plan that are used to pay the exercise price of an award, as applicable, or withheld to satisfy the tax withholding obligations related to any award.

Administration. Our 2024 Plan is expected to be administered by our compensation committee (Committee), all of the members of which are outside directors as defined under applicable federal tax laws, or by our board of directors acting in place of our Committee. Subject to the terms and conditions of the 2024 Plan, the Committee will have the authority, among other things, to select the persons to whom awards may be granted, construe and interpret our 2024 Plan as well as to determine the terms of such awards and prescribe, amend and rescind the rules and regulations relating to the 2024 Plan or any award granted thereunder. The 2024 Plan provides that our board of directors or our Committee may delegate its authority, including the authority to grant awards, to one or more executive officers to the extent permitted by applicable law, provided that awards granted to non-employee directors may only be determined by our board of directors.

Eligibility. Our 2024 Plan provides for the grant of awards to our employees, directors, consultants, independent contractors and advisors.

Options. Our 2024 Plan provides for the grant of both ISOs intended to qualify under Section 422 of the Code, and NSOs to purchase shares of our common stock at a stated exercise price. ISOs may only be granted to employees, including officers and directors who are also employees. The exercise price of stock options granted under the 2024 Plan must be at least equal to the fair market value of our common stock on the date of grant. In addition, ISOs granted to an individual who holds more than 10% of the total combined voting power of all classes of our capital stock must have an exercise price of at least 110% of the fair market value of our common stock on the date of grant. Subject to stock splits, dividends, recapitalizations or similar events, no more than shares may be issued pursuant to the exercise of incentive stock options granted under the 2024 Plan.

Options may vest based on service or achievement of performance conditions. Our Committee may provide for options to be exercised only as they vest or to be immediately exercisable, with any shares issued on exercise being subject to our right of repurchase that lapses as the shares vest. In the event of a participant's termination of service, an option is generally exercisable, to the extent vested, for a period of three months in the case of termination other than due to "cause" or the participant's death or "disability" (as such terms are defined in our 2024 Plan), or 12 months in the case of termination due to the participant's death or disability, or such longer or shorter period as the Committee may provide, but in any event no later than the expiration date of the stock option. Stock options generally terminate upon a participant's termination of employment for cause. The maximum term of options granted under our 2024 Plan is ten years from the date of grant, except that the maximum permitted term of ISOs granted to an individual who holds more than 10% of the total combined voting power of all classes of our capital stock is five years from the date of grant.

Upon exercise of options, the exercise price must be paid in full either in cash, cash equivalents or in other manners approved by the Committee, including by surrender of shares of common stock that are beneficially owned by the participant free of restrictions. Subject to applicable law, the exercise price may also be delivered pursuant to a broker assisted or other form of cashless exercise program implemented by us in connection with the 2024 Plan.

Restricted Stock Awards. An RSA is an offer by us to sell shares of our common stock subject to restrictions, which may lapse based on the satisfaction of service or achievement of performance conditions. The price, if any, of an RSA will be determined by the Committee. Holders of RSAs will have the right to vote and any dividends or stock distributions paid pursuant to unvested RSAs will be accrued and paid only when the restrictions on such shares lapse. Unless otherwise determined by the Committee at the time of award, vesting will cease on the date the participant no longer provides services to us and unvested RSAs may be forfeited to or repurchased by us.

Stock Appreciation Rights. A SAR provides for a payment, in cash or shares of our common stock (up to a specified maximum of shares, if determined by our Committee), to the holder based upon the difference between the fair market value of our common stock on the date of exercise and a predetermined exercise price, multiplied by the number of shares. The exercise price of a SAR must be at least the fair market value of a share of our common stock on the date of grant. SARs may vest based on service or achievement of performance conditions and may not have a term that is longer than ten years from the date of grant.

Restricted Stock Units. RSUs represent the right to receive shares of our common stock at a specified date in the future and may be subject to vesting based on service or achievement of performance conditions. Settlement of vested RSUs will be made as soon as practicable and by a date determined at the time of grant, and may be settled in cash, shares of our common stock or a combination of both. No RSU may have a term that is longer than ten years from the date of grant.

Performance Awards. Performance awards granted to pursuant to the 2024 Plan maybe in the form of a cash bonus, or an award of performance shares or performance units denominated in shares of our common stock that may be settled in cash, property or by issuance of those shares subject to the satisfaction or achievement of specified performance conditions.

Stock Bonus Awards. A stock bonus award provides for payment in the form of cash, shares of our common stock or a combination thereof, based on the fair market value of shares subject such award as determined by our Committee. The awards may be granted as consideration for services already rendered, or at the discretion of the Committee, may be subject to vesting restrictions based on continued service or performance conditions.

Dividend Equivalents Rights. Dividend equivalent rights may be granted at the discretion of our Committee and represent the right to receive the value of dividends, if any, paid by us in respect of the number of shares of our common stock underlying an award. Dividend equivalent rights will be subject to the same vesting or performance conditions as the underlying award, subject to the discretion of the Committee, and may be paid only at such time as the underlying award has become fully vested. Dividend equivalent rights may be settled in cash, shares or other property, or a combination of thereof as determined by our Committee. No dividend equivalent rights will be paid in respect of options or SARs.

Change of Control. In the event of a Corporate Transaction (as defined in the 2024 Plan), any or all outstanding awards shall be subject to the definitive agreement related thereto, and may be (a) continued by the Company, if the Company is the successor entity; (b) assumed or substituted by the successor corporation, or a parent or subsidiary of the successor corporation, for substantially equivalent awards (including, but not limited to, an award to acquire the same consideration paid to the stockholders of the Company pursuant to the Corporate Transaction), in each case after taking into account appropriate adjustments for the number and kind of shares and exercise prices; (c) immediately vested (and exercisable, as applicable) and settled (as applicable), followed by the cancellation of such awards upon or immediately prior to the effectiveness of such transaction or (d) settled for their intrinsic value (whether or not vested or exercisable) in cash or cash equivalents or equity (including cash or equity subject to deferred vesting and delivery consistent with vesting restrictions applicable to such awards or the underlying shares) followed by the cancellation of such awards and, for the avoidance of doubt, if as of the date of the occurrence of the Corporate Transaction, our Committee determines in good faith that no amount would have been attained upon the exercise of such award or realization of the participant’s

rights, then such award may be terminated by the Company without payment, in each case without the participant's consent. The successor corporation also may issue, as replacement of outstanding shares of the Company held by the participant, substantially similar shares or other property subject to repurchase restrictions no less favorable to the participant. In the event such successor corporation refuses to assume, substitute or replace any award in accordance with the 2024 Plan, then notwithstanding any other provision in the 2024 Plan to the contrary, each such award shall become fully vested and, as applicable, exercisable and any rights of repurchase or forfeiture restrictions thereon shall lapse, immediately prior to the consummation of the Corporate Transaction. Performance-based awards not assumed pursuant to the foregoing shall be deemed earned and vested at 100% of target level, unless otherwise indicated pursuant to the terms and conditions of the applicable award agreement. If an award vests in lieu of assumption or substitution in connection with a Corporate Transaction as provided above, our Committee will notify the holder of such award in writing or electronically that such award will be exercisable for a period of time determined by our Committee in its sole discretion, and such award will terminate upon the expiration of such period without consideration. Awards need not be treated similarly in a Corporate Transaction, and treatment may vary from award to award and/or from participant to participant. Notwithstanding any provision to the contrary in the 2024 Plan, in the event of a Corporate Transaction, the vesting of all awards granted to non-employee directors will accelerate and such awards will become exercisable (as applicable) in full prior to the consummation of such event at such times and on such conditions as our Committee determines.

Adjustment. In the event of a change in the number of outstanding shares of our common stock by reason of a stock dividend, extraordinary dividend or distribution (whether in cash, shares, or other property, other than a regular cash dividend), recapitalization, stock split, reverse stock split, subdivision, combination, consolidation reclassification, spin-off or similar change in our capital structure, without consideration, appropriate proportional adjustments will be made to the number of shares reserved for issuance under our 2024 Plan; the exercise prices, number and class of shares subject to outstanding options or SARs; the number and class of shares subject to other outstanding awards; and any applicable maximum award limits with respect to incentive stock options.

Exchange, Repricing and Buyout of Awards. Our Committee may, without prior stockholder approval, (i) reduce the exercise price of outstanding options or SARs without the consent of any participant and (ii) pay cash or issue new awards in exchange for the surrender and cancellation of any, or all, outstanding awards, subject to the consent of any affected participant to the extent required by the terms of the 2024 Plan.

Director Compensation Limit. No non-employee director may receive awards under our 2024 Plan with a grant date value that when combined with cash compensation received for his or her service as a director, exceeds $ in a calendar year or $ in the calendar year of his or her initial service as a non-employee director with us.

Clawback and Transferability. All awards will be subject to clawback or recoupment pursuant to any compensation clawback or recoupment policy adopted by our board of directors or our Committee or required by law during the term of service of the award holder, to the extent set forth in such policy or applicable agreement. Except in limited circumstances, awards granted under our 2024 Plan may generally not be transferred in any manner prior to vesting other than by will or by the laws of descent and distribution.

Sub-Plans. Subject to the terms of the 2024 Plan, the Committee may establish one or more sub-plans under the 2024 Plan and/or modify the terms of awards granted to participants outside of the United States to comply with any laws or regulations applicable to any such jurisdiction.

Amendment and Termination. Our board of directors may amend our 2024 Plan at any time, subject to stockholder approval as may be required. Our 2024 Plan will terminate ten years from the date our board of directors adopts the plan, unless it is terminated earlier by our board of directors. No termination or amendment of the 2024 Plan may adversely affect any then-outstanding award without the consent of the affected participant, except as is necessary to comply with applicable laws or as otherwise provided by the terms of the 2024 Plan.

2024 Employee Stock Purchase Plan

We intend to adopt our ESPP that will become effective on the date of the effectiveness of the registration statement of which this prospectus forms a part in order to enable eligible employees to purchase shares of our common stock with accumulated payroll deductions at a discount beginning on a date to be determined by our board of directors or our Committee. Our ESPP is intended to qualify under Section 423 of the Code *provided that* the Committee may adopt sub-plans under our ESPP designed to be outside of the scope of Section 423 of the Code for participants who are non-U.S. residents.

Shares Available. We have initially reserved shares of our common stock for sale under our ESPP. The aggregate number of shares reserved for sale under our ESPP will increase automatically on January 1st of each of the first ten calendar years after the first offering date by the number of shares equal to the lesser of % of the aggregate number of shares of all classes of our common stock, plus the total number of shares of our common stock issuable upon conversion of any preferred stock (if any) or exercise of any pre-funded warrants, as issued and outstanding as of the immediately preceding December 31 (rounded to the nearest whole share) or a number of shares as may be determined by our board of directors or our Committee in any particular year. The aggregate number of shares issued over the term of our ESPP, subject to stock-splits, recapitalizations or similar events, may not exceed shares of our common stock.

Administration. Our ESPP is expected to be administered by our Committee, or by our board of directors acting in place of our Committee. Among other things, the Committee will have the authority to determine eligibility for participation in the ESPP, designate separate offerings under the plan, and construe, interpret and apply the terms of the plan.

Eligibility. Employees eligible to participate in any offering pursuant to the ESPP generally include any employee that is employed by us or certain of our designated subsidiaries at the beginning of the offering period. However, our Committee may determine that employees who have been employed for less than such time period as specified by the Committee, are customarily employed for 20 hours or less per week, or for five months or less in a calendar year, or certain highly-compensated employees as determined in accordance with applicable tax laws, may not be eligible to participate in the ESPP. In addition, any employee who owns (or is deemed to own as a result of attribution) 5% or more of the total combined voting power or value of all classes of our capital stock, or the capital stock of one of our qualifying subsidiaries, or who will own such amount as a result of participation in the ESPP, will not be eligible to participate in the ESPP. Our Committee may impose additional restrictions on eligibility from time to time, as permitted by applicable law.

Offerings. Under our ESPP, eligible employees will be offered the option to purchase shares of our common stock at a discount over a series of offering periods, which may be consecutive or overlapping, through accumulated payroll deductions over the period. Each offering period may itself consist of one or more purchase periods. No offering period may be longer than 27 months.

No participant may purchase more than shares of our common stock during any one purchase period (or such higher or lower number of shares as may be determined by the Committee in its discretion), and may not subscribe for more than $25,000 in fair market value of shares of our common stock (determined as of the date the offering period commences) in any calendar year in which the offering is in effect.

Participation. Participating employees will be able to purchase the offered shares of our common stock by accumulating funds through payroll deductions. Participants may select a rate of payroll deduction between 1% and 15% of their compensation.

The purchase price for shares of our common stock purchased under the ESPP will be 85% of the lesser of the fair market value of our common stock on (i) the first trading day of the applicable offering period or (ii) the last trading day of each purchase period in the applicable offering period.

Once an employee becomes a participant in an offering period, the participant will be automatically enrolled in each subsequent offering period at the same contribution level. A participant may reduce his or her contribution in accordance with procedures set forth by the Committee and may withdraw from participation in the ESPP at any time prior the end of an offering period, or such other time as may be specified by the Committee. Upon withdrawal, the accumulated payroll deductions will be returned to the participant without interest.

Adjustments Upon Recapitalization. If the number of outstanding shares of our common stock is changed by stock dividend, recapitalization, stock split, reverse stock split, subdivision, combination, reclassification or similar change in our capital structure without consideration, then our Committee will proportionately adjust the number and class of common stock that is available under the ESPP, the purchase price and number of shares any participant has elected to purchase as well as the maximum number of shares which may be purchased by participants.

Change of Control. In the event of a Corporate Transaction (as defined in the ESPP), each outstanding right to purchase common stock will be assumed or an equivalent option substituted by the successor corporation or a parent or a subsidiary of the successor corporation. In the event that the successor corporation refuses to assume or substitute for the purchase right, the offering period with respect to which such purchase right relates will be shortened by setting a new purchase date and will end on such new purchase date. The new purchase date will occur on or prior to the consummation of the Corporate Transaction, and the ESPP will terminate on the consummation of the Corporate Transaction.

Transferability. A participant may not assign, transfer, pledge or otherwise dispose of payroll deductions credited to his or her account, or any rights with regard to an election to purchase shares pursuant to the ESPP other than by will or the laws of descent or distribution.

Amendment and Termination. The Committee may amend, suspend or terminate the ESPP at any time without stockholder consent, except to the extent such amendment would increase the number of shares available for issuance under our ESPP, change the class or designation of employees eligible for participation in the plan or otherwise as required by law. If our ESPP is terminated, the Committee may elect to terminate all outstanding offering periods immediately, upon the next purchase date (which may be sooner than originally scheduled) or upon the last day of such offering period. If any offering period is terminated prior to its scheduled completion, all amounts credited to participants which have not been used to purchase shares will be returned to participants as soon as administratively practicable. Our ESPP will continue until the earlier to occur of (a) termination of the ESPP by the Committee, (b) issuance of all of the shares reserved for issuance under the ESPP, or the tenth anniversary of the first purchase date under the ESPP.

401(k) Plan

We sponsor a retirement savings plan that is intended to qualify for favorable tax treatment under Section 401(a) of the Code and contains a cash or deferred feature that is intended to meet the requirements of Section 401(k) of the Code. Participants may make pre-tax and certain after-tax (Roth) salary deferral contributions to the plan from their eligible earnings up to the statutorily prescribed annual limit under the Code. Participants who are projected to reach 50 years of age or older during a calendar year may contribute additional amounts based on the statutory limits for catch-up contributions. Participant contributions are held in trust as required by law.

Other Benefits

Our named executive officers are eligible to participate in our employee benefit plans on the same basis as our other employees, including our health and welfare plans.

Limitations on Liability and Indemnification Matters

Our restated certificate of incorporation that will become effective immediately before the completion of this offering contains provisions that limit the liability of our directors and officers for monetary damages to the fullest extent permitted by the DGCL. Consequently, our directors and officers will not be personally liable to us or our stockholders for monetary damages for any breach of fiduciary duties as directors or officers, except liability for:

- any breach of the director's or officer's duty of loyalty to us or our stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- with respect to directors, unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the DGCL; or
    - or any transaction from which the director derived an improper personal benefit.

Our restated certificate of incorporation and our restated bylaws that will become effective immediately before the completion of this offering require us to indemnify our directors and officers to the maximum extent not prohibited by the DGCL and allow us to indemnify other employees and agents as set forth in the DGCL. Subject to certain limitations, our restated bylaws will also require us to advance expenses incurred by our directors and officers for the defense of any action for which indemnification is required or permitted, subject to very limited exceptions.

We have entered, and intend to continue to enter, into separate indemnification agreements with our directors, executive officers and certain of our key employees, in addition to the indemnification provided for in our restated certificate of incorporation and restated bylaws. These agreements, among other things, require us to indemnify our directors, officers and key employees for certain expenses, including attorneys' fees, judgments, penalties, fines and settlement amounts actually incurred by these individuals in any action or proceeding arising out of their service to us or any of our subsidiaries or any other company or enterprise to which these individuals provide services at our request. Subject to certain limitations, our indemnification agreements also require us to advance expenses incurred by our directors, officers and key employees for the defense of any action for which indemnification is required or permitted.

We believe that these indemnification provisions and agreements are necessary to attract and retain qualified directors, officers and key employees. We also maintain directors' and officers' liability insurance.

The limitation of liability and indemnification provisions in our restated certificate of incorporation and restated bylaws may discourage stockholders from bringing a lawsuit against our directors and officers for breach of their fiduciary duty. They may also reduce the likelihood of derivative litigation against our directors and officers, even though an action, if successful, might benefit us and other stockholders. Further, a stockholder's investment may be adversely affected to the extent that we pay the costs of settlement and damage awards against directors and executive officers as required by these indemnification provisions.

At present, there is no pending litigation or proceeding involving any of our directors or executive officers as to which indemnification is required or permitted, and we are not aware of any threatened litigation or proceeding that may result in a claim for indemnification.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or persons controlling us, we have been informed that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

In addition to the compensation arrangements, including any employment, termination of employment and change in control arrangements, with our directors and executive officers, including those discussed in the sections titled "Management" and "Executive Compensation," the following is a description of each transaction since January 1, 2021 and each currently proposed transaction in which:

- we have been or are to be a participant;
- the amounts involved exceeded or will exceed the lesser of $120,000 and 1% of our total assets at year-end for the last two completed fiscal years; and
- any of our directors, executive officers or holders of more than 5% of our capital stock, or an affiliate or immediate family member of the foregoing persons, had or will have a direct or indirect material interest.

Series D Convertible Preferred Stock Financing

In two closings in February 2024, we sold an aggregate of 49,713,402 shares of our Series D redeemable convertible preferred stock (Series D Preferred Stock) at a price per share of $3.4196 for total gross proceeds of approximately $170.0 million (the Series D Preferred Stock Financing). Each share of our Series D Preferred Stock will automatically convert into shares of our common stock in connection with the completion of this offering. Pursuant to the current investors' rights agreement, as described below, holders of our Series D Preferred Stock are entitled to certain registration rights. See the section titled "Description of Capital Stock—Registration Rights" for additional information.

Pursuant to the Note Purchase Agreement dated as of February 10, 2023, in February 2023 and March 2023, we issued convertible promissory notes with an aggregate of $23.5 million, which were cancelled and converted in connection with the Series D Preferred Stock Financing into a total of 11,887,535 shares of our Series D-1 redeemable convertible preferred stock (Series D-1 Preferred Stock) pursuant to the Series D Preferred Stock Purchase Agreement dated as of February 1, 2024.

The following table summarizes the Series D Preferred Stock and Series D-1 Preferred Stock purchased by members of our board of directors or their affiliates and holders of more than 5% of our outstanding capital stock. Please refer to the section titled "Principal Stockholders" for additional information regarding the shares held by these entities.

Name of Stockholder	Shares of Series D Preferred Stock	Shares of Series D-1 Preferred Stock	Aggregate Purchase Price
Entities affiliated with Andreesen Horowitz(1)	2,924,318	—	$ 9,999,998
Entities affiliated with Cormorant(2)	5,263,772	—	$ 17,999,995
Entitles affiliated with Longitude Venture Partners IV, L.P.(3)	5,848,637	—	$ 19,999,999
Entities affiliated with Sofinnova Venture Partners XI, L.P.(4)	7,310,796	—	$ 24,999,998
Entities affiliated with RA Capital(5)	5,848,636	—	$ 19,999,996
Entities affiliated with Khosla Ventures(6)	—	6,076,054	$ 12,466,849
Entities affiliated with Horsley Bridge(7)	—	5,054,298	$ 10,370,411

(1) Consists of shares of our Series D Preferred Stock purchased by AH Bio Fund IV, LP, as nominee. AH Bio Fund IV, LP is affiliated with Andreessen Horowitz, which together with its affiliates, beneficially holds more than 5% of our outstanding capital stock. Dr. Pande, a member of our board of directors, is affiliated with Andreessen Horowitz.

(2) Consists of shares of our Series D Preferred Stock purchased by Cormorant Private Healthcare Fund IV, LP and Cormorant Global Healthcare Master Fund, LP, which together with its affiliates, beneficially holds more than 5% of our outstanding capital stock.

(3) Consists of shares of our Series D Preferred Stock purchased by Longitude Venture Partners IV, L.P. Longitude Venture Partners IV, L.P. beneficially holds more than 5% of our outstanding capital stock. Mr. Enright, a member of our board of directors, is affiliated with the Longitude Venture Partners IV, L.P.

(4) Consists of shares of our Series D Preferred Stock purchased by Sofinnova Venture Partners XI, L.P., which together with its affiliates beneficially holds more than 5% of our outstanding capital stock. Dr. Healy, a member of our board of directors, is affiliated with Sofinnova Venture Partners XI, L.P.
(5) Consists of our Series D Preferred Stock purchased by RA Capital Healthcare Fund, L.P. and RA Capital Nexus Fund III, L.P., which together beneficially hold more than 5% of our outstanding capital stock.
(6) Consists of our Series D-1 Preferred Stock purchased by Khosla Ventures Opportunity I, LP. Khosla Ventures Opportunity I, LP is associated with Khosla Ventures, which together with its affiliates, beneficially holds more than 5% of our outstanding capital stock.
(7) Consists of our Series D-1 Preferred Stock purchased by Horsley Bridge Venture 14, L.P. and Horsley Bridge Venture 14+, L.P., which together beneficially hold more than 5% of our outstanding capital stock.

Investors' Rights Agreement

In connection with our Series D Preferred Stock Financing, we entered into the investors' rights agreement (IRA) with certain holders of our redeemable convertible preferred stock, including entities with which certain of our directors are affiliated and who hold more than 5% of our outstanding common stock. Under the IRA, these stockholders are entitled to rights with respect to the registration of their shares under the Securities Act following this offering and the provisions relating registration rights included in the IRA will not terminate as a result of this offering. See the section titled "Description of Capital Stock—Registration Rights" for additional information.

Employment Arrangements with Immediate Family Members of our Executive Officers and Directors

Justin Rebo, M.D., the spouse of Dr. Fortney, our Chief Executive Officer, is employed by the Company in a non-executive officer position. Dr. Rebo received total compensation with respect to base salary, bonus, and the grant date fair value of options of (i) $684,036 in 2021 and (ii) $308,477 in 2022. Dr. Rebo's compensation and stock option grants were established by the Company in accordance with its compensation practices applicable to employees with comparable qualifications and responsibilities and holding similar positions and without the involvement of Dr. Fortney.

Lingling Chen, M.D., the spouse of Dr. Morgen, our Chief Operating Officer, is employed by the Company in a non-executive officer position. Dr. Chen received total compensation with respect to base salary, bonus, and the grant date fair value of options of (i) $300,044 in 2021, (ii) 338,487 in 2022 and (iii) 347,824 in 2023. Dr. Chen's compensation and stock option grants were established by the Company in accordance with its compensation practices applicable to employees with comparable qualifications and responsibilities and holding similar positions and without the involvement of Dr. Morgen.

Indemnification Agreements

We have entered into, and in connection with this offering we intend to enter into, indemnification agreements with our directors and executive officers. The indemnification agreements, our restated certificate of incorporation and our restated bylaws will require us to indemnify our directors to the fullest extent permitted by Delaware law. Subject to certain limitations, our restated bylaws also require us to advance expenses incurred by our directors and executive officers. See the section titled "Executive Compensation—Limitations on Liability and Indemnification Matters" for additional information.

Policies and Procedures for Related Party Transactions

In connection with this offering, we intend to adopt a written related person transactions policy that provides that our executive officers, directors, nominees for election as a director, beneficial owners of more than 5% of our common stock, and any members of the immediate family of and any entity affiliated with any of the foregoing persons, are not permitted to enter into a material related person transaction with us without the review and approval of our audit committee, or a committee composed solely of independent directors in the event it is inappropriate for our audit committee to review such transaction due to a conflict of interest. We expect the policy to provide that any request for us to enter into a transaction with an executive officer, director, nominee

for election as a director, beneficial owner of more than 5% of our common stock or with any of their immediate family members or affiliates in which the amount involved exceeds $120,000 will be presented to our audit committee (or the committee composed solely of independent directors, if applicable) for review, consideration and approval. In approving or rejecting any such proposal, we expect that our audit committee (or the committee composed solely of independent directors, if applicable) will consider the relevant facts and circumstances available and deemed relevant to the audit committee (or the committee composed solely of independent directors, if applicable), including, but not limited to, whether the transaction is on terms no less favorable than terms generally available to an unaffiliated third party under the same or similar circumstances and the extent of the related person's interest in the transaction.

PRINCIPAL STOCKHOLDERS

The following table and accompanying footnotes set forth certain information with respect to the beneficial ownership of shares of our common stock as of June 30, 2024, and as adjusted to reflect the shares of our common stock to be issued and sold in this offering, for:

- each of our directors;
- each of our named executive officers;
- all of our current directors and executive officers as a group; and
- each person, or group of affiliated persons, known by us to be the beneficial owner of more than 5% of the outstanding shares of our common stock.

We have determined beneficial ownership in accordance with the rules of the SEC. Except as indicated by the footnotes below, to our knowledge, the persons and entities named in the table below have sole voting and sole investment power with respect to all shares of our common stock that they beneficially owned, subject to applicable community property laws.

The percentage of shares beneficially owned prior to this offering is based on shares of our common stock outstanding as of , assuming the automatic conversion of all outstanding shares of our convertible preferred stock into shares of our common stock in connection with the completion of this offering. The percentage of beneficial ownership after this offering is based on shares of our common stock outstanding, assuming (i) the automatic conversion of all outstanding shares of our redeemable convertible preferred stock into shares of our common stock as described above and (ii) the issuance of shares of our common stock in this offering, assuming that the underwriters do not exercise their option to purchase additional shares in part or in full. In computing the number of shares of common stock beneficially owned by a person and the percentage ownership of that person, we deemed to be outstanding all shares of common stock subject to stock options held by that person or entity that are currently exercisable or that will become exercisable within 60 days of . We did not deem these shares outstanding, however, for the purpose of computing the percentage ownership of any other person.

Unless otherwise indicated, the address of each beneficial owner listed in the table below is c/o BioAge Labs, Inc., 1445A South 50th Street, Richmond, CA 948064.

	Beneficial ownership prior to this offering		Beneficial ownership after this offering	
Name of Beneficial Owner	Number	Percent (%)	Number	Percent (%)
Directors and Named Executive Officers:				
Kristen Fortney, Ph.D.(1)				
Eric Morgen, M.D.,(2)				
Paul Rubin, M.D.(3)				
Jason Coloma, Ph.D.(4)				
Michael Davidson(5)				
Patrick Enright(6)				
James Healy, M.D., Ph.D.(7)				
Rekha Hemrajani(8)				
Vijay Pande, Ph.D.(9)				
All executive officers and directors as a group (10 persons)(10)				

Name of Beneficial Owner	Beneficial ownership prior to this offering: Number	Beneficial ownership prior to this offering: Percent (%)	Beneficial ownership after this offering: Number	Beneficial ownership after this offering: Percent (%)
Greater than 5% Stockholders:				
Entities Affiliated with Andreesen Horowitz(11)				
Entities Affiliated with Khosla Ventures(12)				
Sofinnova Venture Partners XI, L.P.(13)				
Longitude Venture Partners IV, L.P.(14)				
Entities Affiliated with RA Capital(15)				
Entities Affiliated with Cormorant(16)				
Entities Affiliated with Horsley Bridge(17)				
Entities Affiliated with Kaiser Permanente(18)				

* Represents beneficial ownership of less than 1%.

(1) Consists of (i) shares of common stock directly beneficially owned by Dr. Fortney; and (ii) shares of common stock issuable to Dr. Fortney pursuant to options exercisable within 60 days of , 2024.

(2) Consists of (i) shares of common stock directly beneficially owned by Dr. Morgen; and (ii) shares of common stock issuable to Dr. Morgen pursuant to options exercisable within 60 days of , 2024.

(3) Consists of shares of common stock issuable to Dr. Rubin pursuant to options exercisable within 60 days of , 2024.

(4) Consists of shares of common stock issuable to Dr. Coloma pursuant to options exercisable within 60 days of , 2024.

(5) Consists of shares of common stock issuable to Dr. Davidson pursuant to options exercisable within 60 days of , 2024.

(6) Consists entirely of the shares of common stock held of record by LVPIV (as defined below), as more specifically described in footnote (12), below. The business address of Mr. Enright is: 2740 Sand Hill Road, 2nd Floor, Menlo Park, CA 94025.

(7) Consists entirely of the shares of common stock held of record by SVP XI (as defined below), as more specifically described in footnote (13), below. The business address of Dr. Healy is: c/o Sofinnova Investments, Inc., 3000 Sand Hill Road, Building 4, Suite 250, Menlo Park, CA 94025.

(8) Consists of shares of common stock issuable to Ms. Hemrajani pursuant to options exercisable within 60 days of , 2024.

(9) Consists entirely of the shares of common stock held of record by the AH Affiliates (as defined below), as more specifically described in footnote (10), below. The business address of Dr. Pande is: 2865 Sand Hill Rd #101, Menlo Park, CA 94025.

(10) Represents the total of all securities beneficially owned by our directors and officers, including shares of common stock and shares of common stock issuable pursuant to options exercisable within 60 days of , 2024.

(11) Includes (i) shares of common stock held of record by AH Bio Fund I, L.P., for itself and as nominee for AH Bio Fund I-B, L.P. (collectively, the AH Bio Fund I Entities), (ii) shares of Common Stock held of record by AH Bio Fund III, L.P., for itself and as nominee for AH Bio Fund III-B, L.P. and AH Bio Fund III-Q, L.P. (collectively, the AH Bio Fund III Entities), and (iii) shares of common stock held of record by AH Bio Fund IV, L.P., for itself and as nominee for AH Bio Fund IV-B, L.P., AH 2022 Annual Fund, L.P., AH 2022 Annual Fund-B, L.P., AH 2022 Annual Fund-QC, L.P., and CLF Partners III, LP (collectively, the AH Bio Fund IV Entities). AH Equity Partners Bio I, L.L.C. (AH EP Bio I), the general partner of the AH Bio Fund I Entities may be deemed to have sole voting and dispositive power over the shares held by the AH Bio Fund I Entities. AH Equity Partners Bio III, L.L.C. (AH EP Bio III), the general partner of the AH Bio Fund III Entities may be deemed to have sole voting and dispositive power over the shares held by the AH Bio Fund III Entities. AH Equity Partners Bio IV, L.L.C. (AH EP Bio IV), the general partner of the AH Bio Fund IV Entities may be deemed to have sole voting and dispositive power over the shares held by the AH Bio Fund IV Entities. The managing members of each of AH EP Bio I, AH EP Bio III and AH EP Bio IV are Marc Andreessen and Ben Horowitz, and each of them may be deemed to hold shared voting and dispositive power over the shares held by the AH Bio Fund I Entities, the AH Bio Fund III Entities and the AH Bio Fund IV Entities. Shares held by each of these entities include shares that may be subsequently sold by each of Marc Andreessen, Ben Horowitz and Vijay Pande, a director, following in-kind distributions of shares by these entities. The address for the persons and entities set forth herein is 2865 Sand Hill Road, Suite 101, Menlo Park, CA 94025.

(12) Consists of: (i) shares of common stock directly held by Khosla Ventures VI, LP (KV VI); and (ii) shares of common stock directly held by Khosla Ventures Opportunity I, LP (KV Opp I). Khosla Ventures Associates VI, LLC (KVA VI) is the general partner of KV VI and Khosla Ventures Opportunity Associates I, LLC (KVOA I) is the general partner of KV Opp I. VK Services, LLC (VK Services) is the sole manager of KVA VI and KVOA I. Vinod Khosla is the managing member of VK Services. As such: (i) KVA VI may be deemed to indirectly beneficially own the securities directly held by KV VI; (ii) KVOA I may be deemed to indirectly beneficially own the securities directly held by KV Opp I; (iii) VK Services may be deemed to indirectly beneficially own the securities directly or indirectly beneficially owned by each of KV VI, KV Opp I, KVA VI, and KVOA I; and (iv) Mr. Khosla may be deemed to exercise shared voting and investment discretion with respect to all of the securities described in this footnote. The principal business office address for each of the foregoing entities is: 2128 Sand Hill Road, Menlo Park, California 94025.

(13) Consists of shares of common stock directly held by Sofinnova Venture Partners XI, L.P. (SVP XI). Sofinnova Management XI, L.P. (SM XI LP) is the general partner of SVP XI. Sofinnova Management XI, L.L.C. (SM XI LLC) is the general partner of SM XI LP. Dr. Healy and Dr. Maha Katabi are the managing members of SM XI LLC. As such: (i) SM XI LP and SM XI LLC may each be deemed to indirectly beneficially own the securities directly held by SVP XI; and (ii) Dr. Healy and Dr. Katabi may be deemed to

exercise shared voting and investment discretion with respect to the securities described in this footnote. SM XI LP, SM XI LLC, Dr. Healy and Dr. Katabi disclaim beneficial ownership of any of the securities, except to the extent of their pecuniary interest therein. The business address of each of the aforementioned parties is: c/o Sofinnova Investments, Inc., 3000 Sand Hill Road, Building 4, Suite 250, Menlo Park, CA 94025.

(14) Consists of shares of common stock directly held by Longitude Venture Partners IV, L.P. (LVP IV). Longitude Capital Partners IV, LLC (LCP IV) is the general partner of LVP IV and may be deemed to have voting, investment and dispositive power with respect to these securities. Juliet Tammenoms Bakker and Patrick G. Enright are the managing members of LCP IV and may each be deemed to share voting, investment and dispositive power with respect to the securities held by LVP IV. Each of LCP IV, Ms. Tammenoms Bakker and Mr. Enright disclaim beneficial ownership of such securities except to the extent of their respective pecuniary interests therein. The business address of each of the aforementioned parties is: 2740 Sand Hill Road, 2nd Floor, Menlo Park, CA 94025.

(15) Consists of (i) shares of common stock directly held by RA Capital Nexus Fund III, L.P. (Nexus III); and (ii) shares of common stock directly held by RA Capital Healthcare Fund, L.P. (RA Healthcare). RA Capital Management, L.P. (RA Investment Manager) serves as investment manager for Nexus III and RA Healthcare. RA Capital Management GP, LLC (RA Manager GP) is the general partner of RA Investment Manager. Peter Kolchinsky, Ph.D. and Rajeev Shah are the managing members of RA Manager GP. As such, each of RA Investment Manager, RA Manager GP, Dr. Kolchinsky, and Mr. Shah may be deemed to exercise shared voting and investment discretion with respect to all of the securities described in this footnote. RA Investment Manager, RA Manager GP, Dr. Kolchinsky and Mr. Shah disclaim beneficial ownership of any of the securities, except to the extent of their pecuniary interest therein. The business address of each of the aforementioned parties is: 200 Berkeley Street, 18th Floor, Boston, Massachusetts 02116.

(16) Consists of (i) shares of common stock directly held by Cormorant Private Healthcare Fund IV, LP (Cormorant IV); (ii) shares of common stock directly held by Cormorant Private Healthcare Fund V, LP (Cormorant V); and (iii) shares of common stock directly held by Cormorant Global Healthcare Master Fund, LP (together with Cormorant IV and Cormorant V, the Cormorant Funds and each, a Cormorant Fund). Cormorant Asset Management, LP (the Cormorant Asset Manager) serves as the asset manager of each Cormorant Fund. Bihua Chen is the managing member of the Cormorant Asset Manager. As such, each of the Cormorant Asset Manager and Ms. Chen may be deemed to exercise shared voting and investment discretion with respect to all of the securities described in this footnote. The business address of each of the aforementioned parties is: 200 Clarendon Street, 52nd Floor, Boston, MA 02116.

(17) Consists of (i) shares of common stock directly held by Horsley Bridge Venture 14, L.P. (HBV 14); (ii) shares of common stock directly held by Horsley Bridge Venture 14+, L.P. (HBV 14+). The managing general partner of HBV 14 and HBV 14+ is Horsley Bridge Partners LLC (HBV GP). Du Chai, Lance Cottrill, Josh Freeman, Kathryn Mayne, Yi Sun are the investment committee members of HBV GP. As such: (i) HBV GP may be deemed to indirectly beneficially own the securities directly held by HBV 14 and HBV 14+; and (ii) Du Chai, Lance Cottrill, Josh Freeman, Kathryn Mayne, Yi Sun may be deemed to exercise shared voting and investment discretion with respect to the securities described in this footnote. The business address of each of the aforementioned parties is:140 New Montgomery Street, 16th Floor, San Francisco, CA 94105.

(18) Consists of (i) shares of Series C redeemable convertible preferred stock directly held by Kaiser Permanente Group Trust (Kaiser Trust); and (ii) shares of Series C redeemable convertible preferred stock directly held by Kaiser Foundation Hospitals (Kaiser Hospitals). The Kaiser Permanente Retirement Plans Investment Committee has discretionary authority to manage and control Kaiser Trust assets. The business address for each of the aforementioned parties is: One Kaiser Plaza, The Ordway Building, Oakland, California 94612.

DESCRIPTION OF CAPITAL STOCK

The following description summarizes the most important terms of our capital stock, as will be in effect following this offering. Because it is only a summary, it does not contain all the information that may be important to you. We expect to adopt a restated certificate of incorporation and restated bylaws that will become effective upon the completion of this offering, and this description summarizes provisions that are expected to be included in these documents. For a complete description, you should refer to our restated certificate of incorporation and restated bylaws, which are included as exhibits to the registration statement of which this prospectus forms a part, and to the applicable provisions of Delaware law.

General

Upon the completion of this offering, our authorized capital stock will consist of shares of our common stock, $0.00001 par value per share, and shares of our undesignated preferred stock, $0.00001 par value per share.

Pursuant to the provisions of our current certificate of incorporation, all of our redeemable convertible preferred stock will automatically convert into common stock in connection with the completion of this offering. Our Series A-1 redeemable convertible preferred stock will convert at a ratio of , our Series A-2 redeemable convertible preferred stock will convert at a ratio of , our Series A-3 redeemable convertible preferred stock will convert at a ratio of , our Series A-4 redeemable convertible preferred stock will convert at a ratio of , our Series B redeemable convertible preferred stock will convert at a ratio of , our Series C redeemable convertible preferred stock will convert at a ratio of , our Series D redeemable convertible preferred stock will convert at a ratio of and our Series D-1 redeemable convertible preferred stock will convert at a ratio of . Assuming the effectiveness of this conversion as of , 2024, there were shares of our common stock issued, held by approximately stockholders of record, and no shares of our convertible preferred stock outstanding. Our board of directors is authorized, without stockholder approval, to issue additional shares of our capital stock.

Common Stock

Dividend Rights

Subject to preferences that may apply to any shares of preferred stock outstanding at the time, the holders of our common stock are entitled to receive dividends out of funds legally available if our board of directors, in its discretion, determines to issue dividends and then only at the times and in the amounts that our board of directors may determine. See the section titled “Dividend Policy” for additional information.

Voting Rights

Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders. We have not provided for cumulative voting for the election of directors in our restated certificate of incorporation, which means that holders of a majority of the shares of our common stock will be able to elect all of our directors. Our restated certificate of incorporation will establish a classified board of directors, to be divided into three classes with staggered three-year terms. Only one class of directors will be elected at each annual meeting of our stockholders, with the other classes continuing for the remainder of their respective three-year terms.

No Preemptive or Similar Rights

Our common stock is not entitled to preemptive rights, and is not subject to conversion, redemption or sinking fund provisions.

Right to Receive Liquidation Distributions

Upon our liquidation, dissolution or winding-up, the assets legally available for distribution to our stockholders would be distributable ratably among the holders of our common stock and any participating

preferred stock outstanding at that time, subject to prior satisfaction of all outstanding debt and liabilities and the preferential rights of and the payment of liquidation preferences, if any, on any outstanding shares our of preferred stock.

Preferred Stock

After the completion of this offering, no shares of our preferred stock will be outstanding. Pursuant to our restated certificate of incorporation that will become effective immediately before the completion of this offering, our board of directors will be authorized, subject to limitations prescribed by Delaware law, to issue preferred stock in one or more series, to establish from time to time the number of shares to be included in each series and to fix the designation, powers, preferences and rights of the shares of each series and any of their qualifications, limitations or restrictions, in each case without further vote or action by our stockholders. Our board of directors will also be able to increase or decrease the number of shares of any series of preferred stock, but not below the number of shares of that series then outstanding and not above the number of shares of that series authorized, without any further vote or action by our stockholders. Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of our common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in control of our Company and might adversely affect the market price of our common stock and the voting and other rights of the holders of our common stock. We have no current plan to issue any shares of preferred stock.

Warrants

As of June 30, 2024, we had outstanding the following warrants to purchase shares of our common stock:

Type of Capital Stock Underlying Warrant	Total Number of Shares Subject to Warrants	Exercise Price Per Share (1)
Common Stock	30,000	$ 0.72
Common Stock	111,436	$ 2.30

(1) The exercise price of these warrants may either be paid in cash or by surrendering the right to receive shares having a value equal to the exercise price.

Stock Options

As of June 30, 2024, we had outstanding options to purchase an aggregate of 20,183,532 shares of our common stock, with a weighted-average exercise price of $1.89 per share under our 2015 Plan.

Registration Rights

Pursuant to the terms of the IRA immediately following this offering, the holders of shares of our common stock will be entitled to rights with respect to the registration of such shares under the Securities Act as described below. We refer to these shares collectively as registrable securities. These rights are provided under the terms of the IRA between us and the holders of these shares, which was entered into in connection with our redeemable convertible preferred stock financings prior to this offering.

Demand Registration Rights

Beginning from the earlier of February 1, 2029 or 180 days after the effective date of this registration statement, if we receive a request to file a Registration Statement on Form S-1 from the holders of at least a majority of the registrable securities then outstanding (and the registrable securities subject to such request have

an anticipated offering price, net of selling expenses of at least $50 million), then we are obligated to provide notice of such request to all holders other than the holders that initiated the request, and as soon as practicable but in any event within 90 days after such request is given by the initiating holders, use commercially reasonable efforts to as soon as practicable file a Form S-1 registration statement under the Securities Act covering all registrable securities that the initiating holders requested to be registered and any additional registrable securities requested to be included in such registration by any other holders, as specified by notice given by each such holder to the Company within 20 days after the date the request is given. We are only required to file two registration statements that are declared effective upon exercise of these demand registration rights. We may defer taking action with respect to such filing not more than once during any 12-month period for a total period of not more than 90 days, if after receiving a request for registration, we furnish to the holders requesting such registration a certificate signed by our Chief Executive Officer stating that, in the good faith judgment of our board of directors, it would be materially detrimental to us and our stockholders.

The underwriters of any underwritten offering will have the right to limit the number of shares registered by these holders if they determine that marketing factors require limitation, in which case the number of shares to be registered will be apportioned, in proportion (as nearly as practicable), to the number of registrable securities owned by each holder or in such other proportion as shall mutually be agreed to by all such selling holders. However, the number of shares to be registered by these holders cannot be reduced unless all other securities are first entirely excluded from the underwriting.

Form S-3 Registration Rights

Any holder of the registrable securities then outstanding can request that we file a Form S-3 Registration Statement with respect to outstanding registrable securities of such holders having an anticipated aggregate offering price, net of selling expenses, of at least $5 million. Within 10 days after the request is given, we are obligated to provide notice of such request to all holders of registrable securities other than the initial holders and as soon as practicable, and in any event within 45 days, use commercially reasonable efforts to file a Form S-3 Registration Statement under the Securities Act covering all registrable securities requested to be included in such registration by any other holders as specified by notice given by each such holder to is within 20 days of the date the request is given. We are not required to file more than two registration statements that are declared effective upon exercise of these demand registration rights within any 12-month period. We may defer taking action with respect to such filing not more than once during any 12-month period for a total period of not more than 90 days, if after receiving a request for registration, we furnish to the holders requesting such registration a certificate signed by our Chief Executive Officer stating that, in the good faith judgment of our board of directors, it would be materially detrimental to us and our stockholders.

The underwriters of any underwritten offering will have the right to limit the number of shares registered by these holders if they determine that marketing factors require limitation, in which case the number of shares to be registered will be apportioned, in proportion (as nearly as practicable), to the number of registrable securities owned by each holder or in such other proportion as shall mutually be agreed to by all such selling holders. However, the number of shares to be registered by these holders cannot be reduced unless all other securities are first entirely excluded from the underwriting.

Piggyback Registration Rights

If we register any of our securities for public sale solely for cash, holders of then-outstanding registrable securities or their permitted transferees will have the right to include their registrable securities in the registration statement. However, this right does not apply to a registration relating to the sale or grant of securities to our employees pursuant to a stock option, stock purchase, equity incentive or similar plan, a registration relating to a Rule 145 transaction, a registration on any form that does not include substantially the same information as would be required to be included in a registration statement covering the sale of our common stock, or a registration in which the only common stock being registered is common stock issuable upon conversion of debt securities that are also being registered. If the underwriters determine that less than all the registrable securities

requested to be registered can be included in the offering, the number of registrable shares to be registered will be allocated among holders of our registrable securities, in proportion (as nearly as practicable) to the amount of registrable securities owned by each such holder or in such other proportions as shall mutually be agreed to by all such holders. However, the number of shares to be registered by holders of registrable securities cannot be reduced unless all other securities (other than as offered by us) are first entirely excluded. The number of registrable securities included in the offering may not be reduced below 25% of the total number of securities included in such offering, except for in connection with an initial public offering, in which case the selling holders may be excluded further if the underwriters make the determination described above and no other stockholder's securities are included in such offering.

Expenses of Registration Rights

We generally will pay all expenses (other than selling expenses) incurred in connection with each of the registrations, filings or qualifications described above, including all registration, filing and qualification fees; printers' and accounting fees; fees and disbursements, of our counsel; and the reasonable fees and disbursements of one counsel for the selling holders, not to exceed $30,000, provided, however, that if the registration is subsequently withdrawn at the request of a holders of a majority of the registrable shares to be registered (in which case all selling holders shall bear such expenses pro rata based upon the number of registrable securities that were to be included in the withdrawn registration) unless the holders of a majority of the registrable securities agree to forfeit their right to a registration as described above.

Termination of Registration Rights

The registration rights described above will terminate, with respect to any particular holder of these rights, on the earliest to occur of (i) such time after this offering when all of such holder's registrable securities could be sold without any restriction on volume or manner of sale in any three-month period under Rule 144 or any successor, (ii) upon a deemed liquidation event, as defined in our restated certificate of incorporation or a sale by our stockholders, in one transaction or series of related transactions, of equity securities that represent, immediately prior to such transaction or transactions, at least a majority by voting power of our equity securities pursuant to an agreement approved by our Board and the investors holding at least a majority of our outstanding preferred stock (voting together as a single class on an as-converted basis) and entered into by us or (iii) the fifth anniversary of this offering.

Anti-Takeover Provisions

The provisions of the DGCL, our restated certificate of incorporation and our restated bylaws, as we expect they will be in effect immediately before the completion of this offering, could have the effect of delaying, deferring or discouraging another person from acquiring control of our Company. These provisions, which are summarized below, may have the effect of discouraging takeover bids. They are also designed, in part, to encourage persons seeking to acquire control of us to negotiate first with our board of directors. We believe that the benefits of increased protection of our potential ability to negotiate with an unfriendly or unsolicited acquirer outweigh the disadvantages of discouraging a proposal to acquire us because negotiation of these proposals could result in an improvement of their terms.

Delaware Law

We are subject to the provisions of Section 203 of the DGCL regulating corporate takeovers. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years following the date on which the person became an interested stockholder unless:

- prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;

- the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, but not the outstanding voting stock owned by the interested stockholder, (i) shares owned by persons who are directors and also executive officers and (ii) shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- at or subsequent to the date of the transaction, the business combination is approved by the board of directors of the corporation and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66.67% of the outstanding voting stock that is not owned by the interested stockholder.

Generally, a business combination includes a merger, asset or stock sale, or other transaction or series of transactions together resulting in a financial benefit to the interested stockholder. An interested stockholder is a person who, together with affiliates and associates, owns or, within three years prior to the determination of interested stockholder status, did own 15% or more of a corporation's outstanding voting stock. We expect the existence of this provision to have an anti-takeover effect with respect to transactions our board of directors does not approve in advance. We also anticipate that Section 203 of the DGCL may also discourage attempts that might result in a premium over the market price for the shares of common stock held by stockholders.

Restated Certificate of Incorporation and Restated Bylaw Provisions

Our restated certificate of incorporation and our restated bylaws, as we expect they will be in effect upon the completion of this offering, include a number of provisions that could deter hostile takeovers or delay or prevent changes in control of our Company, including the following:

- *Board of Directors Vacancies*. Our restated certificate of incorporation and restated bylaws will authorize only our board of directors to fill vacant directorships, including newly created seats. In addition, the number of directors constituting our board of directors is permitted to be set only by a resolution adopted by a majority vote of our entire board of directors. These provisions would prevent a stockholder from increasing the size of our board of directors and then gaining control of our board of directors by filling the resulting vacancies with its own nominees. This makes it more difficult to change the composition of our board of directors but promotes continuity of management.
- *Classified Board*. Our restated certificate of incorporation and restated bylaws will provide that our board of directors is classified into three classes of directors, each with staggered three- year terms. A third party may be discouraged from making a tender offer or otherwise attempting to obtain control of us as it is more difficult and time consuming for stockholders to replace a majority of the directors on a classified board of directors. See the section titled "Management—Classified Board of Directors" for additional information.
- *Stockholder Action; Special Meetings of Stockholders*. Our restated certificate of incorporation will provide that our stockholders may not take action by written consent but may only take action at annual or special meetings of our stockholders. As a result, a holder controlling a majority of our capital stock would not be able to amend our restated bylaws or remove directors without holding a meeting of our stockholders called in accordance with our restated bylaws. Further, our restated certificate of incorporation and restated bylaws will provide that special meetings of our stockholders may be called only by a majority of our board of directors, the Chairperson of our board of directors, our Chief Executive Officer or our President, thus prohibiting a stockholder from calling a special meeting. These provisions might delay the ability of our stockholders to force consideration of a proposal or for stockholders controlling a majority of our capital stock to take any action, including the removal of directors.
- *Advance Notice Requirements for Stockholder Proposals and Director Nominations*. Our restated bylaws will provide advance notice procedures for stockholders seeking to bring business before our

annual meeting of stockholders or to nominate candidates for election as directors at our annual meeting of stockholders. Our restated bylaws also will specify certain requirements regarding the form and content of a stockholder's notice. These provisions might preclude our stockholders from bringing matters before our annual meeting of stockholders or from making nominations for directors at our annual meeting of stockholders if the proper procedures are not followed. We expect that these provisions might also discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of our Company.

- *No Cumulative Voting*. The DGCL provides that stockholders are not entitled to the right to cumulate votes in the election of directors unless a corporation's certificate of incorporation provides otherwise. Our restated certificate of incorporation and restated bylaws will not provide for cumulative voting.
- *Directors Removed Only for Cause*. Our restated certificate of incorporation will provide that stockholders may remove directors only for cause and only by the affirmative vote of the holders of at least two-thirds of our outstanding common stock.
- *Amendment of Charter Provisions*. Any amendment of the above expected provisions in our restated certificate of incorporation will require approval by the holders of at least two-thirds of our outstanding common stock, unless such amendments are approved by two thirds of our entire board of directors, in which case stockholders can approve by a simple majority.
- *Issuance of Undesignated Preferred Stock*. Our board of directors has the authority, without further action by the stockholders, to issue up to shares of undesignated preferred stock with rights and preferences, including voting rights, designated from time to time by our board of directors. The existence of authorized but unissued shares of preferred stock would enable our board of directors to render more difficult or to discourage an attempt to obtain control of us by merger, tender offer, proxy contest or other means.
- *Choice of Forum*. Our restated certificate of incorporation will provide that, to the fullest extent permitted by law, the Court of Chancery of the State of Delaware will be the exclusive forum for any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the DGCL, our restated certificate of incorporation or our restated bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. Our restated bylaws will provide that the federal district courts of the United States of America will, to the fullest extent permitted by law, be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, which we refer to as a Federal Forum Provision. Our decision to adopt a Federal Forum Provision followed a decision by the Supreme Court of the State of Delaware holding that such provisions are facially valid under Delaware law. While there can be no assurance that federal courts or other state courts will follow the holding of the Delaware Supreme Court or determine that the Federal Forum Provision should be enforced in a particular case, application of the Federal Forum Provision means that suits brought by our stockholders to enforce any duty or liability created by the Securities Act must be brought in federal court and cannot be brought in state court. While neither the exclusive forum provision nor the Federal Forum Provision applies to suits brought to enforce any duty or liability created by the Exchange Act, Section 27 of the Exchange Act creates exclusive federal jurisdiction over all claims brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. Accordingly, actions by our stockholders to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder also must be brought in federal court. Our stockholders will not be deemed to have waived our compliance with the federal securities laws and the regulations promulgated thereunder. Any person or entity purchasing or otherwise acquiring or holding any interest in any of our securities shall be deemed to have notice of and consented to our exclusive forum provisions, including the Federal Forum Provision. These provisions may limit a stockholder's ability to bring a claim in a judicial forum of their choosing for disputes with us or our directors, executive officers, other employees or agents of our Company, which may discourage lawsuits against us and our directors, executive officers and other employees.

Transfer Agent and Registrar

Upon the completion of this offering, the transfer agent and registrar for our common stock will be Computershare Trust Company, N.A. The transfer agent and registrar's address is 50 Royall Street, Canton, Massachusetts 02021, and its telephone number is (800) 962-4284.

Listing

We have applied to list our common stock on the Nasdaq Global Market under the symbol "BAGE," and this offering is contingent upon obtaining such approval.

Limitations on Liability and Indemnification Matters

For a discussion of liability and indemnification, see the section titled "Executive and Director Compensation—Limitations on Liability and Indemnification Matters."

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for our common stock, and we cannot predict the effect, if any, that market sales of shares of our common stock or the availability of shares of our common stock for sale will have on the market price of our common stock prevailing from time to time. Nevertheless, sales of our common stock, including shares issued upon exercise of outstanding options, in the public market following this offering could adversely affect market prices prevailing from time to time and could impair our ability to raise capital through the sale of our equity securities.

Upon the completion of this offering, based on shares of our capital stock outstanding as of December 31, 2023, we will have a total of shares of our common stock outstanding, assuming (i) the automatic conversion of all outstanding shares of our redeemable convertible preferred stock into an aggregate of shares of our common stock and (ii) the issuance of shares of common stock in this offering, assuming that the underwriters do not exercise their option to purchase up to an additional shares of common stock from us in part or in full. Of these outstanding shares, all of the shares of our common stock sold in this offering will be freely tradable, except that any shares purchased in this offering by our affiliates, as that term is defined in Rule 144 under the Securities Act can only be sold in compliance with the Rule 144 limitations described below.

The remaining outstanding shares of our common stock will be, and shares subject to stock options will be upon issuance, deemed "restricted securities" as defined in Rule 144. Restricted securities may be sold in the public market only if they are registered under the Securities Act or if they qualify for an exemption from registration under Rule 144 or Rule 701 promulgated under the Securities Act, which rules are summarized below. In addition, substantially all of our security holders have, or will have, entered into market standoff agreements with us or lock-up agreements with the underwriters under which they have agreed, subject to specific exceptions, not to sell any of our stock for at least 180 days following the date of this prospectus, as described below.

Lock-Up Agreements

We, our officers, directors and holders of substantially all of our securities, have agreed with the underwriters that for a period of 180 days, after the date of this prospectus, among other things and subject to certain exceptions, we or they will not offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to sell, or otherwise dispose of or transfer any shares of common stock or any securities convertible into or exercisable or exchangeable for shares of common stock, request or demand that we file a registration statement related to our common stock or enter into any swap or other agreement that transfers to another, in whole or in part, directly or indirectly, the economic consequence of ownership of the common stock, or publicly declare an intention to do any of the foregoing. Upon expiration of the lock-up period, certain of our stockholders will have the right to require us to register their shares under the Securities Act. See the subsection titled "Registration Rights" below and the section titled "Description of Capital Stock—Registration Rights."

Goldman Sachs & Co. LLC, Morgan Stanley & Co. LLC and Jefferies LLC, may, in their sole discretion and at any time or from time to time before the termination of the lock-up period, in certain cases without public notice, release all or any portion of the securities subject to lock-up agreements. There are no existing agreements between the underwriters and any of our stockholders who will execute a lock-up agreement providing consent to the sale of shares prior to the expiration of the lock-up period. See the section titled "Underwriting" for additional information.

Upon the expiration of the lock-up period, substantially all of the shares subject to such lock-up restrictions will become eligible for sale, subject to the limitations discussed above.

Rule 144

In general, Rule 144 provides that once we have been subject to public company reporting requirements of Section 13 or Section 15(d) of the Exchange Act for at least 90 days, a person who is not deemed to have been

one of our affiliates for purposes of the Securities Act at any time during the 90 days preceding a sale and who has beneficially owned the shares of our common stock proposed to be sold for at least six months, including the holding period of any prior owner other than our affiliates, is entitled to sell those shares without complying with the manner of sale, volume limitation or notice provisions of Rule 144, subject to compliance with the public information requirements of Rule 144. If such a person has beneficially owned the shares proposed to be sold for at least one year, including the holding period of any prior owner other than our affiliates, then that person would be entitled to sell those shares without complying with any of the requirements of Rule 144.

In general, Rule 144 provides that our affiliates or persons selling shares of our common stock on behalf of our affiliates are entitled to sell upon expiration of the lock-up and market standoff agreements described above, within any three-month period, a number of shares of our common stock that does not exceed the greater of:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately shares immediately after the completion of this offering; or
- the average reported weekly trading volume of shares of our common stock during the four calendar weeks preceding the filing of a notice on Form 144 with respect to that sale.

Sales under Rule 144 by our affiliates or persons selling shares of our common stock on behalf of our affiliates are also subject to certain manner of sale provisions and notice requirements and to the availability of current public information about us.

Rule 701

Rule 701 generally allows a stockholder who purchased shares of our common stock pursuant to a written compensatory plan or contract and who is not deemed to have been an affiliate of our Company during the immediately preceding 90 days to sell these shares in reliance upon Rule 144, but without being required to comply with the public information, holding period, volume limitation or notice provisions of Rule 144. Rule 701 also permits our affiliates to sell their Rule 701 shares under Rule 144 without complying with the holding period requirements of Rule 144. All holders of Rule 701 shares, however, are required to wait until 90 days after the date of this prospectus before selling those shares pursuant to Rule 701 and are subject to the lock-up and market standoff agreements described above.

Form S-8 Registration Statement

In connection with this offering, we intend to file a registration statement on Form S-8 under the Securities Act covering all of the shares of our common stock subject to outstanding options, outstanding shares of restricted stock and the shares of our common stock reserved for issuance under our equity incentive plans. We expect to file this registration statement as soon as permitted under the Securities Act. However, the shares registered on Form S-8 held by affiliates may be subject to the volume limitations and the manner of sale, notice and public information requirements of Rule 144 and will not be eligible for resale until expiration of the lock-up and market standoff agreements to which they are subject. Of the 20,183,532 shares of our common stock that were subject to options outstanding as of June 30, 2024, options to purchase 7,395,191 shares of common stock were vested as of June 30, 2024. Shares of our common stock underlying outstanding options will not be eligible for sale until the expiration of the 180-day lock-up and market standoff agreements to which they are subject.

Registration Rights

We have granted demand, piggyback and Form S-3 registration rights to certain of our stockholders to sell our common stock. Registration of the sale of these shares under the Securities Act would result in these shares becoming freely tradable without restriction under the Securities Act immediately upon the effectiveness of the registration, except for shares purchased by affiliates. See the section titled “Description of Capital Stock—Registration Rights” for additional information.

MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS

The following summary describes the material U.S. federal income tax consequences of the ownership and disposition of shares of our common stock acquired in this offering by Non-U.S. Holders (as defined below). This discussion does not address all aspects of U.S. federal income taxation, does not discuss the potential application of the alternative minimum tax provisions of the U.S. Internal Revenue Code of 1986, as amended (the Code) or the Medicare contribution tax on net investment income, and does not deal with state or local tax laws, any U.S. federal non-income tax laws such as gift and estate tax laws, except to the limited extent provided below, or any non-U.S. tax laws that may be relevant to Non-U.S. Holders in light of their particular circumstances.

Special rules different from those described below may apply to certain Non-U.S. Holders that are subject to special treatment under the Code, such as:

- insurance companies, banks, investment funds and other financial institutions;
- tax-exempt organizations (including private foundations) and tax-qualified retirement plans;
- foreign governments and international organizations;
- broker-dealers and traders in securities;
- U.S. expatriates and certain former citizens or long-term residents of the United States;
- persons required for U.S. federal income tax purposes to conform the timing of income accruals to their financial statements under Section 451(b) of the Code;
- "qualified foreign pension funds" as defined in Section 897(l)(2) of the Code and entities all of the interests of which are held by qualified foreign pension funds;
- persons that own, or are deemed to own, more than 5% of our common stock;
- "controlled foreign corporations," "passive foreign investment companies" and corporations that accumulate earnings to avoid U.S. federal income tax;
- persons that hold our common stock as part of a "straddle," "hedge," "conversion transaction," "synthetic security" or integrated investment or other risk reduction strategy;
- persons who do not hold our common stock as a capital asset within the meaning of Section 1221 of the Code (generally, for investment purposes); and
- partnerships and other entities or arrangements treated as pass-through entities for U.S. federal income tax purposes, and investors in such entities (regardless of their places of organization or formation).

Such Non-U.S. Holders are urged to consult their own tax advisors to determine the U.S. federal, state, local and other tax consequences that may be relevant to them. If an entity or arrangement that is classified as a partnership for U.S. federal income tax purposes holds our common stock, the U.S. federal income tax treatment of the partnership and the partners thereof generally will depend on the status of the partner and the activities of the partnership. Partnerships holding our common stock and the partners in such partnerships are urged to consult their tax advisors about the particular U.S. federal income tax consequences to them of holding and disposing of our common stock.

Furthermore, the discussion below is based upon the provisions of the Code, U.S. Treasury Regulations promulgated thereunder, published rulings and administrative pronouncements of the U.S. Internal Revenue Service (IRS), and judicial decisions, in each case as of the date hereof, and such authorities may be repealed, revoked or modified, possibly retroactively, or could be subject to differing interpretations which could result in U.S. federal income tax consequences different from those discussed below. We have not requested a ruling from the IRS with respect to the statements made and the conclusions reached in the following summary, and there can

be no assurance that the IRS will not take a contrary position regarding the tax consequences described herein, or that any such contrary position would not be sustained by a court.

NON-U.S. HOLDERS CONSIDERING THE PURCHASE OF OUR COMMON STOCK PURSUANT TO THIS OFFERING SHOULD CONSULT THEIR OWN TAX ADVISORS CONCERNING THE U.S. FEDERAL INCOME TAX CONSEQUENCES OF ACQUIRING, OWNING AND DISPOSING OF OUR COMMON STOCK IN LIGHT OF THEIR PARTICULAR SITUATIONS AS WELL AS ANY CONSEQUENCES ARISING UNDER THE LAWS OF ANY OTHER TAXING JURISDICTION, INCLUDING ANY STATE, LOCAL OR NON-U.S. TAX CONSEQUENCES OR ANY U.S. FEDERAL NON-INCOME TAX CONSEQUENCES, AND THE POSSIBLE APPLICATION OF TAX TREATIES.

For the purposes of this discussion, a "Non-U.S. Holder" is a beneficial owner of common stock, other than a partnership or other entity or arrangement treated as a pass-through entity, that is not, for U.S. federal income tax purposes, (a) an individual who is a citizen or resident of the United States, (b) a corporation (or other entity taxable as a corporation for U.S. federal income tax purposes) created or organized in or under the laws of the United States, any state thereof or the District of Columbia, (c) an estate, the income of which is subject to U.S. federal income taxation regardless of its source, or (d) a trust that (1) is subject to the primary supervision of a court within the United States and one or more United States persons (within the meaning of Section 7701(a)(30) of the Code) have the authority to control all substantial decisions of the trust or (2) has a valid election in effect under applicable U.S. Treasury Regulations to be treated as a United States person.

If you are an individual non-U.S. citizen, you may, in some cases, be deemed to be a resident alien (as opposed to a nonresident alien) by virtue of being present in the United States for at least 31 days in the calendar year and for an aggregate of at least 183 days during a three-year period ending in the current calendar year. Generally, for this purpose, all the days present in the current year, one-third of the days present in the immediately preceding year, and one-sixth of the days present in the second preceding year, are counted.

Resident aliens are generally subject to U.S. federal income tax as if they were U.S. citizens. Individuals who are uncertain of their status as resident or nonresident aliens for U.S. federal income tax purposes are urged to consult their own tax advisors regarding the U.S. federal income tax consequences of the ownership or disposition of our common stock.

Distributions

We do not expect to make any distributions on our common stock in the foreseeable future. If we do make distributions on our common stock, however, such distributions will constitute dividends for U.S. tax purposes to the extent paid out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles). Distributions in excess of our current and accumulated earnings and profits will constitute a return of capital that is applied against and reduces, but not below zero, a Non-U.S. Holder's adjusted tax basis in our common stock. Any remaining excess will be treated as gain realized on the sale or exchange of our common stock as described below under the section titled "Material U.S. Federal Income Tax Consequences to Non-U.S. Holders– Gain on Disposition of Our Common Stock."

Subject to the discussions below under the sections titled "Material U.S. Federal Income Tax Consequences to Non-U.S. Holders—Backup Withholding and Information Reporting" and "Material U.S. Federal Income Tax Consequences to Non-U.S. Holders—Foreign Accounts," any distribution on our common stock that is treated as a dividend paid to a Non-U.S. Holder will generally be subject to U.S. federal withholding tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and the Non-U.S. Holder's country of residence. To obtain a reduced rate of withholding under an income tax treaty, a Non-U.S. Holder generally will be required to provide the applicable withholding agent with a properly executed IRS Form W-8BEN, IRS Form W-8BEN-E or other appropriate form, certifying the Non-U.S. Holder's entitlement to benefits under the treaty. Such form must be provided prior to the payment of dividends and

generally must be updated periodically. If a Non-U.S. Holder holds stock through a financial institution or other agent acting on the holder's behalf, the holder will be required to provide appropriate documentation to such agent. The holder's agent may then be required to provide certification to the applicable withholding agent, either directly or through other intermediaries. If you are eligible for a reduced rate of U.S. withholding tax under an income tax treaty, you should consult with your own tax advisor to determine if you are able to obtain a refund of any excess amounts withheld by timely filing an appropriate claim for a refund with the IRS.

We generally are not required to withhold tax on dividends paid to a Non-U.S. Holder that are effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, are attributable to a permanent establishment that the holder maintains in the United States) if a properly executed IRS Form W-8ECI, stating that the dividends are so connected, is furnished to the applicable withholding agent. In general, such effectively connected dividends will be subject to U.S. federal income tax on a net income basis at the same rates applicable to United States persons. A corporate Non-U.S. Holder receiving effectively connected dividends may also be subject to an additional "branch profits tax," which is imposed, under certain circumstances, at a rate of 30% (or such lower rate as may be specified by an applicable treaty) on the corporate Non-U.S. Holder's effectively connected earnings and profits, subject to certain adjustments.

Gain on Disposition of Our Common Stock

Subject to the discussions below under the sections titled "Material U.S. Federal Income Tax Consequences to Non-U.S. Holders—Backup Withholding and Information Reporting" and "Material U.S. Federal Income Tax Consequences to Non-U.S. Holders —Foreign Accounts," a Non-U.S. Holder generally will not be subject to U.S. federal income or withholding tax with respect to gain realized on a sale or other disposition of our common stock unless (a) the gain is effectively connected with a trade or business of the Non-U.S. Holder in the United States (and, if required by an applicable income tax treaty, is attributable to a permanent establishment that the holder maintains in the United States), (b) the Non-U.S. Holder is a nonresident alien who is an individual and is present in the United States for 183 or more days in the taxable year of the disposition and certain other conditions are met, or (c) we are or have been a "United States real property holding corporation" within the meaning of Code Section 897(c)(2) at any time within the shorter of the five- year period preceding such disposition or the Non-U.S. Holder's holding period in the common stock.

If you are a Non-U.S. Holder described in (a) above, you will be required to pay tax on the net gain derived from the sale at the same U.S. federal income tax rates applicable to United States persons. Corporate Non-U.S. Holders described in (a) above may also be subject to the additional branch profits tax at a 30% rate (or such lower rate as may be specified by an applicable income tax treaty) of their effectively connected earnings and profits for the taxable year, as adjusted for certain items. If you are an individual Non-U.S. Holder described in (b) above, you will be required to pay a flat 30% tax on the gain derived from the sale, which gain may be offset by certain U.S.-source capital losses (even though you are not considered a resident of the United States), provided you have timely filed U.S. federal income tax returns with respect to such losses. With respect to (c) above, in general, we would be a United States real property holding corporation if U.S. real property interests as defined in the Code and the U.S. Treasury Regulations comprised (by fair market value) at least half of the sum of our worldwide real property interests plus our other assets used or held for use in a trade or business. We believe that we are not, and do not anticipate becoming, a United States real property holding corporation. However, there can be no assurance that we will not become a United States real property holding corporation in the future. Even if we were to be treated as a U.S. real property holding corporation, gain realized by a Non-U.S. Holder on a disposition of our common stock would not be subject to U.S. federal income tax so long as (1) the Non-U.S. Holder owned, directly, indirectly or constructively, no more than 5% of our common stock at all times within the shorter of (i) the five-year period preceding the disposition or (ii) the Non-U.S. Holder's holding period and (2) our common stock is regularly traded on an established securities market. There can be no assurance that our common stock will qualify as regularly traded on an established securities market.

U.S. Federal Estate Tax

The estates of nonresident alien individuals generally are subject to U.S. federal estate tax on property with a U.S. situs. Because we are a U.S. corporation, our common stock will be U.S. situs property and, therefore, will be included in the taxable estate of a nonresident alien decedent, unless an applicable estate tax treaty between the United States and the decedent's country of residence provides otherwise. The terms "resident" and "nonresident" are defined differently for U.S. federal estate tax purposes than for U.S. federal income tax purposes. Investors are urged to consult their own tax advisors regarding the U.S. federal estate tax consequences of the ownership or disposition of our common stock, including the application of any applicable estate tax treaty.

Backup Withholding and Information Reporting

Generally, we or certain financial middlemen must report information to the IRS with respect to any distributions we pay on our common stock, including the amount of any such distributions, the name and address of the recipient, and the amount, if any, of tax withheld. A similar report is sent to the holder to whom any such dividends are paid. Pursuant to tax treaties or certain other agreements, the IRS may make its reports available to tax authorities in the recipient's country of residence.

Distributions paid by us (or our paying agents) to a Non-U.S. Holder may also be subject to U.S. federal backup withholding. U.S. federal backup withholding generally will not apply to a Non-U.S. Holder who provides a properly executed IRS Form W-8BEN, IRS Form W-8BEN-E, or IRS Form W-8 ECI, as applicable, or otherwise establishes an exemption, *provided that* the applicable withholding agent does not have actual knowledge or reason to know the holder is a United States person.

Under current U.S. federal income tax law, U.S. information reporting and backup withholding requirements generally will apply to the proceeds of a disposition of our common stock effected by or through a U.S. broker or a U.S. office of any broker, U.S. or non-U.S., unless the Non-U.S. Holder provides a properly executed IRS Form W-8BEN or IRS Form W-8BEN-E, or IRS Form W-8 ECI, as applicable, or otherwise establishes an exemption. Generally, U.S. information reporting and backup withholding requirements will not apply to a payment of disposition proceeds to a Non-U.S. Holder where the transaction is effected outside the United States through a non-U.S. office of a non-U.S. broker. Information reporting and backup withholding requirements may, however, apply to a payment of disposition proceeds if the broker has actual knowledge, or reason to know, that the holder is, in fact, a United States person. For information reporting purposes, certain brokers with substantial U.S. ownership or operations will generally be treated in a manner similar to U.S. brokers.

Backup withholding is not an additional tax. If backup withholding is applied to you, you should consult with your own tax advisor to determine whether you have overpaid your U.S. federal income tax, and whether you are able to obtain a tax refund or credit of the overpaid amount.

Foreign Accounts

In addition, U.S. federal withholding taxes may apply under the Foreign Account Tax Compliance Act, or FATCA, on certain types of payments, including dividends paid to non-U.S. financial institutions and certain other non-U.S. entities. Specifically, a 30% withholding tax may be imposed on dividends on our common stock paid to a "foreign financial institution" or a "non-financial foreign entity" (each as defined in the Code), unless (1) the foreign financial institution agrees to undertake certain diligence and reporting obligations, (2) the non-financial foreign entity either certifies it does not have any "substantial United States owners" (as defined in the Code) or furnishes identifying information regarding each substantial United States owner, or (3) the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from these rules. The 30% federal withholding tax described in this paragraph cannot be reduced under an income tax treaty with the

United States. If the payee is a foreign financial institution and is subject to the diligence and reporting requirements in (1) above, it must enter into an agreement with the U.S. Department of the Treasury requiring, among other things, that it undertake to identify accounts held by certain "specified United States persons" or "United States-owned foreign entities" (each as defined in the Code), annually report certain information about such accounts, and withhold 30% on certain payments to non-compliant foreign financial institutions and certain other account holders. Foreign financial institutions located in jurisdictions that have an intergovernmental agreement with the United States governing FATCA may be subject to different rules. Under the applicable Treasury Regulations and administrative guidance, withholding under FATCA generally also would apply to payments of gross proceeds from the sale or other disposition of common stock. Under proposed regulations, however, no withholding will apply with respect to payments of gross proceeds. The preamble to the proposed regulations specifies that taxpayers are permitted to rely on such proposed regulations pending finalization.

Prospective investors should consult their tax advisors regarding the potential application of withholding under FATCA to their investment in our common stock.

EACH PROSPECTIVE INVESTOR SHOULD CONSULT ITS OWN TAX ADVISOR REGARDING THE TAX CONSEQUENCES OF PURCHASING, HOLDING AND DISPOSING OF OUR COMMON STOCK, INCLUDING THE CONSEQUENCES OF ANY PROPOSED CHANGE IN APPLICABLE LAW, AS WELL AS TAX CONSEQUENCES ARISING UNDER ANY STATE, LOCAL, NON-U.S. OR U.S. FEDERAL NON-INCOME TAX LAWS SUCH AS ESTATE AND GIFT TAX OR UNDER ANY APPLICABLE TAX TREATY.

UNDERWRITING

We and the underwriters named below have entered into an underwriting agreement with respect to the shares being offered. Subject to certain conditions, each underwriter has severally agreed to purchase the number of shares indicated in the following table. Goldman Sachs & Co. LLC, Morgan Stanley & Co. LLC, Jefferies LLC and Citigroup Global Markets Inc. are the representatives of the underwriters.

Underwriters	Number of Shares
Goldman Sachs & Co. LLC	
Morgan Stanley & Co. LLC	
Jefferies LLC	
Citigroup Global Markets Inc.	
Total	

The underwriters are committed to take and pay for all of the shares being offered, if any are taken, other than the shares covered by the option described below unless and until this option is exercised.

The underwriters have an option to buy up to an additional shares of our common stock from us to cover sales by the underwriters of a greater number of shares than the total number set forth in the table above. They may exercise that option for 30 days. If any shares are purchased pursuant to this option, the underwriters will severally purchase shares in approximately the same proportion as set forth in the table above.

The following table shows the per share and total underwriting discounts and commissions to be paid to the underwriters by us. Such amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase up to an additional shares of common stock from us.

	No Exercise	Full Exercise
Per Share	$	$
Total	$	$

Shares sold by the underwriters to the public will initially be offered at the initial public offering price set forth on the cover of this prospectus. Any shares sold by the underwriters to securities dealers may be sold at a discount of up to $ per share from the initial public offering price. After the initial offering of the shares, the representatives may change the offering price and the other selling terms. The offering of the shares by the underwriters is subject to receipt and acceptance and subject to the underwriters' right to reject any order in whole or in part.

We and our officers, directors, and holders of substantially all of our capital stock and securities convertible into or exchangeable for our common stock have agreed or will agree with the underwriters, subject to certain exceptions, not to dispose of or hedge any of our or their common stock or securities convertible into or exchangeable for shares of common stock during the period from the date of this prospectus continuing through the date 180 days after the date of this prospectus, except with the prior written consent of Goldman Sachs & Co. LLC, Morgan Stanley & Co. LLC, and Jefferies LLC. This agreement does not apply to any existing employee benefit plans. See the section titled "Shares Eligible for Future Sale" for a discussion of certain transfer restrictions.

The restrictions described above do not apply, subject in certain cases to various conditions, to our officers, directors and holders of substantially all of our capital stock with respect to certain transactions, including:

i. as one or more *bona fide* gifts or charitable contributions, or for *bona fide* estate planning purposes;

ii. upon death by will, testamentary document or the laws of intestate succession;

iii. if the stockholder is a natural person, to any member of the stockholder's immediate family (for purposes of the lock-up agreement, "immediate family" shall mean any relationship by blood, current or former marriage, domestic partnership or adoption, not more remote than first cousin) or to any trust for the direct or indirect benefit of the stockholder or the immediate family of the stockholder or, if the stockholder is a trust, to a trustor or beneficiary of the trust or the estate of a beneficiary of such trust;

iv. to a corporation, partnership, limited liability company or other entity of which the stockholder and the immediate family of the stockholder are the legal and beneficial owner of all of the outstanding equity securities or similar interests;

v. to a nominee or custodian of a person or entity to whom a disposition or transfer would be permissible under clauses (a)(i) through (iv) above;

vi. if the stockholder is a corporation, partnership, limited liability company or other business entity, (A) to another corporation, partnership, limited liability company or other business entity that is an affiliate (as defined in Rule 405 under the Securities Act) of the stockholder, or to any investment fund or other entity which fund or entity is controlled or managed by the stockholder or affiliates of the stockholder, or (B) as part of a distribution by the stockholder to its stockholders, partners, members or other equityholders or to the estate of any such stockholders, partners, members or other equityholders;

vii. by operation of law, such as pursuant to a qualified domestic order, divorce settlement, divorce decree or separation agreement;

viii. to us from our employee upon death, disability or termination of employment, in each case, of such employee;

ix. if the stockholder is not our officer or director, in connection with a sale of the stockholder's shares of common stock acquired (A) from the underwriters in the Public Offering or (B) in open market transactions after the closing date of the Public Offering;

x. to us in connection with the vesting, settlement or exercise of restricted stock units, options, warrants or other rights to purchase shares of common stock (including, in each case, by way of "net" or "cashless" exercise) that are scheduled to expire or automatically vest during the restricted period, including any transfer to us for the payment of tax withholdings or remittance payments due as a result of the vesting, settlement or exercise of such restricted stock units, options, warrants or other rights, or in connection with the conversion of convertible securities, in all such cases pursuant to equity awards granted under a stock incentive plan or other equity award plan, or pursuant to the terms of convertible securities, each as described in this registration statement, the preliminary prospectus relating to the Shares included in the Registration Statement immediately prior to the time the underwriting agreement is executed and the Prospectus, provided that any securities received upon such vesting, settlement, exercise or conversion shall be subject to the terms of the lock-up agreement;

xi. in connection with the sale on the open market or other similar transfer of up to 26,000 shares of common stock in the aggregate by certain of our former employees to satisfy any payment of exercise price, tax obligations or tax payments due as a result of the exercise of stock options, if such options expire or the post-termination exercise period applicable to such options expire during the restricted period, provided that any securities received upon such exercise that are not transferred to cover any such tax obligations shall be subject to the same lock-up restrictions, and provided further that no filing by any party (including, without limitation, any donor, donee, devisee, transferor, transferee, distributor or distributee) under the Exchange Act or other public filing, report or announcement shall be required or shall be voluntarily made in connection with such sale or transfer;

xii. with the prior written consent of Goldman Sachs & Co. LLC, Morgan Stanley & Co. LLC and Jefferies LLC on behalf of the underwriters;

xiii. entering into a written plan meeting the requirements of Rule 10b5-1 under the Exchange Act relating to the transfer, sale or other disposition of the securityholder's securities, if then permitted by us, provided that none of the securities subject to such plan may be transferred, sold or otherwise disposed of until after the expiration of the restricted period and no public announcement, report or filing under the Exchange Act, or any other public filing, report or announcement, shall be required or shall be voluntarily made regarding the establishment of such plan during the restricted period;

xiv. transfers pursuant to a bona fide third-party tender offer, merger, consolidation or other similar transaction that is approved by our board of directors and made to all holders of our capital stock involving a Change of Control (for purposes hereof, "Change of Control" shall mean the transfer (whether by tender offer, merger, consolidation or other similar transaction), in one transaction or a series of related transactions, to a person or group of affiliated persons, of shares of capital stock if, after such transfer, such person or group of affiliated persons would hold at least a majority of our outstanding voting securities (or the surviving entity)); provided that in the event that such tender offer, merger, consolidation or other similar transaction is not completed, the securityholder's securities shall remain subject to the provisions of the lock-up agreement; and

xv. conversions of our outstanding preferred stock into shares of common stock, provided that any such shares received upon such conversion shall remain subject to the provisions of the lock-up agreement.

provided that (A) in the case of clauses (i), (ii), (iii), (iv), (v) and (vi) above, such transfer or distribution shall not involve a disposition for value, (B) in the case of clauses (i), (ii), (iii), (iv), (v), (vi) and (vii) above, it shall be a condition to the transfer or distribution that the donee, devisee, transferee or distributee, as the case may be, shall sign and deliver a lock-up agreement in the form of this Lock-Up Agreement, (C) in the case of clauses (ii), (iii), (iv), (v) and (vi) above, no filing by any party (including, without limitation, any donor, donee, devisee, transferor, transferee, distributor or distributee) under the Exchange Act, or other public filing, report or announcement reporting a reduction in beneficial ownership of the stockholder's holdings shall be required or shall be voluntarily made in connection with such transfer or distribution, and (D) in the case of clauses (i), (vii), (viii), (ix) and (x) above, no filing under the Exchange Act or other public filing, report or announcement shall be voluntarily made, and if any such filing, report or announcement shall be legally required during the restricted period, such filing, report or announcement shall clearly indicate in the footnotes thereto (A) the circumstances of such transfer or distribution and (B) in the case of a transfer or distribution pursuant to clauses a(i) or (vii) above, that the donee, devisee, transferee or distributee has agreed to be bound by a lock-up agreement.

Prior to the offering, there has been no public market for the shares of our common stock. The initial public offering price has been negotiated among the company and the representatives. Among the factors to be considered in determining the initial public offering price of the shares, in addition to prevailing market conditions, will be the company's historical performance, estimates of the business potential and earnings prospects of the company, an assessment of our management and the consideration of the above factors in relation to market valuation of companies in related businesses.

We have applied to list our common stock on Nasdaq Global Market under the symbol "BAGE," and this offering is contingent upon obtaining such approval.

In connection with the offering, the underwriters may purchase and sell shares of our common stock in the open market. These transactions may include short sales, stabilizing transactions and purchases to cover positions created by short sales. Short sales involve the sale by the underwriters of a greater number of shares than they are

required to purchase in the offering, and a short position represents the amount of such sales that have not been covered by subsequent purchases. A "covered short position" is a short position that is not greater than the amount of additional shares for which the underwriters' option described above may be exercised. The underwriters may cover any covered short position by either exercising their option to purchase additional shares or purchasing shares in the open market. In determining the source of shares to cover the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase additional shares pursuant to the option described above. "Naked" short sales are any short sales that create a short position greater than the amount of additional shares for which the option described above may be exercised. The underwriters must cover any such naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of various bids for or purchases of common stock made by the underwriters in the open market prior to the completion of the offering.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representatives have repurchased shares sold by or for the account of such underwriter in stabilizing or short covering transactions.

Purchases to cover a short position and stabilizing transactions, as well as other purchases by the underwriters for their own accounts, may have the effect of preventing or retarding a decline in the market price of our common stock, and together with the imposition of the penalty bid, may stabilize, maintain or otherwise affect the market price of our common stock. As a result, the price of our common stock may be higher than the price that otherwise might exist in the open market. The underwriters are not required to engage in these activities and may end any of these activities at any time. These transactions may be effected on Nasdaq; in the over-the-counter market or otherwise.

We estimate that our share of the total expenses of the offering, excluding underwriting discounts and commissions, will be approximately $. We have agreed to reimburse the underwriters for certain of their expenses in an amount up to $.

We have agreed to indemnify the several underwriters against certain liabilities, including liabilities under the Securities Act.

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include sales and trading, commercial and investment banking, advisory, investment management, investment research, principal investment, hedging, market making, brokerage and other financial and non-financial activities and services. Certain of the underwriters and their respective affiliates may in the future provide, a variety of these services to us and to persons and entities with relationships with us, for which they will receive customary fees and expenses.

In the ordinary course of their various business activities, the underwriters and their respective affiliates, officers, directors and employees may purchase, sell or hold a broad array of investments and actively trade securities, derivatives, loans, commodities, currencies, credit default swaps and other financial instruments for their own account and for the accounts of their customers, and such investment and trading activities may involve or relate to assets, securities and/or instruments of ours (directly, as collateral securing other obligations or otherwise) and/or persons and entities with relationships with us. The underwriters and their respective affiliates may also communicate independent investment recommendations, market color or trading ideas and/or publish or express independent research views in respect of such assets, securities or instruments and may at any time hold, or recommend to clients that they should acquire, long and/or short positions in such assets, securities and instruments.

European Economic Area

In relation to each Member State of the European Economic Area (each a Relevant Member), no shares have been offered or will be offered pursuant to the offering to the public in that Relevant Member prior to the publication of a prospectus in relation to the shares which has been approved by the competent authority in that Relevant Member or, where appropriate, approved in another Relevant Member and notified to the competent authority in that Relevant Member, all in accordance with the Prospectus Regulation, except that the shares may be offered to the public in that Relevant Member at any time:

(a) to any legal entity which is a qualified investor as defined under Article 2 of the Prospectus Regulation;

(b) to fewer than 150 natural or legal persons (other than qualified investors as defined under Article 2 of the Prospectus Regulation), subject to obtaining the prior consent of the representatives for any such offer; or

(c) in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of the shares shall require us or any of the representatives to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation.

For the purposes of this provision, the expression an "offer to the public" in relation to the shares in any Relevant Member means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares, and the expression "Prospectus Regulation" means Regulation (EU) 2017/1129.

United Kingdom

No shares have been offered or will be offered pursuant to the offering to the public in the United Kingdom prior to the publication of a prospectus in relation to the shares which has been approved by the Financial Conduct Authority, except that the shares may be offered to the public in the United Kingdom at any time:

(a) to any legal entity which is a qualified investor as defined under Article 2 of the UK Prospectus Regulation;

(b) to fewer than 150 natural or legal persons (other than qualified investors as defined under Article 2 of the UK Prospectus Regulation), subject to obtaining the prior consent of the representatives for any such offer; or

(c) in any other circumstances falling within Section 86 of the FSMA;

provided that no such offer of the shares shall require the Issuer or Manager to publish a prospectus pursuant to Section 85 of the FSMA or supplement a prospectus pursuant to Article 23 of the UK Prospectus Regulation. For the purposes of this provision, the expression an "offer to the public" in relation to the shares in the United Kingdom means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares and the expression. "UK Prospectus Regulation" means Regulation (EU) 2017/1129 as it forms part of domestic law by virtue of the European Union (Withdrawal) Act 2018.

Canada

The securities may be sold in Canada only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions, and Ongoing Registrant Obligations. Any resale of the securities must be made in accordance with an exemption form, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory of these rights or consult with a legal advisor.

Pursuant to section 3A.3 of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

Hong Kong

The shares may not be offered or sold in Hong Kong by means of any document other than (i) in circumstances which do not constitute an offer to the public within the meaning of the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32 of the Laws of Hong Kong) (Companies (Winding Up and Miscellaneous Provisions) Ordinance) or which do not constitute an invitation to the public within the meaning of the Securities and Futures Ordinance (Cap. 571 of the Laws of Hong Kong) (Securities and Futures Ordinance), or (ii) to "professional investors" as defined in the Securities and Futures Ordinance and any rules made thereunder, or (iii) in other circumstances which do not result in the document being a "prospectus" as defined in the Companies (Winding Up and Miscellaneous Provisions) Ordinance, and no advertisement, invitation or document relating to the shares may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public in Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to shares which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" in Hong Kong as defined in the Securities and Futures Ordinance and any rules made thereunder.

Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares may not be circulated or distributed, nor may the shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor (as defined under Section 4A of the Securities and Futures Act, Chapter 289 of Singapore (the SFA)) under Section 274 of the SFA, (ii) to a relevant person (as defined in Section 275(2) of the SFA) pursuant to Section 275(1) of the SFA, or any person pursuant to Section 275(1A) of the SFA, and in accordance with the conditions specified in Section 275 of the SFA or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA, in each case subject to conditions set forth in the SFA.

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor, the securities (as defined in Section 239(1) of the SFA) of that corporation shall not be transferable for 6 months after that corporation has acquired the shares under Section 275 of the SFA except: (1) to an institutional investor under Section 274 of the SFA or to a relevant person (as defined in Section 275(2) of the SFA), (2) where such transfer arises from an offer in that corporation's securities pursuant to Section 275(1A) of the SFA, (3) where no consideration is or will be given for the transfer, (4) where the transfer is by operation of law, (5) as specified in Section 276(7) of the SFA, or (6) as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore (Regulation 32).

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is a trust (where the trustee is not an accredited investor (as defined in Section 4A of the SFA)) whose sole purpose is to hold investments and each beneficiary of the trust is an accredited investor, the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferable for 6 months after that trust has acquired the shares under Section 275 of the SFA except: (1) to an institutional investor under Section 274 of the SFA or to a relevant person (as defined in Section 275(2) of the SFA), (2) where such transfer arises from an offer that is made on terms that such rights or interest are acquired at a consideration of not less than $200,000 (or its equivalent in a foreign currency) for each transaction (whether such amount is to be paid for in cash or by exchange of securities or other assets), (3) where no consideration is or will be given for the transfer, (4) where the transfer is by operation of law, (5) as specified in Section 276(7) of the SFA, or (6) as specified in Regulation 32.

Solely for the purposes of its obligations pursuant to Section 309B of the SFA, we have determined, and hereby notify all relevant persons (as defined in the CMP Regulations 2018), that the shares are "prescribed capital markets products" (as defined in the CMP Regulations 2018) and Excluded Investment Products (as defined in MAS Notice SFA 04-N12: Notice on the Sale of Investment Products and MAS Notice FAA-N16: Notice on Recommendations on Investment Products).

Japan

The securities have not been and will not be registered under the Financial Instruments and Exchange Act of Japan (Act No. 25 of 1948, as amended), or the FIEA. The securities may not be offered or sold, directly or indirectly, in Japan or to or for the benefit of any resident of Japan (including any person resident in Japan or any corporation or other entity organized under the laws of Japan) or to others for reoffering or resale, directly or indirectly, in Japan or to or for the benefit of any resident of Japan, except pursuant to an exemption from the registration requirements of the FIEA and otherwise in compliance with any relevant laws and regulations of Japan.

Australia

No placement document, prospectus, product disclosure statement or other disclosure document has been lodged with the Australian Securities and Investments Commission (ASIC), in relation to the offering. This offering document does not constitute a prospectus, product disclosure statement or other disclosure document under the Corporations Act 2001 (the Corporations Act), and does not purport to include the information required for a prospectus, product disclosure statement or other disclosure document under the Corporations Act.

Any offer in Australia of the shares may only be made to persons (the Exempt Investors) who are "sophisticated investors" (within the meaning of section 708(8) of the Corporations Act), "professional investors" (within the meaning of section 708(11) of the Corporations Act) or otherwise pursuant to one or more exemptions contained in section 708 of the Corporations Act so that it is lawful to offer the shares without disclosure to investors under Chapter 6D of the Corporations Act.

The shares applied for by Exempt Investors in Australia must not be offered for sale in Australia in the period of 12 months after the date of allotment under the offering, except in circumstances where disclosure to investors under Chapter 6D of the Corporations Act would not be required pursuant to an exemption under section 708 of the Corporations Act or otherwise or where the offer is pursuant to a disclosure document which complies with Chapter 6D of the Corporations Act. Any person acquiring shares must observe such Australian on-sale restrictions.

This offering document contains general information only and does not take account of the investment objectives, financial situation or particular needs of any particular person. It does not contain any securities recommendations or financial product advice. Before making an investment decision, investors need to consider whether the information in this offering document is appropriate to their needs, objectives and circumstances, and, if necessary, seek expert advice on those matters.

Dubai International Financial Centre

This offering document relates to an Exempt Offer in accordance with the Offered Securities Rules of the Dubai Financial Services Authority (DFSA). This offering document is intended for distribution only to persons of a type specified in the Offered Securities Rules of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus nor taken steps to verify the information set forth in this prospectus and has no responsibility for the offering document. The securities to which this offering document relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the securities offered should conduct their own due diligence on the securities. If you do not understand the contents of this offering document you should consult an authorized financial advisor.

Switzerland

This offering document is not intended to constitute an offer or solicitation to purchase or invest in the shares of our common stock. The shares of common stock may not be publicly offered, directly or indirectly, in Switzerland within the meaning of the Swiss Financial Services Act (FinSA), and no application has or will be made to admit the shares of common stock to trading on any trading venue (exchange or multilateral trading facility) in Switzerland. Neither this offering document nor any other offering or marketing material relating to the shares of common stock constitutes a prospectus pursuant to the FinSA, and neither this offering document nor any other offering or marketing material relating to the shares of common stock may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this offering document nor any other offering or marketing material relating to the offering, us or the securities have been or will be filed with or approved by any Swiss regulatory authority. In particular, this offering document will not be filed with, and the offer of securities will not be supervised by, the Swiss Financial Market Supervisory Authority, or the FINMA, and the offer of securities has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes (CISA). The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of securities.

Brazil

The offer and sale of securities have not been and will not be registered with the Brazilian Securities Commission (Commisão de Valores Mobilários, or CVM) and, therefore, will not be carried out by any means that would constitute a public offering in Brazil under CVM Resolution no 160, dated 13 July 2022, as amended (CVM Resolution 160) or unauthorized distribution under Brazilian laws and regulations. The securities may only be offered to Brazilian professional investors (as defined by applicable CVM regulation), who may only acquire the securities through a non-Brazilian account, with settlement outside Brazil in non-Brazilian currency. The trading of these securities on regulated securities markets in Brazil is prohibited.

LEGAL MATTERS

The validity of the shares of our common stock offered by this prospectus will be passed upon for us by Fenwick & West LLP, San Francisco, California. As of the date of this prospectus, individuals and entities associated with Fenwick & West LLP beneficially own an aggregate of 74,326 shares of our common stock. Cooley LLP, San Diego, California is acting as counsel for the underwriters in connection with this offering.

EXPERTS

The consolidated financial statements of BioAge Labs, Inc. as of December 31, 2023 and 2022 and for each of the years in the two-year period ended December 31, 2023, have been included herein and in the registration statement in reliance upon the report of KPMG LLP, independent registered public accounting firm, appearing elsewhere herein, and upon the authority of said firm as experts in accounting and auditing.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of our common stock offered hereby. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement or the exhibits filed therewith. For further information about us and the common stock offered hereby, reference is made to the registration statement and the exhibits filed therewith. Statements contained in this prospectus concerning the contents of any contract or any document are not necessarily complete. Each statement in this prospectus relating to a contract or document filed as an exhibit is qualified in all respects by the filed exhibit. The exhibits to the registration statement should be reviewed for the complete contents of these contracts and documents.

We currently do not file periodic reports with the SEC. Upon the completion of this offering, we will be required to file periodic reports, proxy statements and other information with the SEC pursuant to the Exchange Act. The SEC maintains a website that contains reports, proxy and information statements and other information regarding registrants that file electronically with the SEC. The address of the website is www.sec.gov.

We also maintain a website at https://www.escientpharma.com. Upon completion of this offering, you may access our proxy statements, annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act with the SEC on our website free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. The information contained on, or that can be accessed through, our website is not part of, and is not incorporated into, this prospectus, and you should not consider the contents of our website in making an investment decision with respect to our common stock. We have included our website in this prospectus solely as an inactive textual reference.

BIOAGE LABS, INC.
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors
BioAge Labs, Inc.:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of BioAge Labs, Inc. and subsidiary (the Company) as of December 31, 2023 and 2022, the related consolidated statements of operations and comprehensive loss, redeemable convertible preferred stock and stockholders' deficit, and cash flows for each of the years in the two-year period ended December 31, 2023, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2023, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (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 and in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated 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 consolidated 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 consolidated 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 consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ KPMG LLP

We have served as the Company's auditor since 2021.

San Francisco, California
May 31, 2024

BIOAGE LABS, INC.
Consolidated Balance Sheets
(in thousands, except share and per share information)

	December 31, 2023	December 31, 2022
Assets:		
Current assets:		
Cash and cash equivalents	$ 21,644	$ 27,644
Restricted cash	3,313	—
Prepaid expenses and other current assets	349	386
Total current assets	25,306	28,030
Investments	100	—
Property and equipment, net	323	323
Operating right-of-use asset, net	195	51
Other assets	—	25
Total assets	$ 25,924	$ 28,429
Liabilities, redeemable convertible preferred stock and stockholders' deficit:		
Current liabilities:		
Accounts payable	$ 1,866	$ 2,261
Accrued expenses and other current liabilities	7,938	3,384
Current portion of term loan	6,000	167
Operating lease liabilities, current	194	49
Convertible promissory notes	20,674	—
Convertible promissory notes embedded derivative liability	18,183	—
Deferred grant income	3,313	—
Total current liabilities	58,168	5,861
Term loan	8,201	2,252
Warrant liability	229	153
Total liabilities	66,598	8,266
Redeemable convertible preferred stock, par value of $0.00001, 31,634,362 shares authorized as of December 31, 2023 and 2022, and 31,465,128 shares issued and outstanding as of December 31, 2023 and 2022; aggregate liquidation preference of $131,864 as of December 31, 2023 and 2022	132,722	132,722
Commitments and Contingencies (note 8)		
Stockholders' deficit:		
Common stock, $0.00001 par value; 52,400,000 shares authorized as of December 31, 2023 and 2022; 7,467,378 and 7,464,463 shares issued and outstanding as of December 31, 2023 and 2022, respectively	—	—
Additional paid-in capital	8,142	5,122
Accumulated other comprehensive income	164	167
Accumulated deficit	(181,702)	(117,848)
Total stockholders' deficit	(173,396)	(112,559)
Total liabilities, redeemable convertible preferred stock, and stockholders' deficit	$ 25,924	$ 28,429

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

BIOAGE LABS, INC.
Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share information)

	Year Ended December 31,	
	2023	2022
Operating expenses:		
Research and development	$ 33,886	$ 30,522
General and administrative	14,514	9,447
Total operating expenses	48,400	39,969
Loss from operations	(48,400)	(39,969)
Other income (expense), net:		
Interest expense	(7,794)	(241)
Interest and other income	2,431	465
Gain (loss) from changes in fair value of warrants and derivative liabilities	(10,091)	23
Total other income (expense), net	(15,454)	247
Net loss	$ (63,854)	$ (39,722)
Net loss per share attributable to common stockholders, basic and diluted	$ (8.55)	$ (5.32)
Weighted-average common shares outstanding, basic and diluted	7,465,008	7,460,403
Comprehensive loss		
Net loss	(63,854)	(39,722)
Foreign currency translation adjustment	(3)	246
Total comprehensive loss	$ (63,857)	$ (39,476)

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

BIOAGE LABS, INC.
Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Deficit
(in thousands, except share information)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount				
Balance, December 31, 2021	31,465,128	$132,722	7,452,115	$ —	$ 2,538	$ (79)	$ (78,126)	$ (75,667)
Issuance of common stock upon exercise of options	—	—	12,348	—	44	—	—	44
Stock-based compensation expense	—	—	—	—	2,540	—	—	2,540
Translation adjustment	—	—	—	—	—	246	—	246
Net loss	—	—	—	—	—	—	(39,722)	(39,722)
Balance, December 31, 2022	31,465,128	$132,722	7,464,463	$ —	$ 5,122	$ 167	$ (117,848)	$ (112,559)
Issuance of common stock upon exercise of options	—	—	2,915	—	4	—	—	4
Stock-based compensation expense	—	—	—	—	3,016	—	—	3,016
Translation adjustment	—	—	—	—	—	(3)	—	(3)
Net loss	—	—	—	—	—	—	(63,854)	(63,854)
Balance, December 31, 2023	31,465,128	$132,722	7,467,378	$ —	$ 8,142	$ 164	$ (181,702)	$ (173,396)

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

BIOAGE LABS, INC.
Consolidated Statements of Cash Flows
(in thousands)

	Year Ended December 31,	
	2023	2022
Cash flows used in operating activities:		
Net loss	$ (63,854)	$ (39,722)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	3,016	2,540
Depreciation expense	162	129
Non-cash interest expense	6,512	90
Non-cash lease expense	1	10
Loss from changes in fair value on derivative liability and warrants	10,091	(23)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	37	(30)
Other assets	25	352
Accounts payable	(393)	994
Accrued expenses and other current liabilities	3,728	(521)
Deferred grant income	3,313	—
Net cash used in operating activities	(37,362)	(36,181)
Cash flows used in investing activities:		
Purchases of property and equipment	(166)	(103)
Purchases of investments	(100)	—
Net cash used in investing activities	(266)	(103)
Cash flows provided by financing activities:		
Proceeds from issuance of convertible notes	23,500	—
Issuance costs paid on convertible notes	(46)	—
Proceeds from term loan	12,500	2,500
Issuance costs paid on term loan	(17)	(45)
Term loan principal payments	(1,000)	—
Proceeds from option exercises	4	44
Net cash provided by financing activities	34,941	2,499
Effects of exchange rate changes on cash and cash equivalents	—	246
Net decrease in cash, cash equivalents and restricted cash	(2,687)	(33,539)
Cash, cash equivalents and restricted cash as of beginning of the year	27,644	61,183
Cash, cash equivalents, and restricted cash as of end of the year	$ 24,957	$ 27,644
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 1,155	$ 129
Right-of-use assets obtained in exchange for lease obligation	$ 407	$ 334
Cash, cash equivalents, and restricted cash reconciliation		
Cash and cash equivalents	$ 21,644	$ 27,644
Restricted cash	3,313	—
Cash, cash equivalents, and restricted cash ending balance	24,957	27,644

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

BIOAGE LABS, INC.
Notes to Consolidated Financial Statements

Note 1. Nature of Business and Liquidity

Nature of Business

BioAge Labs, Inc. (the "Company"), is a clinical-stage biotechnology company developing therapeutic product candidates for metabolic diseases, such as obesity, by targeting a key risk factor: aging. The Company's lead product candidate, azelaprag, is an orally available small molecule that has been well-tolerated in over 240 individuals in seven Phase 1 clinical trials to date. The Company is also developing orally available, brain-penetrant inhibitors of NLRP3, a key driver of neuroinflammation, which is linked to many diseases including obesity.

The Company was incorporated in 2015 in the State of Delaware and is headquartered in Richmond, California.

Liquidity and Capital Resources

Since inception, the Company's operations have consisted primarily of organizing and staffing the Company, business planning, raising capital, establishing its intellectual property portfolio, acquiring or discovering product candidates, research and development activities for its product candidates, establishing arrangements with third parties for the manufacture of its product candidates and component materials, and providing general and administrative support for these operations. The Company has not generated any product revenue to date.

The Company has incurred losses and negative cash flows from operations since inception and had an accumulated deficit of $181.7 million and $117.8 million as of December 31, 2023 and 2022, respectively. The Company anticipates incurring additional losses until such time, if ever, that it can generate significant sales of its products currently in development. As of December 31, 2023, the Company had cash, cash equivalents, and restricted cash of $25.0 million. In February 2024 (subsequent to year-end) the Company sold 49,713,402 shares of its Series D redeemable convertible preferred stock ("Series D") at $3.4196 per share for gross proceeds of $170.0 million (the "Series D Financing").

Current cash and cash equivalents are sufficient to fund planned operations for at least one year after the date these consolidated financial statements are issued given the cash proceeds received from the Company's Series D Financing. Accordingly, these consolidated financial statements have been prepared on a going concern basis and do not include any adjustments to the amounts and classification of assets and liabilities that may be necessary in the event the Company can no longer continue as a going concern.

Until such time, if ever, the Company can generate substantial product revenues, it expects to finance its cash needs through equity offerings, debt financings or other capital sources, which could include collaborations, strategic alliances or licensing arrangements. To the extent that the Company raises additional capital through the sale of equity or convertible debt securities, the ownership interests of its existing stockholders may be diluted, and the terms of these securities may include liquidation or other preferences that could adversely affect the rights of such stockholders. Debt financing, if available, may involve agreements that include restrictive covenants that limit the Company's ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, that could adversely impact the Company's ability to conduct its business. If the Company raises additional funds through collaborations, strategic alliances or licensing arrangements with third parties, the Company may have to relinquish valuable rights to the Company's technologies, future revenue streams, research program or product candidates, or grant licenses on terms that may not be favorable to the Company. If the Company is unable to raise additional funds through equity or debt financings when needed, the Company may be required to delay, limit, reduce or terminate its product development or future commercialization efforts or grant rights to develop and market product candidates that the Company would otherwise prefer to develop and market itself.

BIOAGE LABS, INC.
Notes to Consolidated Financial Statements

Note 2. Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

The accompanying consolidated financial statements have been prepared in conformity with United States of America generally accepted accounting principles ("GAAP") and applicable rules and regulations of the Securities and Exchange Commission (the "SEC") regarding annual financial reporting. Any reference in these notes to applicable guidance is meant to refer to GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") promulgated by the Financial Accounting Standards Board ("FASB"). The consolidated financial statements include the accounts of BioAge Labs, Inc. and its wholly owned subsidiary, BioAge Labs PTY LTD. BioAge Labs PTY LTD was incorporated in Australia in December 2020. All intercompany accounts and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities as of the date of the consolidated financial statements and the reported amounts of expenses during the reporting period. Actual results could differ materially and adversely from those estimates.

Estimates and assumptions are periodically reviewed and the effects of revisions are reflected in the consolidated financial statements in the period they are determined to be necessary. Areas that require management's estimates include the fair values of common and redeemable convertible preferred stock, warrant liability, embedded derivative liability, stock-based compensation expense assumptions, valuation of deferred tax assets, and accruals for research and development expenses.

Foreign Currency

Results of foreign operations are translated from their functional currency into U.S. dollars (reporting currency) using average exchange rates in effect during the year while assets and liabilities are translated into U.S. dollars using exchange rates in effect at the balance sheet date. The resulting translation adjustments are recorded in accumulated other comprehensive income (loss). Transaction gains and losses resulting from exchange rate changes on transactions denominated in currencies other than the U.S. dollar are included in operations in the period in which the transaction occurs.

Segments

The Company operates and manages its business as one reportable and operating segment, which is the business of extending healthy human life by targeting molecular causes of aging. The Company's Chief Executive Officer, who is the chief operating decision maker, reviews financial information on an aggregate basis for allocating and evaluating financial performance. All long-lived assets are maintained in, and all losses are attributable to, the United States of America.

Cash, Cash Equivalents, and Restricted Cash

The Company considers all highly liquid investments that have original maturities of three months or less when acquired to be cash equivalents. Cash and cash equivalents as of December 31, 2023 and 2022 consisted of bank deposits and money market mutual funds invested in short-term U.S. government obligations. As of December 31, 2023 the Company had $3.3 million in restricted cash related to the Wellcome Leap Commercial Research Funding Agreement (Note 9). As of December 31, 2022, the Company did not have any restricted cash.

BIOAGE LABS, INC.
Notes to Consolidated Financial Statements

Concentrations of Credit Risk

Cash and cash equivalents are financial instruments that are potentially subject to concentrations of credit risk to the extent they exceed the federal depository insurance limits. The Company is exposed to credit risk in the event of default by the financial institutions holding its cash and cash equivalents to the extent recorded in the balance sheets. While the Company has not experienced any losses in such accounts, the failure of Silicon Valley Bank ("SVB") in 2023, at which the Company held cash and cash equivalents in multiple accounts, potentially exposed the Company to significant credit risk. The Federal Deposit Insurance Corporation ("FDIC") issued a statement on March 13, 2023 that they intended to take action to fully protect SVB depositors, which they did on March 27, 2023, by making SVB a division of First Citizens Bank. As of the date of the issuance of these consolidated financial statements, the Company has full access to and control over all of its cash and cash equivalents. The Company has no financial instruments with off-balance sheet risk of loss.

Risks and Uncertainties

The Company faces risks and uncertainties associated with companies in the biotechnology industry, including but not limited to the uncertainty of success of its preclinical studies and clinical trials, regulatory approval of product candidates, uncertainty of market acceptance of products, competition from substitute products and larger companies, the need for additional financing, compliance with government regulations, dependence on third parties, recruiting and retaining skilled personnel, and dependence on key members of management.

The Company's product candidates require approvals from the U.S. Food and Drug Administration ("FDA") and comparable foreign regulatory agencies prior to commercial sales in their respective jurisdictions. There can be no assurance that any product candidates will receive the necessary approvals. If the Company was denied approval, approval was delayed or the Company was unable to maintain approval for any product candidate, it could have a materially adverse impact on the Company.

Property and Equipment, Net

Property and equipment, net is carried at cost less accumulated depreciation. Depreciation is computed over the estimated useful lives of the respective assets using the straight-line method. Useful lives of property and equipment range from three to five years. Operating lease leasehold improvements are amortized over the lesser of the useful lives of the leasehold improvements or the lease term. Upon retirement or sale, the costs of the assets disposed of and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is credited or charged to operations. Maintenance and repairs are expensed as incurred. Asset improvements are capitalized.

Impairment of Long-lived Assets

The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability is measured by a comparison of the carrying amount of an asset to future undiscounted net cash flows which the assets are expected to generate. If such assets are considered to be impaired, the impairment is measured by the excess of the carrying amount of the assets over fair value less the costs to sell the assets, generally determined using the projected discounted future net cash flows arising from the asset. The Company did not recognize any impairment of long-lived assets during the years ended December 31, 2023 or 2022.

Redeemable Convertible Preferred Stock

The Company records redeemable convertible preferred stock net of issuance costs on the date of issuance, which represents the carrying value. Redeemable convertible preferred stock is classified outside of stockholders'

deficit as temporary equity on the accompanying consolidated balance sheets as events triggering the liquidation preferences, including a deemed liquidation event, are not solely within the Company's control. The Company has not remeasured redeemable convertible preferred stock. The carrying values of the redeemable convertible preferred stock will be adjusted to their liquidation preferences if and when it becomes probable that such a liquidation event will occur.

Convertible Promissory Notes and Embedded Derivative Liability

Convertible promissory notes are recorded at the issued value. Debt discount and issuance costs, consisting of legal and other fees directly related to the debt, are offset against gross proceeds from the issuance of the convertible promissory notes and are amortized to interest expense over the life of the debt based on the effective interest method. Amortization expense is presented in interest expense in the consolidated statement of operations and comprehensive loss.

The Company reviews the terms of its convertible promissory notes to determine whether there are conversion features or embedded derivative instruments including embedded conversion options that are required to be bifurcated and accounted for separately as a derivative financial instrument. In circumstances where the convertible promissory notes contain more than one embedded derivative instrument, including conversion options that are required to be bifurcated, the bifurcated derivative instruments are accounted for as a single compound instrument. When convertible debt contains embedded derivative instruments that are to be bifurcated and accounted for separately, the total proceeds allocated to the convertible host instruments are first allocated to the fair value of the bifurcated derivative instrument. The remaining proceeds, if any, are then allocated to the convertible instruments themselves, usually resulting in those instruments being recorded at a discount from their face amount.

As of December 31, 2023, the Company had bifurcated embedded derivatives related to its convertible promissory notes that are accounted for separately as derivative liabilities. Derivative liabilities are initially recorded at fair value and subsequently revalued at each reporting date with changes in fair value recognized separately on the consolidated statement of operations and comprehensive loss. Derivative liabilities are presented separately in the consolidated balance sheet.

Term Loan

Term loans are measured at net proceeds less debt discounts and issuance costs, which and accreted to the face value of the term loan over its expected term using the effective interest method. The Company considers whether there are any embedded features in its debt instruments that require bifurcation and separate accounting as derivative financial instruments pursuant to ASC Topic 815, *Derivatives and Hedging* (Note 5).

Warrant Liability

Freestanding warrants for the Company's common stock are classified as liabilities and recorded at fair value, with any change in fair value recognized as a component of other income (loss). Such warrant liabilities are subject to re-measurement at each balance sheet date until the earlier of the exercise of the warrants, expiration, or the completion of a change in control event. Upon exercise, the warrant liability would be reclassified to additional paid-in capital, at its then fair value.

Research and Development Expenses

Research and development costs are expensed as incurred and include all direct and indirect costs associated with the development of the Company's product candidates and other research programs. These expenses consist

primarily of personnel costs, stock-based compensation charges, consulting fees, and payments to third parties for research, development, and manufacturing services as well as other allocated facility-related costs and overhead expenses. Nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities are capitalized and expensed as the goods are delivered or the related services are performed.

Accrued Research and Development Expenses

The Company records accruals for estimated costs of research, preclinical studies, clinical trials, and manufacturing, which are significant components of research and development expenses. A substantial portion of the Company's ongoing research and development activities is conducted by third-party service providers, clinical research organizations ("CROs"), and clinical manufacturing organizations ("CMOs"). The Company's contracts with CROs generally include pass-through fees such as laboratory supplies and services, regulatory expenses, investigator fees, travel costs and other miscellaneous costs, including shipping and printing fees. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided to the Company under such contracts. The Company accrues the costs incurred under agreements with these third parties based on estimates of actual work completed in accordance with the respective agreements. The Company determines the estimated costs through discussions with internal personnel and external service providers as to the progress, or stage of completion or actual timeline (start-date and end-date) of the services and the agreed-upon fees to be paid for such services. In the event the Company makes advance payments, the payments are recorded as a prepaid expense and recognized as the services are performed.

As actual costs become known, including subsequent to the reporting date, the Company adjusts its accruals. Although the Company does not expect its estimates to be materially different from amounts actually incurred, such estimates for the status and timing of services performed relative to the actual status and timing of services performed may vary and could result in the Company reporting amounts that are too high or too low in any particular period. The Company's accrual is dependent, in part, upon the receipt of timely and accurate reporting from CROs and other third-party vendors. Variations in the assumptions used to estimate accruals including, but not limited to, the number of patients enrolled, the rate of patient enrollment and the actual services performed, may vary from the Company's estimates, resulting in adjustments to clinical trial expenses in future periods. Changes in these estimates that result in material changes to the Company's accruals could materially affect its financial condition and results of operations.

Acquired In-Process Research and Development Expenses

Acquired in-process research and development expense consists of payments incurred in connection with the acquisition or licensing of products or technologies that do not meet the definition of a business under FASB ASC Topic 805, *Business Combinations*. Costs incurred in obtaining technology licenses including upfront and milestone payments incurred under licensing agreements are recorded as expense in the period in which they are incurred, provided that the licensed technology, method or process has no alternative future uses other than for the specific research and development activities. Such payments are classified as cash flows from operating activities in the Company's consolidated statements of cash flows. Milestone payments within the Company's licensing arrangements are recognized when achievement of the milestone payment is legally due and payable. To the extent products are commercialized and future economic benefit has been established, commercial milestones that become probable are capitalized and amortized over the estimated remaining useful life of the intellectual property. In addition, the Company accrues royalty expense and sublicense nonroyalty payments, as applicable, for the amount it is obligated to pay, with adjustments as sales are made.

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Stock-Based Compensation

The Company's stock-based compensation program allows for grants of stock options and restricted stock awards. Grants are awarded to employees and non-employees, including directors.

Compensation cost for the Company's stock-based payments to employees, non-employees and directors, are based on estimated fair value of the awards on the date of grant. The Company estimates the fair value of options granted using the Black-Scholes option pricing model for stock option grants to both employees and non-employees.

The Company's stock-based compensation awards are subject to service-based vesting conditions. Compensation expense related to awards to employees, directors and non-employees with service-based vesting conditions is recognized on a straight-line basis based on the vesting date fair value over the associated service period of the award, which is generally the vesting term.

Income Taxes

Income taxes are accounted for under the asset and liability method in accordance with ASC Topic 740, *Income Taxes*. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to the differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and the operating loss and tax credit carry forwards. Deferred tax assets and liabilities are measured at the balance sheet date using the enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. Deferred tax assets are reduced by a valuation allowance if it is more likely than not that these assets may not be realized. The Company determines whether it is more-likely-than-not that a tax position will be sustained upon examination. If it is not more-likely-than-not that a position will be sustained, none of the benefit attributable to the position is recognized. The tax benefit to be recognized for any tax position that meets the more-likely-than-not recognition threshold is calculated as the largest amount that is more than 50% likely of being realized upon resolution of the contingency. The Company accounts for interest and penalties related to uncertain tax positions as part of its provision for income taxes. No interest or penalties were charged to the Company related to uncertain tax positions for the years ended December 31, 2023 or 2022.

Leases

The Company determines if an arrangement is a lease at the inception of the arrangement. Operating leases are included in right-of-use assets, current portion of operating lease liability, and operating lease liability, net of current portion in the accompanying consolidated balance sheets. Right-of-use assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Operating lease right-of-use assets and liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term. In determining the present value of lease payments, the Company uses its incremental borrowing rate based on the information available at the lease commencement date. The operating lease right-of-use assets also include any lease payments made and exclude lease incentives. The Company's lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise any such options. Lease expense is recognized on a straight-line basis over the expected lease term. The Company has elected not to separate lease and non-lease components, such as common area maintenance charges, and instead it accounts for these as a single lease component. Leases with an initial term of 12 months or less are not recorded on the balance sheet, unless they include an option to purchase the underlying asset or to extend the lease that the Company is reasonably certain to exercise.

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Comprehensive Loss

Comprehensive loss is defined as a change in equity of a business enterprise during a period, resulting from transactions from non-owner sources. Comprehensive loss is comprised of net loss and other comprehensive income (loss). The Company's other comprehensive loss consists of foreign currency translation adjustments. Total comprehensive loss for all periods presented has been disclosed in the consolidated statements of operations and comprehensive loss.

Net Loss Per Share Attributable to Common Stockholders

Basic net loss per share attributable to common stockholders is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period, without consideration for potentially dilutive securities.

Diluted net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common stock and potentially dilutive securities outstanding for the period. For purposes of the diluted net loss per share attributable to common stockholders' calculation, redeemable convertible preferred stock, stock options, and warrants are considered to be potentially dilutive securities.

The Company applies the two-class method to calculate its basic and diluted net loss per share attributable to common stockholders as the Company has issued shares that meet the definition of participating securities. The two-class method is an earnings allocation formula that treats a participating security as having rights to earnings that otherwise would have been available to common stockholders. Participating securities consist of common stock and redeemable convertible preferred stock. The Company's participating securities contractually entitle the holders of such shares to participate in dividends, but do not contractually require the holders of such shares to participate in losses of the Company. Accordingly, in periods in which the Company reports a net loss, such losses are not allocated to such participating securities.

Accordingly, in periods in which the Company reports a net loss, diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders, since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive.

Fair Value of Financial Instruments

GAAP establishes a fair value hierarchy for instruments measured at fair value that distinguishes between assumptions based on market data (observable inputs) and the Company's own assumptions (unobservable inputs). Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company.

Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing the asset or liability and are developed based on the best information available in the circumstances.

Fair value is established as the exchange price, or exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As a basis for considering market participant assumptions in fair value measurements, an established three-tier fair value hierarchy distinguishes between the following:

- Level 1 inputs are quoted prices in active markets that are accessible at the market date for identical assets or liabilities.

- Level 2 inputs are inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly.
- Level 3 inputs are unobservable inputs that reflect the Company's own assumptions about the assumptions market participants would use in pricing the assets or liability. Financial assets and liabilities are classified in their entirety based on the lowest level of input that is significant to the fair value measurement.

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

The carrying amounts of the Company's other current assets, accounts payable, accrued expenses and other current liabilities reported in the consolidated financial statements approximate their fair values due to their short-term nature.

Recent Accounting Pronouncements Not Yet Adopted

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*, to improve its income tax disclosure requirements. Under the ASU, entities must annually (i) disclose specific categories in the rate reconciliation, (ii) provide additional information for reconciling items that meet a quantitative threshold, and (iii) disclose more detailed information about income taxes paid, including by jurisdiction; pretax income (or loss) from continuing operations; and income tax expense (or benefit). The ASU is effective for fiscal years beginning after December 15, 2024, with early adoption permitted. The Company does not expect this update to have a material impact on its consolidated financial statements.

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*, which requires disclosure of incremental segment information on an annual and interim basis. This ASU is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024 on a retrospective basis. The Company is currently evaluating the potential impact that this standard may have on its consolidated financial statements and related disclosures.

Note 3. Fair Value Measurements

The following fair value hierarchy table presents information about each major category of the Company's financial assets and liabilities measured at fair value on a recurring basis (in thousands):

	December 31, 2023			
	(Level 1)	(Level 2)	(Level 3)	Total
Assets:				
Cash equivalents	$ 21,061	$ —	$ —	$ 21,061
Liabilities:				
Convertible promissory notes embedded derivative liability	—	—	18,183	18,183
Warrant liability	—	—	229	229
Total liabilities	$ —	$ —	$ 18,412	$ 18,412

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	December 31, 2022			
	(Level 1)	(Level 2)	(Level 3)	Total
Assets:				
Cash equivalents	$ 14,875	$ —	$ —	$ 14,875
Liabilities:				
Warrant liability	—	—	153	153
Total liabilities	$ —	$ —	$ 153	$ 153

There were no changes in valuation techniques or transfers between category levels during the years ended December 31, 2023 and 2022.

Cash Equivalents

Cash equivalents include U.S. government obligation money market mutual funds that have a maturity of three months or less from the original acquisition date. The Company's cash equivalents are classified using Level 1 inputs within the fair value hierarchy because they are valued using quoted market prices.

Convertible Promissory Notes Embedded Derivative Liability

The Company's Convertible Promissory Notes (as defined in Note 5) contain equity conversion options, and certain repayment features, that have been identified as a single compound embedded derivative requiring bifurcation from the Convertible Promissory Notes. The Company estimated the fair value of the convertible promissory note embedded derivative liabilities on issuance using a with-and-without scenario analysis. The estimated probability and timing of underlying events triggering the conversion and liquidity repayment features as well as discount rates, volatility and share prices are inputs used to determine the estimated fair value of the embedded derivative.

The following table provides a summary of the change in the estimated fair value of the Company's convertible promissory note embedded derivative liability for the year ended December 31, 2023 (in thousands):

	Convertible Promissory Note Embedded Derivative Liability
Fair value at December 31, 2022	$ —
Upon issuance of convertible promissory notes	8,131
Change in fair value	10,052
Fair value at December 31, 2023	$ 18,183

Warrant Liability

The Company's warrant liability is classified using Level 3 inputs within the fair value hierarchy because the warrant liability is valued using both observable and unobservable inputs. For further discussion of the warrant liability fair value inputs and related fair value changes during the years ended December 31, 2023 and 2022 refer to Note 6.

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Notes to Consolidated Financial Statements

Note 4. Balance Sheet Components

Property and Equipment

Property and equipment consisted of the following (in thousands):

	December 31,	
	2023	2022
Lab equipment	$ 366	$ 271
Computer equipment and software	323	252
Furniture and fixtures	53	53
Property and equipment, gross	742	576
Accumulated depreciation	(419)	(253)
Property and equipment, net	$ 323	$ 323

Depreciation expense for the years ended December 31, 2023 and 2022 was $0.2 million and $0.1 million, respectively.

Accrued Expenses and Other Current Liabilities

Accrued expenses consisted of the following (in thousands):

	December 31,	
	2023	2022
Research and development expenses	$ 2,516	$ 190
Payroll and related costs	4,033	3,170
Other	1,389	24
Total accrued expenses and other current liabilities	$ 7,938	$ 3,384

Note 5. Debt

Convertible Promissory Notes

In February 2023, the Company issued four convertible promissory notes with an aggregate principal amount of $23.5 million. Each note has an interest rate of 4% per annum and a maturity date of May 10, 2024 (the “Convertible Promissory Notes”). The weighted-average effective interest rate of the convertible promissory notes at issuance was 40.0%.

The notes and any accrued but unpaid interest are convertible at either the date of a qualified financing of at least $20.0 million (a “Qualified Financing”), or on the maturity date, at the option of the respective holder, and are convertible into the same securities issued in the Qualified Financing, or if no qualified financing occurs prior to maturity, then shall be convertible into the Company’s Series C redeemable convertible preferred stock.

Upon a Qualified Financing, the Convertible Promissory Notes automatically convert into shares of the Company’s redeemable convertible preferred stock on the same conditions applicable for the Qualified Financing at a conversion price equal to the lowest price per share paid in the Qualified Financing multiplied by a discount factor ranging from 0.6 to 1.0 depending on the timing of the Qualified Financing.

The fair value of the convertible promissory notes and related embedded derivative liability was $39.2 million as of December 31, 2023.

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Term Loan

In May 2022, the Company entered into a loan and security agreement (the "Loan Agreement") with SVB Innovative Credit Growth Fund IX, LP and Innovative Credit Growth Fund VIII-A, LP, (collectively, the "Lenders") pursuant to which the Company was eligible to borrow, and the Lenders are obligated to fund up to $25.0 million in borrowing capacity across two potential tranches (the "Term Loan"). At the closing of the Loan Agreement in May 2022, the Company drew $2.5 million from the first tranche (the "Initial Term Loan") and in May 2023 the Company drew $12.5 million from the second tranche (the "Additional Term Loan").

In connection with the Initial Term Loan of $2.5 million, the Company issued to the Lenders warrants to purchase 86,672 shares of the Company's common stock. The warrants expire on May 20, 2032 and had a fair value of $125,602 at issuance. Similarly, in connection with the Additional Term Loan draw, the Company issued an additional warrant to purchase 24,764 shares of the Company's common stock. The warrants expire on May 20, 2032 and had a fair value of $37,050 at issuance. As a result, proceeds from the debt equal to the fair value were allocated to these warrants and are amortized as part of the debt discount over the life of the Term Loan.

Interest for the Term Loan accrues at a floating per annum rate equal to the greater of (i) the Prime rate plus 4.00% or (ii) 7.50%. Interest is due monthly on the first business day of each month, commencing in June 2022. The Term Loan is scheduled to mature on April 1, 2026 and commencing on November 1, 2023 the Company is required to make monthly principal payments. The Company may prepay all of the outstanding principal balance of the Term Loan, at its option, prior to the maturity date subject to a prepayment premium ranging from 1.0% to 2.0%. The prepayment premium will apply to any mandatory or voluntary prepayment, but will not be due upon a refinancing of the outstanding Term Loan with another credit facility from SVB. In addition, the Company will also be required to pay a final payment fee equal to 4.4% of the total amount borrowed.

The Company's obligations under the Loan Agreement are subject to acceleration upon the occurrence of customary events of default, including payment default, insolvency and the occurrence of certain events having a material adverse effect on the Company, including (but not limited to) material adverse effects upon the business, operations, properties, assets or financial condition of the Company and its subsidiaries, taken as a whole.

The Loan Agreement includes positive and negative covenants that the Company must comply with and is secured by the assets of the Company that are pledged as collateral.

Debt issuance costs, including the fair value of the warrants, have been treated as debt discounts in the consolidated balance sheet and together with the final payment are being amortized to interest expense throughout the life of the Term Loan using the effective interest rate method. As of December 31, 2023 and 2022, there were unamortized issuance costs and debt discounts of $0.1 million, which are recorded as a direct deduction from the Term Loan in the consolidated balance sheet. Interest expense related to the Loan Agreement was $1.5 million and $0.2 million for the years ended December 31, 2023, and 2022, respectively. As of December 31, 2023, the stated rate on the Term Loan was 12.5%. As of December 31, 2023, the effective interest rate on the Term Loan, including the amortization of the debt discount and accretion of the final payment, was 16.8% for the Initial Term Loan and 15.2% Additional Term Loan. The carrying amount of the Term Loan is subject to variable interest rates, which are based on current market rates, and as such, approximate fair value.

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The components of the Term Loan balance were as follows (in thousands):

	December 31, 2023	December 31, 2022
Principal loan balance	$ 14,000	$ 2,500
Final fee	298	36
Unamortized debt discount	(97)	(117)
Total Term Loan	14,201	2,419
Less current portion of Term loan	(6,000)	(167)
Term loan	$ 8,201	$ 2,252

As of December 31, 2023, the estimated future principal payments under the Term Loan are as follows (in thousands):

Year ending December 31,	Total Principal Payments
2024	$ 6,000
2025	6,000
2026	2,000
Principal amount of Term Loan	$ 14,000

Note 6. Capital Structure

Redeemable Convertible Preferred Stock

Redeemable convertible preferred stock consisted of the following at December 31, 2023 and 2022 (in thousands, except share information):

	Shares Issued and Outstanding	Shares Authorized	Carrying Value	Aggregate Liquidation Preference
Series A-1	4,753,466	4,753,466	$ 11,558	$ 11,822
Series A-2	2,948,071	2,948,071	3,085	1,808
Series A-3	203,821	203,821	272	250
Series A-4	27,643	27,643	49	55
Series B	7,455,241	7,455,241	22,854	22,929
Series C	16,076,886	16,246,120	94,904	95,000
Total	31,465,128	31,634,362	$ 132,722	$ 131,864

In 2017, the Company issued 4,753,466 shares of Series A-1 redeemable convertible preferred stock (the "Series A-1 Preferred Stock"), 2,948,071 shares of Series A-2 redeemable convertible preferred stock (the "Series A-2 Preferred Stock"), 203,821 shares of Series A-3 redeemable convertible preferred stock (the "Series A-3 Preferred Stock"), and 27,643 shares of Series A-4 redeemable convertible preferred stock (the "Series A-4 Preferred Stock" and together with the Series A-1 Preferred Stock, Series A-2 Preferred Stock and Series A-3 Preferred Stock, the "Series A Preferred Stock"), and in connection with the settlement of the Simple Agreement for Future Equity ("SAFE") instruments that were outstanding. SAFEs were originally provided to early investors in exchange for cash. The investors who held these SAFEs converted their respective SAFEs to Series A Preferred Stock. The Series A Preferred Stock have the same rights and preferences except for their initial original issuance prices in connection with any future liquidation events as defined in the Company's articles of incorporation.

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Notes to Consolidated Financial Statements

In 2018, the Company sold 7,455,241 shares of its Series B redeemable convertible preferred stock at $3.0756 per share (the "Series B Preferred Stock") for gross proceeds of $22.9 million.

During the year ended December 31, 2020, the Company sold 15,230,734 shares of Series C redeemable convertible preferred stock (the "Series C Preferred Stock") at $5.9091 per share for gross proceeds of $90.0 million.

During the year ended December 31, 2021, the Company issued 846,152 shares of Series C in connection with the Amgen Agreement (Note 9).

The following is a summary of the amended rights, preferences, and privileges of the Series A-1 through A-4, Series B and Series C redeemable convertible preferred stock:

Rank—The redeemable convertible preferred stock ranks senior to the common stock as to payment of dividends, distributions of assets upon a liquidation event, or otherwise.

Dividends—The holders of the redeemable convertible preferred stock are entitled to receive non-cumulative dividends at the rate of 6.00% per year if and when declared by the Company's board of directors (the "Board of Directors"). Any declared but unpaid dividends are payable upon a liquidation event or conversion of the applicable shares of convertible preferred stock to common stock. No dividends have been declared through December 31, 2023.

Voting Rights—The holders of the redeemable convertible preferred stock are entitled to a number of votes equal to the number of shares of common stock into which their shares can be converted. The holders of the redeemable convertible preferred stock are entitled to elect one member of the Board of Directors.

Liquidation Preference—In the event of a liquidation, dissolution, or winding up of the Company, or in the event the Company merges with or is acquired by another entity, the holders of the redeemable convertible preferred stock are entitled to their liquidation preference payments plus any accrued but unpaid dividends. Once the liquidation preference has been paid, any remaining assets would be distributed pro rata among the holders of the Series C Preferred Stock, Series B Preferred Stock, Series A Preferred Stock and common stock on an "as converted" basis. Liquidation preference payments equal an amount per share equal to the greater of (i) the Original Issue Price for such series, plus any dividends declared but unpaid thereon, or (ii) such amount per share as would have been payable on an as-converted basis., where "Original Issue Price" means $2.4870 per share for Series A-1 Preferred Stock, $0.6133 per share for Series A-2 Preferred Stock, $1.2266 per share for Series A-3 Preferred Stock, $1.9896 per share for Series A-4, $3.0756 per share for Series B Preferred Stock, and $5.9091 per share for Series C Preferred Stock.

Conversion—At any time, at the option of the holder, each share of redeemable convertible preferred stock is convertible into one share of common stock, subject to certain antidilution adjustments. The conversion of the redeemable convertible preferred stock is not considered probable at this time, therefore, subsequent measurement adjustments have not been made. The redeemable convertible preferred stock is automatically converted in the event of an initial public offering ("IPO") of specified characteristics, or upon the agreement of holders of a majority of the outstanding redeemable convertible preferred stock.

Down-Round Antidilution Protection—In the event the Company issues its common stock without consideration or for consideration per share that is less than the conversion price in effect for each series of the redeemable convertible preferred stock, then the conversion price for that series shall be reduced in order to increase the number of ordinary shares into which such series of redeemable convertible preferred stock is convertible into.

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Common Stock

In connection with the Series C stock financing in 2020, the number of Board of Directors seats was increased from four board seats to five board seats. The holders of the common stock are entitled to elect two members of the Board of Directors. The common stockholders are entitled to one vote for each share of common stock held. There are 52,400,000 shares of common stock authorized as of December 31, 2023 and 2022. Common stock reserved for future issuance, on an as-if-converted basis, as of December 31, 2023 and December 31, 2022, consisted of the following:

	December 31,	
	2023	2022
Common stock, issued and outstanding	7,467,378	7,464,463
Convertible preferred shares, issued and outstanding	31,465,128	31,465,128
Stock options, issued and outstanding	10,550,273	8,679,090
Stock options, authorized for future issuance	2,740,142	1,774,224
Warrants, issued and outstanding	141,436	116,672
Total	52,364,357	49,499,577

Warrants to Acquire Shares of Common Stock

At December 31, 2023 there are warrants outstanding to acquire 141,436 shares of the Company's common stock.

In July 2018, in connection with a 2018 loan agreement, the Company issued warrants to acquire 30,000 shares of common stock with an exercise price of $0.72 (the "2018 Warrants"). These warrants expire on July 31, 2028 and had a fair value of $15,930 at issuance.

In May 2022, additional warrants to acquire 86,672 shares of common stock were issued with an exercise price of $2.30 in connection with the SVB Loan Agreement (the "2022 Warrants").

In May 2023, additional warrants to acquire 24,764 shares of common stock were issued with an exercise price of $2.30 in connection with the SVB Loan Agreement (the "2023 Warrants").

The 2023 Warrants, 2022 Warrants, and 2018 Warrants are not indexed to the Company's own stock, as the settlement amount may be adjusted in the event of a non-cash / public acquisition in which the surviving entity does not assume the warrants. Therefore, these warrants are classified as a liability at fair value with changes in fair value recorded in the consolidated statement of operations and comprehensive loss.

The fair value of the liability related to the 2018 Warrants as of December 31, 2023 and 2022 was estimated using a Black-Scholes pricing model with the following assumptions:

	December 31, 2023	December 31, 2022
Risk-free interest rate	3.84%	2.78%
Expected term	4.6 years	5.6 years
Expected volatility	106.28%	77.87%
Expected dividend yield	—	—
Estimated fair value of the Company's common stock (per share)	$ 1.85	$ 1.71
Exercise price (per share)	$ 0.72	$ 0.72

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The fair value of the liability related to the 2022 Warrants as of December 31, 2023 and 2022 was estimated using a Black-Scholes pricing model with the following assumptions:

	December 31, 2023	December 31, 2022
Risk-free interest rate	3.88%	2.78%
Expected term	8.4 years	9.4 years
Expected volatility	104.51%	76.74%
Expected dividend yield	—	—
Estimated fair value of the Company's common stock (per share)	$ 1.85	$ 1.71
Exercise price (per share)	$ 2.30	$ 2.30

The fair value of the liability related to the 2023 Warrants as of December 31, 2023 and May 18, 2023 was estimated using a Black-Scholes pricing model with the following assumptions:

	December 31, 2023	May 18, 2023
Risk-free interest rate	3.88%	3.65%
Expected term	8.4 years	9.0 years
Expected volatility	104.51%	100.25%
Expected dividend yield	—	—
Estimated fair value of the Company's common stock (per share)	$ 1.85	$ 1.72
Exercise price (per share)	$ 2.30	$ 2.30

The Black-Scholes pricing model requires inputs based on the subjective assumptions described below:

For volatility, the Company considers comparable public companies as a basis for its expected volatility to calculate the fair value of warrants to acquire common stock. The risk-free interest rate is based on U.S. Treasury notes with a term approximating the expected term of the warrants to acquire common stock. The Company uses an expected dividend yield of zero based on the fact that the Company has never paid cash dividends and does not expect to pay cash dividends in the foreseeable future. The expected term at each measurement date is equal to the remaining contractual life of the warrants. The fair value of the Company's common stock at each measurement date is determined by the Board, taking into account information, such as a valuation performed by an independent third party. Any significant changes in the inputs may result in significantly higher or lower fair value measurements.

The following table sets forth the changes in fair value of the warrant liability for the year ended December 31, 2023 (in thousands):

Fair value at December 31, 2022	$153
Issuance of 2023 Warrants	37
Changes in fair value	39
Fair value at December 31, 2023	$229

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Note 7. Stock-Based Compensation

Stock Option Plan

The Company issues stock-based awards pursuant to its 2015 Equity Incentive Plan, as amended (the "Plan"). In December 2021, the Company amended the Plan and increased the total number of shares authorized under the Plan to 14,149,677. As of December 31, 2023, 2,740,142 shares are available for future grants. Eligible participants include employees, directors, and consultants. The Plan permits the granting of incentive stock options, non-statutory stock options, stock awards, and stock purchase rights. The terms of the agreements are determined by the Board of Directors. The Company's stock options have a term of 10 years and vest based on the terms in the agreements, generally over 4 years.

The following table summarizes the stock option activity for the year ended December 31, 2023:

	Shares Available to Grant	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value (in thousands)
Balance-December 31, 2022	1,774,224	8,679,090	$ 1.75	7.9	$ 2,918
Increase in authorized shares	2,840,016	—	—		
Granted	(2,144,108)	2,144,108	2.43		
Exercised	—	(2,915)	1.66		
Forfeited/expired	270,010	(270,010)	2.22		
Balance - December 31, 2023	2,740,142	10,550,273	$ 1.88	7.4	$ 2,864
Vested and exercisable - December 31, 2023		6,277,373	$ 1.72	6.9	$ 2,403

The fair value of the stock options that were exercised during the years ended December 31, 2023 and December 31, 2022 was less than $0.1 million and $0.1 million, respectively.

The fair value of options granted during the years ended December 31, 2023 and 2022 was estimated on the date of grant using a Black-Scholes option pricing model with the following weighted-average assumptions:

	Year Ended December 31,	
	2023	2022
Risk-free interest rate	3.8%	2.7%
Expected term	6.0 years	5.4 years
Expected volatility	90.3%	86.7%
Expected dividend yield	—	—
Estimated fair value of the Company's common stock (per share)	$ 1.70	$ 1.92

The fair value of each stock option is estimated on the grant date using the Black-Scholes option pricing model, which requires inputs based on certain subjective assumptions, including:

Risk-Free Interest Rate—The risk-free interest rate is based on the U.S. Treasury zero coupon issues in effect at the time of grant for periods corresponding with the expected term of option.

Expected Term—The Company uses the simplified method (based on the mid-point between the vesting date and the end of the contractual term) to estimate the expected term of the option. Management has limited

historical information to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior for Company stock option grants. The simplified method makes the assumption that the employee will exercise share options evenly over the period when the share options are vested and ending on the date when the share options would expire.

Expected Volatility—Since the Company's shares are not publicly traded, expected volatility is estimated based on the average historical volatility of similar entities with publicly traded shares. When selecting comparable publicly traded biopharmaceutical companies on which the Company has based its expected stock price volatility, the Company selected companies with comparable characteristics, including enterprise value, risk profiles, development stage, and with historical share price information sufficient to meet the expected term of the stock-based awards.

Expected Dividend Yield—The Company has never paid dividends on its common stock and has no plans to pay dividends on its common stock. Therefore, the Company used an expected dividend yield of zero.

Estimated Fair Value of Common Stock—The estimated fair value of the shares of common stock underlying stock options was determined by the Board of Directors. Because there was no public market for the Company's common stock, the Board of Directors determined fair value of the common stock at the time of grant of the options by considering a number of objective and subjective factors including important developments in the Company's operations, valuations performed by an independent third party, sales of redeemable convertible preferred stock, actual operating results and financial performance, the conditions in the biotechnology industry and the economy in general, the stock price performance and volatility of comparable public companies, and the lack of liquidity of the Company's common stock, among other factors.

Stock-based compensation expense recorded as research and development and general and administrative expenses in the statements of operations and comprehensive loss was as follows (in thousands):

	Year Ended December 31,	
	2023	2022
Research and development expense	$ 1,091	$ 1,732
General and administrative expense	1,925	808
Total stock-based compensation expense	$ 3,016	$ 2,540

As of December 31, 2023, there was $5.7 million of unrecognized compensation cost that is expected to be recognized over a weighted average period of 2.5 years.

Note 8. Commitments and Contingencies

Indemnification

The Company entered into indemnification agreements with directors and certain officers that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. No demands have been made upon the Company to provide indemnification under such agreements, and thus, there are no claims that the Company is aware of that could have a material effect on the consolidated financial statements. The Company also maintains director and officer insurance, which may cover certain liabilities arising from the Company's obligation to indemnify its directors and officers. To date, the Company has not incurred any costs and have not accrued any liabilities in the consolidated financial statements as a result of these provisions.

BIOAGE LABS, INC.
Notes to Consolidated Financial Statements

Legal Proceedings

The Company is not a party to any litigation and does not have contingency reserves established for any litigation liabilities.

Employee Benefit Plan

The Company maintains a defined contribution 401(k) plan, under which employee contributions are voluntary and are determined on an individual basis, limited by the maximum amounts allowable under federal tax regulations. The Company provides an automatic matching contribution of employee contributions into the plan up to a maximum of 4% of employee deferral. The Company's matching contributions to employees was $0.5 million and $0.4 million during each of the years ended December 31, 2023 and 2022, respectively.

Leases

In August 2017, the Company entered into an agreement to lease approximately 6,436 square feet of office and lab space in Richmond California, which the Company uses for its corporate offices and research facility (the "Richmond Lease"). The Richmond lease had an initial term of three years but was amended in October 2017 and August 2019 to add additional space for a total of 18,829 square feet and to extend the term of the lease through February 2023. The Company entered into an amendment in January 2023 which extended the term of the lease through August 2024. The Richmond Lease includes escalating rent payments but does not provide for any renewal options. The Company recognizes rent expense on a straight-line basis over the lease term. The Richmond lease does not provide a bargain purchase option nor does it transfer ownership at any point during the lease to the Company and is classified as an operating lease.

As of December 31, 2023, the remaining lease term was 0.67 years and the discount rate used to determine the operating leases liability was 14.65%.

Cash paid for amounts included in the measurement of operating lease liabilities was $0.3 million for the years ended December 31, 2023 and 2022, respectively, and was included in net cash used in operating activities in the consolidated statement of cash flows.

Future minimum rental payments of $0.2 million will be made in 2024. Rent expense was $0.4 million and $0.3 million for the years ended December 31, 2023 and 2022, respectively. Variable lease payments related to operating leases for the years ended December 31, 2022 were not material.

Note 9. License Agreements

Wellcome Leap Commercial Research Funding Agreement

In September 2023, the Company entered into a Commercial Research Funding Agreement with Wellcome Leap, Inc.(the "Wellcome Leap Agreement") in which Wellcome Leap was to fund certain research and development work performed by the Company. In connection with the Wellcome Leap Agreement, the Company entered into a statement of work in which the Company was to evaluate Azelaprag's efficacy at preventing muscle atrophy and frailty during hospitalization in chronic obstructive pulmonary disease ("COPD") patients through a Phase 2 clinical trial (the "COPD Trial").

Also, in September 2023, Wellcome Leap made a payment of $3.3 million to the Company to cover costs to be incurred related to the COPD Trial (the "Grant Funds"). As the Grant Funds are maintained in a separate bank account from the Company's other funds and are only to be expended on the COPD Trial, it was determined that the Grant Funds represent restricted cash and are classified as such in the consolidated balance sheet as of December 31, 2023.

BIOAGE LABS, INC.
Notes to Consolidated Financial Statements

In March 2024, the Company informed Wellcome Leap that it planned to terminate the COPD Trial due to concerns regarding commercial feasibility. The entire $3.3 million in Grant Funds will be returned to Wellcome Leap in 2024. Accordingly, no grant income will be recognized from the Wellcome Leap Agreement as the COPD Trial was not completed, and any costs incurred by the Company related to the COPD trial are recorded as research and development expense as incurred.

Amgen Exclusive License Agreement

On April 5, 2021, the Company entered into an exclusive license agreement (the Amgen Agreement) with Amgen Inc. ("Amgen") pursuant to which Amgen granted the Company an exclusive, worldwide license, with the right to sublicense (subject to certain conditions), under Amgen's rights in specified patents relating to Amgen's proprietary compound, AMG 986, a novel apelin J receptor agonist, to research, develop, and commercialize AMG 986 in all diagnostic, preventative or therapeutic uses. Amgen also granted the Company a non-exclusive, worldwide license, with the right to sublicense (subject to certain conditions), under Amgen's rights in specified know-how relating to AMG 986, including research reports, clinical data, manufacturing processes, regulatory documents, and other information pertaining to AMG 986, to research, develop, and commercialize AMG 986 in all diagnostic, preventative or therapeutic uses. Although the Company maintains the exclusive rights described above with respect to the specified patents, Amgen retains research-only rights solely for Amgen's internal research. All right, title and interest to inventions conceived or created by a party under the Amgen Agreement that are exclusively related to AMG 986 will be owned exclusively by the Company, regardless of inventorship.

Under the Amgen Agreement, the Company is obligated to use commercially reasonable efforts to develop and commercialize at least one licensed product in each of the United States, European Union, Japan and the rest of the world ("ROW"). If the Company fails to materially develop or commercialize such products for twelve months in the United States, European Union, Japan, or ROW, and such failure is not due to reasons out of the Company's control, in addition to other available remedies, Amgen may terminate the agreement with respect to the failing region, subject to a cure period.

In consideration for the rights granted under the Amgen Agreement, the Company paid an upfront fee of $1.0 million and issued Amgen 846,152 shares of its Series C Preferred Stock. Additionally, the Company may also be required to pay up to an additional $120.0 million in the aggregate for future development, regulatory and commercial milestone payments, as well as tiered royalties at percentages ranging in the low-to upper-single digits on future net sales by the Company and its sublicensees of licensed products, if any. Royalties are paid on a product-by-product basis and commence with respect to a particular country upon the first commercial sale in such country and terminate in such country on the latest to occur of the date on which such product is no longer covered by a valid claim in such country, the loss of regulatory exclusivity for such product in such country, and for a specified time period after the first commercial sale of such product in such country. Such royalties may be decreased if, among other reasons, the Company is required to pay a third party for rights to intellectual property for the exploitation of a licensed product in a given country, but in no event be reduced in aggregate by a specified percentage.

The term of the Amgen Agreement will end on a licensed product-by-licensed product basis and country-by-country basis upon the expiration of the Company's obligation to pay royalties to Amgen with respect to such licensed products in such countries. The Company may terminate the Amgen Agreement in its entirety for convenience upon a specified written notice period. Amgen has the right to terminate the agreement if the Company, or one of its affiliates or sublicensees, challenges the patentability, enforceability, or validity of a licensed patent, subject to a cure period. Additionally, either party will be able to terminate the Amgen Agreement for the other party's uncured material breach or bankruptcy.

BIOAGE LABS, INC.
Notes to Consolidated Financial Statements

Note 10. Income Taxes

Substantially all of the Company's loss before income tax was generated in the United States of America, and no income tax expense or benefit has been recorded for the years ended December 31, 2023 and 2022. This is due to the Company's history of losses before income tax since inception and the establishment of a valuation allowance against deferred tax assets generated during those periods. As of December 31, 2023, the Company has concluded that it is more likely than not that the Company may not realize the benefit of its deferred tax assets due to its history of losses. Accordingly, the Company has recorded a 100% valuation allowance against the net deferred tax assets.

A reconciliation of income tax benefit at the statutory federal income tax rate and income taxes as reflected in the consolidated financial statements as of December 31, 2023 and 2022 is as follows (in thousands, except percentages):

	Year Ended December 31,			
	2023		2022	
	Amount	% of Pretax Earnings	Amount	% of Pretax Earnings
Income tax benefit at statutory rate	$(13,415)	21.0%	$(8,563)	21.0%
State income taxes, net of federal benefit	(58)	0.1%	(542)	1.3%
R&D credits	(1,794)	2.8%	(1,192)	2.9%
Change in unrecognized tax benefit	515	(0.8%)	420	(1.0%)
Stock compensation	276	(0.4%)	378	(0.9%)
Other	(553)	0.9%	73	(0.2%)
Disallowed interest expense	1,303	(2.0%)	—	—
Change in fair value - derivative liability	2,120	(3.3%)	—	—
Change in valuation allowance	$ 11,606	(18.3%)	9,426	(23.1%)
Provision for income tax benefit	$ —	0.0%	$ —	0.0%

Deferred tax asset and liabilities are determined based on the differences between the financial statement carrying amounts and tax bases of assets and liabilities using enacted tax rates in effect for the years in which differences are expected to reverse.

BIOAGE LABS, INC.
Notes to Consolidated Financial Statements

Significant components of the Company's deferred taxes as of December 31, 2023 and 2022 consisted of the following (in thousands):

	December 31,	
	2023	2022
Deferred tax assets:		
Net operating loss carryforwards	$ 18,482	$ 14,392
General business credits	5,381	3,444
Amortization of temporary differences	2,358	2,405
Stock-based compensation	796	227
Capitalized R&D	11,098	6,354
Lease liability	41	10
Other	914	611
Gross deferred tax assets	39,070	27,443
Less: Valuation allowance	(39,019)	(27,415)
Total deferred tax assets	51	28
Deferred tax liability:		
Fixed assets	(10)	(17)
ROU Asset	(41)	(11)
Net deferred tax assets	$ —	$ —

The Company had U.S. federal and state operating loss carryforwards ("NOL") of $83.8 and $13.4 million, respectively, at December 31, 2023. Net operating loss carryforwards of $3.8 and $12.5 million begin to expire in 2035 for federal and state income tax purposes respectively. Net operating loss carryforwards of $80.0 and $0.9 million for federal and state income tax purposes, respectively do not expire. The Company also had $0.1 million in foreign net operating loss carry forwards that do not expire. The Company had $4.3 million and $2.9 million in federal and state research and development credits, respectively, that begin to expire in 2038 for federal income tax purposes and that do not expire for state income tax purposes. The Company recorded a 100% valuation allowance against the net deferred tax assets as of December 31, 2023 and 2022 because realization is not more likely than not based on available positive and negative evidence. The change in valuation allowance was $11.6 million and $9.4 million as of December 31, 2023 and 2022, respectively.

The Company's net operating losses and other tax attributes may be subject to limitation under Section 382 and 383 of the U.S. Internal Revenue Code of 1986, as amended (the Code), if the Company has undergone an ownership change. An ownership change is generally defined as a greater than 50 percentage point change (by value) in equity ownership by certain stockholders or groups of stockholders over a three-year period. It is possible that the Company has undergone one or more ownership changes in the past or may undergo one in the future. An ownership change limits the Company's ability to use pre-change net operating loss carryforwards and other pre-change tax attributes to offset post-change income. Similar provisions of state tax law may also apply to limit the use of state net operating losses and attributes.

BIOAGE LABS, INC.
Notes to Consolidated Financial Statements

The Company has the following activity relating to the gross amount of unrecognized tax benefits (in thousands):

Balance at December 31, 2021	$1,547
Increases related to 2022	420
Increases related to prior periods	—
Balance at December 31, 2022	1,967
Increases related to 2023	449
Increases related to prior periods	67
Balance at December 31, 2023	$2,483

As of December 31, 2023 and 2022, the Company had gross unrecognized tax benefits of $2.5 million and $2.0 million, respectively. None of the unrecognized benefit at December 31, 2023 would impact the effective tax rate if recognized. The Company does not anticipate any significant changes to unrecognized tax benefits over the next 12 months.

The Company accounts for interest and penalties related to uncertain tax positions as part of its provision for income taxes. No amounts were accrued for the payment of interest and penalties as December 31, 2023 or 2022.

All years of the Company are open to examination by federal, state and foreign tax authorities. The Company has not been informed by any tax authorities for any jurisdiction that any of its tax years is under examination as of December 31, 2023.

Note 11. Net Loss Per Share Attributable to Common Stockholders

The following table sets forth the computation of the basic and diluted net loss per share attributable to common stockholders (in thousands except for share and per share data):

	Year ended December 31,	
	2023	2022
Numerator:		
Net loss	$ (63,854)	$ (39,722)
Denominator:		
Weighted-average shares of common stock outstanding used to compute net loss per share attributable to common stockholders, basic and diluted	7,465,008	7,460,403
Net loss per share attributable to common stockholders, basic and diluted:	$ (8.55)	$ (5.32)

BIOAGE LABS, INC.
Notes to Consolidated Financial Statements

The Company's potentially dilutive securities have been excluded from the computation of diluted net loss per share attributable to common stockholders as the effect would be antidilutive. Therefore, the weighted-average number of shares of common stock outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same. Potentially dilutive securities that were not included in the diluted per share calculations because they would be anti-dilutive were as follows:

	Year Ended December 31,	
	2023	2022
Series A-1 redeemable convertible preferred stock	4,753,466	4,753,466
Series A-2 redeemable convertible preferred stock	2,948,071	2,948,071
Series A-3 redeemable convertible preferred stock	203,821	203,821
Series A-4 redeemable convertible preferred stock	27,643	27,643
Series B redeemable convertible preferred stock	7,455,241	7,455,241
Series C redeemable convertible preferred stock	16,076,886	16,076,886
Stock options, issued and outstanding	10,550,273	8,679,090
Warrants to purchase common stock	141,436	116,672
Total	42,156,837	40,260,890

Note 12. Subsequent Events

The Company has evaluated subsequent events from December 31, 2023 through May 31, 2024, the date these consolidated financial statements were available to be issued, and has not identified any items requiring disclosure except as noted below.

In January 2024, the Company amended its 2015 Equity Incentive Plan and increased the total number of shares authorized under the Plan to 26,573,224.

In February 2024, the Company issued 49,713,402 shares of its Series D redeemable convertible preferred stock at $3.4196 per share for gross proceeds of $170.0 million. Simultaneously with the closing of this Series D redeemable convertible preferred stock financing, the Convertible Promissory Notes (including accrued interest) and derivative liability converted into 11,887,535 shares of the Company's Series D-1 redeemable convertible preferred stock at a discount factor of 0.6 relative to the price paid by the Series D investors.

In March 2024, the Company entered into an amendment to the Richmond Lease which extended the term from August 2024 to August 2025 and increased future minimum lease payments by $0.3 million.

In April 2024, the Board of Directors approved the grant of 9,545,749 options to purchase shares of the Company's common stock to employees, officers, board members, and advisors under the 2015 Equity Incentive Plan. The options vest over three- and four-year periods and have an exercise price of $1.88 per share.

BIOAGE LABS, INC. Unaudited
Condensed Consolidated Balance Sheets
(in thousands, except share and per share information)

	June 30, 2024	December 31, 2023
Assets:		
Current assets:		
Cash and cash equivalents	$ 159,085	$ 21,644
Restricted cash	—	3,313
Prepaid expenses and other current assets	4,567	349
Total current assets	163,652	25,306
Investments	100	100
Property and equipment, net	285	323
Operating right-of-use asset, net	340	195
Other assets	25	—
Total assets	164,402	$ 25,924
Liabilities, redeemable convertible preferred stock and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 1,465	$ 1,866
Accrued expenses and other current liabilities	5,218	7,938
Current portion of term loan	6,000	6,000
Operating lease liabilities, current	298	194
Convertible promissory notes	—	20,674
Convertible promissory notes embedded derivative liability	—	18,183
Deferred grant income	—	3,313
Total current liabilities	12,981	58,168
Term loan	5,371	8,201
Warrant liability	307	229
Operating lease liabilities	43	—
Total liabilities	18,702	66,598
Redeemable convertible preferred stock, par value of $0.00001; 93,066,066 and 31,634,362 shares authorized as of June 30, 2024 and December 31, 2023; 93,066,065 and 31,465,128 shares issued and outstanding as of June 30, 2024 and December 31, 2023; aggregate liquidation preference of $326,255 and $131,864 as of June 30, 2024 and December 31, 2023	342,831	132,722
Commitments and Contingencies (note 8)		
Stockholders' deficit:		
Common stock, $0.00001 par value, 132,700,000 and 52,400,000 shares authorized as of June 30, 2024 and December 31, 2023; 7,692,086 and 7,467,378 shares issued and outstanding as of June 30, 2024 and December 31, 2023, respectively	1	—
Additional paid-in capital	10,976	8,142
Accumulated other comprehensive income	167	164
Accumulated deficit	(208,275)	(181,702)
Total stockholders' deficit	(197,131)	(173,396)
Total liabilities, redeemable convertible preferred stock, and stockholders' deficit	$ 164,402	$ 25,924

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

BIOAGE LABS, INC.
Unaudited Condensed Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share information)

	Six Months Ended June 30,	
	2024	2023
Operating expenses:		
Research and development	19,792	17,272
General and administrative	8,290	7,645
Total operating expenses	28,082	24,917
Loss from operations	(28,082)	(24,917)
Other income (expense), net		
Interest expense	(1,660)	(2,832)
Interest and other income	3,497	1,553
Loss from changes in fair value on warrants and derivative liabilities	(78)	(2,075)
Loss on extinguishment of convertible promissory notes	(250)	—
Total other income (expense), net	1,509	(3,354)
Net loss	(26,573)	(28,271)
Net loss per share attributable to common stockholders, basic and diluted	(3.52)	(3.79)
Weighted-average common shares outstanding, basic and diluted	7,551,784	7,464,578
Comprehensive loss		
Net loss	(26,573)	(28,271)
Foreign currency translation adjustment	3	32
Total comprehensive loss	(26,570)	(28,239)

BIOAGE LABS, INC.
Unaudited Condensed Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Deficit
(in thousands, except share information)

	Redeemable Convertible Preferred stock		Common stock		Additional paid-in capital	Accumulated Other Comprehensive Income	Accumulated deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount				
Balance, December 31, 2022	31,465,128	$ 132,722	7,464,463	$ —	$ 5,122	$ 167	$ (117,848)	$ (112,559)
Issuance of common stock upon exercise of options	—	—	200	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	1,492	—	—	1,492
Translation adjustment	—	—	—	—	—	32	—	32
Net loss	—	—	—	—	—	—	(28,271)	(28,271)
Balance, June 30, 2023	31,465,128	$ 132,722	7,464,663	$ —	$ 6,614	$ 199	$ (146,119)	$ (139,306)
Balance, December 31, 2023	31,465,128	132,722	7,467,378	—	8,142	164	(181,702)	(173,396)
Series D redeemable convertible preferred stock	49,713,402	169,458	—	—	—	—	—	—
Conversion of convertible promissory notes into Series D-1 redeemable convertible preferred stock	11,887,535	40,651	—	—	—	—	—	—
Issuance of common stock upon exercise of options	—	—	224,708	1	424	—	—	425
Stock-based compensation expense	—	—	—	—	2,410	—	—	2,410
Translation adjustment	—	—	—	—	—	3	—	3
Net loss	—	—	—	—	—	—	(26,573)	(26,573)
Balance, June 30, 2024	93,066,065	$ 342,831	7,692,086	$ 1	$ 10,976	$ 167	$ (208,275)	$ (197,131)

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

BIOAGE LABS, INC.
Unaudited Condensed Consolidated Statements of Cash Flows
(in thousands)

	Six Months Ended June 30,	
	2024	2023
Cash flows used in operating activities:		
Net loss	$ (26,573)	$ (28,271)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	2,410	1,492
Depreciation expense	82	73
Loss on extinguishment of convertible promissory notes	250	—
Non-cash interest expense	935	2,643
Non-cash lease expense	2	1
Loss from changes in fair value on warrants and derivative liabilities	78	2,075
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(1,621)	(229)
Other assets	(25)	—
Accounts payable	(1,211)	(803)
Accrued expenses and other current liabilities	(5,780)	1,923
Net cash used in operating activities	(31,453)	(21,096)
Cash flows used in investing activities:		
Purchases of property and equipment	(35)	(67)
Purchases of investments	—	(100)
Net cash used in investing activities	(35)	(167)
Cash flows provided by financing activities:		
Proceeds from Series D Issuance, net of issuance costs	169,458	—
Proceeds from issuance of convertible notes	—	23,500
Issuance costs paid on convertible notes	—	(4)
Term loan principal payments	(3,000)	—
Proceeds from term loan	—	12,500
Issuance costs paid on term loan	—	(4)
Proceeds from option exercises	425	—
Deferred offering costs	(1,269)	—
Net cash provided by financing activities	165,614	35,992
Effects of exchange rate changes on cash, cash equivalents, and restricted cash	2	30
Net increase in cash and cash equivalents	134,128	14,759
Cash and cash equivalents as of beginning of the year	24,957	27,644
Cash and cash equivalents as of end of period	$ 159,085	$ 42,403
Supplemental disclosure of cash flow information:		
Conversion of convertible promissory notes into Series D-1 redeemable convertible preferred stock	$ 40,651	—
Cash paid for interest	$ 810	$ 213
Right-of-use assets obtained in exchange for lease obligation	$ 282	$ 407
Deferred offering costs included in accounts payable, accrued expenses, and other current liabilities	$ 1,328	$ —

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

BIOAGE LABS, INC.
Notes to Condensed Consolidated Financial Statements

Note 1. Nature of Business and Liquidity

Nature of Business

BioAge Labs, Inc. (the "Company"), is a clinical-stage biotechnology company developing therapeutic product candidates for metabolic diseases, such as obesity, by targeting a key risk factor: aging. The Company's lead product candidate, azelaprag, is an orally available small molecule that has been well-tolerated in over 240 individuals in seven Phase 1 clinical trials to date. The Company's second product candidate, BGE-100, is an orally available small molecule brain-penetrant NLRP3 antagonist that is being initially developed for the treatment of diseases driven by neuroinflammation.

The Company was incorporated in 2015 in Delaware and is headquartered in Richmond, California.

Liquidity and Capital Resources

Since inception, the Company's operations have consisted primarily of organizing and staffing the Company, business planning, raising capital, establishing its intellectual property portfolio, acquiring or discovering product candidates, research and development activities for its product candidates, establishing arrangements with third parties for the manufacture of its product candidates and component materials, and providing general and administrative support for these operations. The Company has not generated any product revenue to date.

The Company has incurred losses and negative cash flows from operations since inception and had an accumulated deficit of $208.3 million and $181.7 million as of June 30, 2024 and December 31, 2023, respectively. The Company anticipates incurring additional losses until such time, if ever, that it can generate significant sales of its products currently in development. As of June 30, 2024, the Company had cash and cash equivalents of $159.1 million.

Current cash and cash equivalents are sufficient to fund planned operations for at least 12 months from the date of issuance of these financial statements. Accordingly, these condensed consolidated financial statements have been prepared on a going concern basis and do not include any adjustments to the amounts and classification of assets and liabilities that may be necessary in the event the Company can no longer continue as a going concern.

Until such time, if ever, the Company can generate substantial product revenues, it expects to finance its cash needs through equity offerings, debt financings or other capital sources, which could include collaborations, strategic alliances or licensing arrangements. To the extent that the Company raises additional capital through the sale of equity or convertible debt securities, the ownership interests of the Company's existing stockholders may be diluted, and the terms of these securities may include liquidation or other preferences that could adversely affect the rights of such stockholders. Debt financing, if available, may involve agreements that include restrictive covenants that limit the Company's ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, that could adversely impact the Company's ability to conduct its business. If the Company raises additional funds through collaborations, strategic alliances or licensing arrangements with third parties, the Company may have to relinquish valuable rights to its technologies, future revenue streams, research program or product candidates, or grant licenses on terms that may not be favorable to the Company. If the Company is unable to raise additional funds through equity or debt financings when needed, the Company may be required to delay, limit, reduce or terminate its product development or future commercialization efforts or grant rights to develop and market product candidates that the Company would otherwise prefer to develop and market itself.

BIOAGE LABS, INC.
Notes to Condensed Consolidated Financial Statements

Note 2. Summary of Significant Accounting Policies

Unaudited interim condensed consolidated financial statements

The interim condensed consolidated balance sheet as of June 30, 2024, interim condensed consolidated statements of operations and comprehensive loss, interim condensed consolidated statements of redeemable convertible preferred stock and stockholders' deficit, and interim condensed consolidated statements of cash flows for the six months ended June 30, 2024 and 2023 are unaudited. These unaudited interim condensed consolidated financial statements have been prepared on a basis consistent with the Company's audited consolidated financial statements and include, in the opinion of management, all adjustments of a normal or recurring nature that management considers necessary for a fair presentation of the Company's consolidated financial information. The financial data and the other financial information disclosed in these notes to the condensed consolidated financial statements related to the six-month periods are also unaudited. The condensed consolidated results of operations and cash flows for the six months ended June 30, 2024 are not necessarily indicative of the results of operations that may be expected for the year ended December 31, 2024 or for any future period. The condensed consolidated balance sheet as of December 31, 2023 was derived from the audited consolidated financial statements as of that date.

These unaudited condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements as of and for the year ended December 31, 2023 and the accompanying notes thereto.

Use of Estimates

The preparation of condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities as of the date of the condensed consolidated financial statements and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

Estimates and assumptions are periodically reviewed and the effects of revisions are reflected in the condensed consolidated financial statements in the period they are determined to be necessary. Areas that require management's estimates include the fair values of the Company's common and redeemable convertible preferred stock, warrant liability, embedded derivative liability, stock-based compensation expense assumptions, deferred tax assets and accruals for research and development expenses.

Foreign Currency

Results of foreign operations are translated from their functional currency into U.S. dollars (reporting currency) using average exchange rates in effect during the year while assets and liabilities are translated into U.S. dollars using exchange rates in effect at the balance sheet date. The resulting translation adjustments are recorded in accumulated other comprehensive income (loss). Transaction gains and losses resulting from exchange rate changes on transactions denominated in currencies other than the U.S. dollar are included in operations in the period in which the transaction occurs.

Segments

The Company operates and manages its business as one reportable and operating segment, which is the business of extending healthy human life by targeting molecular causes of aging. The Company's Chief Executive Officer, who is the chief operating decision maker, reviews financial information on an aggregate basis for allocating and evaluating financial performance. All long-lived assets are maintained in, and all losses are attributable to, the United States of America.

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Cash, Cash Equivalents, and Restricted Cash

The Company considers all highly liquid investments that have original maturities of three months or less when acquired to be cash equivalents. Cash and cash equivalents as of June 30, 2024 and December 31, 2023 consisted of bank deposits and money market mutual funds invested in short-term U.S. government obligations. The Company had no restricted cash as of June 30, 2024. As of December 31, 2023 the Company had $3.3 million in restricted cash related to the Wellcome Leap Commercial Research Funding Agreement.

Concentrations of Credit Risk

Cash and cash equivalents are financial instruments that are potentially subject to concentrations of credit risk to the extent they exceed the federal depository insurance limits. The Company is exposed to credit risk in the event of default by the financial institutions holding its cash and cash equivalents to the extent recorded in the balance sheets. While the Company has not experienced any losses in such accounts, the failure of Silicon Valley Bank ("SVB") in 2023, at which the Company held cash and cash equivalents in multiple accounts, potentially exposed the Company to significant credit risk. The Federal Deposit Insurance Corporation ("FDIC") issued a statement on March 13, 2023 that they intended to take action to fully protect SVB depositors, which they did on March 27, 2023, by making SVB a division of First Citizens Bank. As of the date of the issuance of these condensed consolidated financial statements, the Company has full access to and control over all of its cash and cash equivalents. The Company has no financial instruments with off-balance sheet risk of loss.

Risks and Uncertainties

The Company faces risks and uncertainties associated with companies in the biotechnology industry, including but not limited to the uncertainty of success of its preclinical studies and clinical trials, regulatory approval of product candidates, uncertainty of market acceptance of products, competition from substitute products and larger companies, the need for additional financing, compliance with government regulations, dependence on third parties, recruiting and retaining skilled personnel, and dependence on key members of management.

The Company's product candidates require approvals from the U.S. Food and Drug Administration ("FDA") and comparable foreign regulatory agencies prior to commercial sales in their respective jurisdictions. There can be no assurance that any product candidates will receive the necessary approvals. If the Company was denied approval, approval was delayed or the Company was unable to maintain approval for any product candidate, it could have a materially adverse impact on the Company.

Property and Equipment, Net

Property and equipment, net is carried at cost less accumulated depreciation. Depreciation is computed over the estimated useful lives of the respective assets using the straight-line method. Useful lives of property and equipment range from three to five years. Operating lease leasehold improvements are amortized over the lesser of the useful lives of the leasehold improvements or the lease term. Upon retirement or sale, the costs of the assets disposed of and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is credited or charged to operations. Maintenance and repairs are expensed as incurred. Asset improvements are capitalized.

Impairment of Long-lived Assets

The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability is measured by a

comparison of the carrying amount of an asset to future undiscounted net cash flows which the assets are expected to generate. If such assets are considered to be impaired, the impairment is measured by the excess of the carrying amount of the assets over fair value less the costs to sell the assets, generally determined using the projected discounted future net cash flows arising from the asset. The Company did not recognize any impairment of long-lived assets during the six months ended June 30, 2024 and 2023.

Redeemable Convertible Preferred Stock

The Company records redeemable convertible preferred stock net of issuance costs on the date of issuance, which represents the carrying value. Redeemable convertible preferred stock is classified outside of stockholders' deficit as temporary equity on the accompanying condensed consolidated balance sheets as events triggering the liquidation preferences, including a deemed liquidation event, are not solely within the Company's control. The Company has not remeasured redeemable convertible preferred stock. The carrying values of the redeemable convertible preferred stock will be adjusted to their liquidation preferences if and when it becomes probable that such a liquidation event will occur.

Convertible Promissory Notes and Embedded Derivative Liability

Convertible promissory notes are recorded at the issued value. Debt discount and issuance costs, consisting of legal and other fees directly related to the debt, are offset against gross proceeds from the issuance of the convertible promissory notes and are amortized to interest expense over the life of the debt based on the effective interest method. Amortization expense is presented in interest expense in the condensed consolidated statement of operations and comprehensive loss.

The Company reviews the terms of its convertible promissory notes to determine whether there are conversion features or embedded derivative instruments including embedded conversion options that are required to be bifurcated and accounted for separately as a derivative financial instrument. In circumstances where the convertible promissory notes contain more than one embedded derivative instrument, including conversion options that are required to be bifurcated, the bifurcated derivative instruments are accounted for as a single compound instrument. When convertible debt contains embedded derivative instruments that are to be bifurcated and accounted for separately, the total proceeds allocated to the convertible host instruments are first allocated to the fair value of the bifurcated derivative instrument. The remaining proceeds, if any, are then allocated to the convertible instruments themselves, usually resulting in those instruments being recorded at a discount from their face amount.

As of December 31, 2023, the Company had bifurcated embedded derivatives related to its convertible promissory notes that were accounted for separately as derivative liabilities. Derivative liabilities are initially recorded at fair value and subsequently revalued at each reporting date with changes in fair value recognized separately in the condensed consolidated statement of operations and comprehensive loss. Derivative liabilities are presented separately in the condensed consolidated balance sheet.

On February 1, 2024, in connection with the closing of the Series D redeemable convertible preferred stock financing, the Convertible Promissory Notes (including accrued interest) and related embedded derivative liability converted into 11,887,535 shares of Series D-1 redeemable convertible preferred stock.

Term Loan

Term loans are measured at net proceeds less debt discounts and issuance costs are accreted to the face value of the term loan over its expected term using the effective interest method. The Company considers whether there are any embedded features in its debt instruments that require bifurcation and separate accounting as derivative financial instruments pursuant to ASC Topic 815, *Derivatives and Hedging* (Note 5).

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Notes to Condensed Consolidated Financial Statements

Warrant Liability

Freestanding warrants for the Company's common stock are classified as liabilities and recorded at fair value, with any change in fair value recognized as a component of other income (loss). Such warrant liabilities are subject to re-measurement at each balance sheet date until the earlier of the exercise of the warrants, expiration, or the completion of a change in control event. Upon exercise, the warrant liability would be reclassified to additional paid-in capital, at its then fair value.

Research and Development Expenses

Research and development costs are expensed as incurred and include all direct and indirect costs associated with the development of the Company's product candidates and other research programs. These expenses consist primarily of personnel costs, stock-based compensation charges, consulting fees, and payments to third parties for research, development, and manufacturing services as well as other allocated facility-related costs and overhead expenses. Nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities are capitalized and expensed as the goods are delivered or the related services are performed.

Accrued Research and Development Expenses

The Company records accruals for estimated costs of research, preclinical studies, clinical trials, and manufacturing, which are significant components of research and development expenses. A substantial portion of the Company's ongoing research and development activities is conducted by third-party service providers, clinical research organizations ("CROs"), and clinical manufacturing organizations ("CMOs"). The Company's contracts with CROs generally include pass-through fees such as laboratory supplies and services, regulatory expenses, investigator fees, travel costs and other miscellaneous costs, including shipping and printing fees. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided to the Company under such contracts. The Company accrues the costs incurred under agreements with these third parties based on estimates of actual work completed in accordance with the respective agreements. The Company determines the estimated costs through discussions with internal personnel and external service providers as to the progress, or stage of completion or actual timeline (start-date and end-date) of the services and the agreed-upon fees to be paid for such services. In the event the Company makes advance payments, the payments are recorded as a prepaid expense and recognized as the services are performed.

As actual costs become known, including subsequent to the reporting date, the Company adjusts its accruals. Although the Company does not expect its estimates to be materially different from amounts actually incurred, such estimates for the status and timing of services performed relative to the actual status and timing of services performed may vary and could result in the Company reporting amounts that are too high or too low in any particular period. The Company's accrual is dependent, in part, upon the receipt of timely and accurate reporting from CROs and other third-party vendors. Variations in the assumptions used to estimate accruals including, but not limited to, the number of patients enrolled, the rate of patient enrollment and the actual services performed, may vary from the Company's estimates, resulting in adjustments to clinical trial expenses in future periods. Changes in these estimates that result in material changes to the Company's accruals could materially affect its financial condition and results of operations.

Acquired In-Process Research and Development Expenses

Acquired in-process research and development expense consists of payments incurred in connection with the acquisition or licensing of products or technologies that do not meet the definition of a business under FASB ASC Topic 805, *Business Combinations*. Costs incurred in obtaining technology licenses including

upfront and milestone payments incurred under licensing agreements are recorded as expense in the period in which they are incurred, provided that the licensed technology, method or process has no alternative future uses other than for the specific research and development activities. Such payments are classified as cash flows from operating activities in the Company's condensed consolidated statements of cash flows. Milestone payments within the Company's licensing arrangements are recognized when achievement of the milestone payment is legally due and payable. To the extent products are commercialized and future economic benefit has been established, commercial milestones that become probable are capitalized and amortized over the estimated remaining useful life of the intellectual property. In addition, the Company accrues royalty expense and sublicense nonroyalty payments, as applicable, for the amount it is obligated to pay, with adjustments as sales are made.

Stock-Based Compensation

The Company's stock-based compensation program allows for grants of stock options and restricted stock awards. Grants are awarded to employees and non-employees, including directors.

Compensation cost for the Company's stock-based payments to employees, non-employees and directors, are based on estimated fair value of the awards on the date of grant. The Company estimates the fair value of options granted using the Black-Scholes option pricing model for stock option grants to both employees and non-employees. The fair value of restricted stock awards is measured as the fair value per share of the Company's common stock on the date of grant and are presented as an outstanding share of common stock when vested and no longer subject to repurchase.

The Company's stock-based compensation awards are subject to service-based vesting conditions. Compensation expense related to awards to employees, directors and non-employees with service-based vesting conditions is recognized on a straight-line basis based on the vesting date fair value over the associated service period of the award, which is generally the vesting term.

Income Taxes

Income taxes are accounted for under the asset and liability method in accordance with ASC Topic 740, *Income Taxes.* Deferred tax assets and liabilities are recognized for the future tax consequences attributable to the differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and the operating loss and tax credit carry forwards. Deferred tax assets and liabilities are measured at the balance sheet date using the enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. Deferred tax assets are reduced by a valuation allowance if it is more likely than not that these assets may not be realized. The Company determines whether it is more-likely-than-not that a tax position will be sustained upon examination. If it is not more-likely-than-not that a position will be sustained, none of the benefit attributable to the position is recognized. The tax benefit to be recognized for any tax position that meets the more-likely-than-not recognition threshold is calculated as the largest amount that is more than 50% likely of being realized upon resolution of the contingency. The Company accounts for interest and penalties related to uncertain tax positions as part of its provision for income taxes. No interest or penalties were charged to the Company related to uncertain tax positions for the six months ended June 30, 2024 or 2023.

Leases

The Company determines if an arrangement is a lease at the inception of the arrangement. Operating leases are included in right-of-use assets, current portion of operating lease liability, and operating lease liability, net of current portion in the Company's balance sheets. Right-of-use assets represent the Company's

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right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Operating lease right-of-use assets and liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term. In determining the present value of lease payments, the Company uses its incremental borrowing rate based on the information available at the lease commencement date. The operating lease right-of-use assets also include any lease payments made and exclude lease incentives. The Company's lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise any such options. Lease expense is recognized on a straight-line basis over the expected lease term. The Company has elected not to separate lease and non-lease components, such as common area maintenance charges, and instead it accounts for these as a single lease component. Leases with an initial term of 12 months or less are not recorded on the balance sheet, unless they include an option to purchase the underlying asset or to extend the lease that the Company is reasonably certain to exercise.

Comprehensive Loss

Comprehensive loss is defined as a change in equity of a business enterprise during a period, resulting from transactions from non-owner sources. Comprehensive loss is comprised of net loss and other comprehensive income (loss). The Company's other comprehensive loss consists of foreign currency translation adjustments. Total comprehensive loss for all periods presented has been disclosed in the condensed consolidated statements of operations and comprehensive loss.

Net Loss Per Share Attributable to Common Stockholders

Basic net loss per share attributable to common stockholders is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period, without consideration for potentially dilutive securities.

Diluted net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common stock and potentially dilutive securities outstanding for the period. For purposes of the diluted net loss per share attributable to common stockholders' calculation, redeemable convertible preferred stock, stock options, and warrants are considered to be potentially dilutive securities.

The Company applies the two-class method to calculate its basic and diluted net loss per share attributable to common stockholders as the Company has issued shares that meet the definition of participating securities. The two-class method is an earnings allocation formula that treats a participating security as having rights to earnings that otherwise would have been available to common stockholders. Participating securities consist of common stock and redeemable convertible preferred stock. The Company's participating securities contractually entitle the holders of such shares to participate in dividends, but do not contractually require the holders of such shares to participate in losses of the Company. Accordingly, in periods in which the Company reports a net loss, such losses are not allocated to such participating securities.

Accordingly, in periods in which the Company reports a net loss, diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders, since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive.

Fair Value of Financial Instruments

GAAP establishes a fair value hierarchy for instruments measured at fair value that distinguishes between assumptions based on market data (observable inputs) and the Company's own assumptions (unobservable inputs). Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company.

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Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing the asset or liability and are developed based on the best information available in the circumstances.

Fair value is established as the exchange price, or exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As a basis for considering market participant assumptions in fair value measurements, an established three-tier fair value hierarchy distinguishes between the following:

- Level 1 inputs are quoted prices in active markets that are accessible at the market date for identical assets or liabilities.
- Level 2 inputs are inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly.
- Level 3 inputs are unobservable inputs that reflect the Company's own assumptions about the assumptions market participants would use in pricing the assets or liability. Financial assets and liabilities are classified in their entirety based on the lowest level of input that is significant to the fair value measurement.

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

The carrying amounts of the Company's other current assets, accounts payable, accrued expenses and other current liabilities reported in the condensed consolidated financial statements approximate their fair values due to their short-term nature.

Note 3. Fair Value Measurements

The following fair value hierarchy table presents information about each major category of the Company's financial assets and liabilities measured at fair value on a recurring basis (in thousands):

	June 30, 2024			
	(Level 1)	(Level 2)	(Level 3)	Total
Assets				
Cash equivalents	$ 158,802	$ —	$ —	$ 158,802
Liabilities				
Warrant liability	—	—	307	307

	December 31, 2023			
	(Level 1)	(Level 2)	(Level 3)	Total
Assets				
Cash equivalents	$ 21,061	$ —	$ —	$ 21,061
Liabilities				
Convertible promissory notes embedded derivative liability	—	—	18,183	18,183
Warrant liability	—	—	229	229
Total	$ —	$ —	$ 18,412	$ 18,412

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There were no changes in valuation techniques or transfers between category levels during the six months ended June 30, 2024 and 2023.

Cash Equivalents

Cash equivalents include U.S. government obligation money market mutual funds that have a maturity of three months or less from the original acquisition date. The Company's cash equivalents are classified using Level 1 inputs within the fair value hierarchy because they are valued using quoted market prices.

Convertible Promissory Notes Embedded Derivative Liability

The Company's Convertible Promissory Notes (as defined in Note 5) contained equity conversion options, and certain repayment features, that have been identified as a single compound embedded derivative requiring bifurcation from the Convertible Promissory Notes. The Company estimated the fair value of the convertible promissory note embedded derivative liabilities on issuance using a with-and-without scenario analysis. The estimated probability and timing of underlying events triggering the conversion and liquidity repayment features as well as discount rates, volatility and share prices are inputs used to determine the estimated fair value of the embedded derivative. The Convertible Promissory Notes and related embedded derivative liability converted into Series D-1 Redeemable Convertible Preferred Stock on February 1, 2024.

Warrant Liability

The Company's warrant liability is classified using Level 3 inputs within the fair value hierarchy because the warrant liability is valued using both observable and unobservable inputs.

Note 4. Balance Sheet Components

Property and Equipment, Net

Property and equipment, net consisted of the following (in thousands):

	June 30, 2024	December 31, 2023
Lab equipment	$ 410	$ 366
Computer equipment and software	323	323
Furniture and fixtures	53	53
Property and equipment, gross	786	742
Accumulated depreciation	(501)	(419)
Property and equipment, net	$ 285	$ 323

Depreciation expense for the six months ended June 30, 2024 and 2023 was immaterial.

Accrued Expenses and Other Current Liabilities

Accrued expenses consisted of the following (in thousands):

	June 30, 2024	December 31, 2023
Research and development expenses	$ 1,718	$ 2,516
Payroll and related costs	2,198	4,033
Other	1,302	1,389
Total accrued expenses and other current liabilities	$ 5,218	$ 7,938

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Note 5. Debt

Convertible Promissory Notes

In February 2023, the Company issued four convertible promissory notes with an aggregate principal amount of $23.5 million. Each note has an interest rate of 4% per annum and a maturity date of May 10, 2024 (the "Convertible Promissory Notes"). The notes and any accrued but unpaid interest were convertible at either the date of a qualified financing of at least $20.0 million (a "Qualified Financing"), or on the maturity date, at the option of the respective holder, and are convertible into the same securities issued in the Qualified Financing, or if no qualified financing occurs prior to maturity, then shall be convertible into the Company's Series C Preferred Stock.

Upon a Qualified Financing, the Convertible Promissory Notes automatically convert into shares of the Company's redeemable convertible preferred stock on the same conditions applicable for the Qualified Financing at a conversion price equal to the lowest price per share paid in the Qualified Financing multiplied by a discount factor ranging from 0.6 to 1.0 depending on the timing of the Qualified Financing.

On February 1, 2024, in connection with the closing of the Series D redeemable convertible preferred stock financing, the Convertible Promissory Notes (including accrued interest) and related embedded derivative liability converted into 11,887,535 shares of Series D-1 redeemable convertible preferred stock at a discount factor of 0.6 relative to the price paid by the Series D investors. The conversion resulted in a $0.3 million loss on extinguishment of the Convertible Promissory Notes.

Term Loan

In May 2022, the Company entered into a loan and security agreement (the "Loan Agreement") with SVB Innovative Credit Growth Fund IX, LP and Innovative Credit Growth Fund VIII-A, LP, (collectively, the "Lenders") pursuant to which the Company was eligible to borrow, and the Lenders are obligated to fund up to $25.0 million in borrowing capacity across two potential tranches (the "Term Loan"). At the closing of the Loan Agreement in May 2022, the Company drew $2.5 million from the first tranche (the Initial Term Loan) and in May 2023 the Company drew $12.5 million from the second tranche (the "Additional Term Loan").

In connection with the Initial Term Loan of $2.5 million, the Company issued to the Lenders warrants to purchase 86,672 shares of the Company's common stock. The warrants expire on May 20, 2032 and had a fair value of $125,602 at issuance. Similarly, in connection with the Additional Term Loan draw, the Company issued additional warrants to purchase 24,764 shares of the Company's common stock. The warrants expire on May 20, 2032 and had a fair value of $37,050 at issuance. As a result, proceeds from the debt equal to the fair value were allocated to these warrants and are amortized as part of the debt discount over the life of the Term Loan.

Interest for the Term Loan accrues at a floating per annum rate equal to the greater of (i) the Prime rate plus 4.00% or (ii) 7.50%. Interest is due monthly on the first business day of each month, commencing in June 2022. The Term Loan is scheduled to mature on April 1, 2026 and commencing on November 1, 2023 the Company is required to make monthly principal payments. The Company may prepay all of the outstanding principal balance of the Term Loan, at its option, prior to the maturity date subject to a prepayment premium ranging from 1.0% to 2.0%. The prepayment premium will apply to any mandatory or voluntary prepayment, but will not be due upon a refinancing of the outstanding Term Loan with another credit facility from SVB. In addition, the Company will also be required to pay a final payment fee equal to 4.4% of the total amount borrowed.

The Company's obligations under the Loan Agreement are subject to acceleration upon the occurrence of customary events of default, including payment default, insolvency and the occurrence of certain events having a material adverse effect on the Company, including (but not limited to) material adverse effects upon the business, operations, properties, assets or financial condition of the Company and its subsidiaries, taken as a whole.

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The Loan Agreement includes positive and negative covenants that the Company must comply with and is secured by the assets of the Company that are pledged as collateral.

Debt issuance costs, including the fair value of the warrants, have been treated as debt discounts in the condensed consolidated balance sheet and together with the final payment are being amortized to interest expense throughout the life of the Term Loan using the effective interest rate method. As of June 30, 2024 and December 31, 2023, there were unamortized issuance costs and debt discounts of less than $0.1 million, which are recorded as a direct deduction from the Term Loan on the condensed consolidated balance sheet. Interest expense related to the Loan Agreement was $1.0 million and $0.3 million for the six months ended June 30, 2024 and 2023, respectively. As of June 30, 2024 the stated rate on the Term Loan was 12.5%. As of June 30, 2024, the effective interest rate on the Term Loan, including the amortization of the debt discount and accretion of the final payment, was 16.8% for the Initial Term Loan and 15.2% Additional Term Loan. The carrying amount of the Term Loan is subject to variable interest rates, which are based on current market rates, and as such, approximate fair value.

The components of the Term Loan balance were (in thousands):

	June 30, 2024
Principal loan balance	$ 11,000
Final fee	433
Unamortized debt discount	(62)
Total Term Loan	$ 11,371
Less current portion of Term loan	(6,000)
Term loan	$ 5,371

As of June 30, 2024, the estimated future principal payments under the Term Loan are as follows (in thousands):

Year ending December 31,	Total Principal Payments
2024 (excluding the six months ended June 30, 2024)	$ 3,000
2025	6,000
2026	2,000
Principal amount of Term Loan	$ 11,000

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Note 6. Capital Structure

Redeemable Convertible Preferred Stock

Redeemable convertible preferred stock consisted of the following as of June 30, 2024 (in thousands, except share information):

	Shares Issued and Outstanding	Shares Authorized	Carrying Value	Aggregate Liquidation Preference
Series A-1	4,753,466	4,753,466	$ 11,558	$ 11,822
Series A-2	2,948,071	2,948,071	3,085	1,808
Series A-3	203,821	203,821	272	250
Series A-4	27,643	27,643	49	55
Series B	7,455,241	7,455,241	22,854	22,929
Series C	16,076,886	16,076,886	94,904	95,000
Series D	49,713,402	49,713,403	169,458	170,000
Series D-1	11,887,535	11,887,535	40,651	24,391
Total	93,066,065	93,066,066	$ 342,831	$ 326,255

In 2017, the Company issued 4,753,466 shares of Series A-1 redeemable convertible preferred stock (the "Series A-1 Preferred Stock"), 2,948,071 shares of Series A-2 redeemable convertible preferred stock (the "Series A-2 Preferred Stock"), 203,821 shares of Series A-3 redeemable convertible preferred stock (the "Series A-3 Preferred Stock"), and 27,643 shares of Series A-4 redeemable convertible preferred stock (the "Series A-4 Preferred Stock" and together with the Series A-1 Preferred Stock, Series A-2 Preferred Stock and Series A-3 Preferred Stock, the "Series A Preferred Stock"), and in connection with the settlement of the Simple Agreement for Future Equity ("SAFE") instruments that were outstanding. SAFEs were originally provided to early investors in exchange for cash. The investors who held these SAFEs converted their respective SAFEs to Series A Preferred Stock. The Series A Preferred Stock have the same rights and preferences except for their initial original issuance prices in connection with any future liquidation events as defined in the Company's articles of incorporation.

In 2018, the Company sold 7,455,241 shares of its Series B redeemable convertible preferred stock at $3.0756 per share for gross proceeds of $22.9 million (the "Series B Preferred Stock").

During the year ended December 31, 2020, the Company sold 15,230,734 shares of Series C redeemable convertible preferred stock (the "Series C Preferred Stock") at $5.9091 per share for gross proceeds of $90.0 million.

During the year ended December 31, 2021, the Company issued 846,152 shares of Series C Preferred Stock in connection with the Amgen Agreement.

In February 2024, the Company issued 49,713,402 shares of Series D redeemable convertible preferred stock at $3.4196 per share for gross proceeds of $170.0 million (the "Series D Preferred Stock"). Simultaneously with the closing of the Series D Preferred Stock, the Convertible Promissory Notes (including accrued interest) and derivative liability converted into 11,887,535 shares of Series D-1 redeemable convertible preferred stock at a discount factor of 0.6 relative to the price paid by the Series D investors (the "Series D-1 Preferred Stock").

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The following is a summary of the amended rights, preferences, and privileges of the Series A-1 through A-4, Series B and Series C, Series D, and Series D-1 redeemable convertible preferred stock:

Rank—The redeemable convertible preferred stock ranks senior to the common stock as to payment of dividends, distributions of assets upon a liquidation event, or otherwise.

Dividends—The holders of the redeemable convertible preferred stock are entitled to receive non-cumulative dividends at the rate of 6.00% per year if and when declared by the Company's board of directors (the "Board of Directors"). Any declared but unpaid dividends are payable upon a liquidation event or conversion of the applicable shares of convertible preferred stock to common stock. No dividends have been declared through June 30, 2024.

Voting Rights—The holders of the redeemable convertible preferred stock are entitled to a number of votes equal to the number of shares of common stock into which their shares can be converted. The holders of the redeemable convertible preferred stock are entitled to elect one member of the Board of Directors.

Liquidation Preference—In the event of a liquidation, dissolution, or winding up of the Company, or in the event the Company merges with or is acquired by another entity, the holders of the redeemable convertible preferred stock are entitled to their liquidation preference payments plus any accrued but unpaid dividends. Once the liquidation preference has been paid, any remaining assets would be distributed pro rata among the holders of the Series C Preferred Stock, Series B Preferred Stock, Series A Preferred Stock and common stock on an "as converted" basis. Liquidation preference payments equal an amount per share equal to the greater of (i) the Original Issue Price for such series, plus any dividends declared but unpaid thereon, or (ii) such amount per share as would have been payable on an as-converted basis., where "Original Issue Price" means $2.4870 per share for Series A-1 Preferred Stock, $0.6133 per share for Series A-2 Preferred Stock, $1.2266 per share for Series A-3 Preferred Stock, $1.9896 per share for Series A-4, $3.0756 per share for Series B Preferred Stock, $5.9091 per share for Series C Preferred Stock, $3.4196 per share for Series D Preferred Stock, and $2.0518 per share for Series D-1 Preferred Stock.

Conversion—At any time, at the option of the holder, each share of redeemable convertible preferred stock is convertible into one share of common stock, subject to certain antidilution adjustments. The conversion of the redeemable convertible preferred stock is not considered probable at this time, therefore, subsequent measurement adjustments have not been made. The redeemable convertible preferred stock is automatically converted in the event of an initial public offering ("IPO") of specified characteristics, or upon the agreement of holders of a majority of the outstanding redeemable convertible preferred stock.

Down-Round Antidilution Protection—In the event the Company issues its common stock without consideration or for consideration per share that is less than the conversion price in effect for each series of the redeemable convertible preferred stock, then the conversion price for that series shall be reduced in order to increase the number of ordinary shares into which such series of redeemable convertible preferred stock is convertible into.

BIOAGE LABS, INC.
Notes to Condensed Consolidated Financial Statements

Common Stock

In connection with the Series D Preferred Stock and Series D-1 Preferred Stock financings in 2024, the number of Board of Directors seats were increased from five board seats to up to nine board seats. The holders of the common stock are exclusively entitled to elect two members of the Board of Directors. The common stockholders are entitled to one vote for each share of common stock held. There are 132,700,000 and 52,400,000 shares of common stock authorized as of June 30, 2024 and December 31, 2023, respectively. Common stock reserved for future issuance, on an as-if-converted basis, as of June 30, 2024 and December 31, 2023, consisted of the following:

	June 30, 2024	December 31, 2023
Common stock, issued and outstanding	7,692,086	7,467,378
Redeemable convertible preferred stock, issued and outstanding	93,066,065	31,465,128
Stock options, issued and outstanding	20,183,532	10,550,273
Stock options, authorized for future issuance	5,305,722	2,740,142
Warrants, issued and outstanding	141,436	141,436
Total	126,388,841	52,364,357

Note 7. Stock-Based Compensation

Stock Option Plan

The Company issues stock-based awards pursuant to its 2015 Equity Incentive Plan, as amended (the "Plan"). In January 2024, the Company amended the Plan and increased the total number of shares authorized under the Plan to 26,573,224. As of June 30, 2024, 5,305,722 shares are available for future grants. Eligible participants include employees, directors, and consultants. The Plan permits the granting of incentive stock options, non-statutory stock options, stock awards, and stock purchase rights. The terms of the agreements are determined by the Board of Directors. The Company's stock options have a term of 10 years and vest based on the terms in the agreements, generally over 4 years.

The following table summarizes the stock option activity for the six months ended June 30, 2024:

	Shares Available to Grant	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value (in thousands)
Balance-December 31, 2023	2,740,142	10,550,273	$ 1.88	7.4	$ 2,864
Increase in authorized shares	12,423,547	—	—		
Granted	(10,089,562)	10,089,562	1.89		
Exercised	—	(224,708)	1.89		
Forfeited/expired	231,595	(231,595)	1.64		
Balance-June 30, 2024	5,305,722	20,183,532	$ 1.89	8.3	$ 10,466
Vested and Exercisable-June 30, 2024		7,395,191	$ 1.77	6.6	$ 4,659

The fair value of the stock options that were exercised during the six months ended June 30, 2024 and 2023 were $0.5 million and less than $0.1 million, respectively.

BIOAGE LABS, INC.
Notes to Condensed Consolidated Financial Statements

The fair value of options granted during the six months ended June 30, 2024 and 2023 was estimated on the date of grant using a Black-Scholes option pricing model with the following weighted-average assumptions:

	Six Months Ended June 30,	
	2024	2023
Risk-free interest rate	4.6%	3.7%
Expected term	6.0 years	6.0 years
Expected volatility	110.2%	91.6%
Expected dividend yield	—	—
Estimated fair value of the Company's common stock (per share)	$ 1.89	$ 1.69

Stock-based compensation expense recorded as research and development and general and administrative expenses in the statements of operations and comprehensive loss is as follows (in thousands):

	Six Months Ended June 30,	
	2024	2023
Research and development	$ 776	$ 549
General and administrative	1,634	943
Total stock-based compensation expense	$ 2,410	$ 1,492

As of June 30, 2024 there was $19.2 million of unrecognized compensation cost that is expected to be recognized over a weighted average period of 3.3 years.

Note 8. Commitments and Contingencies

Indemnification

The Company entered into indemnification agreements with directors and certain officers that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. No demands have been made upon the Company to provide indemnification under such agreements, and thus, there are no claims that the Company is aware of that could have a material effect on the condensed consolidated financial statements. The Company also maintains director and officer insurance, which may cover certain liabilities arising from the Company's obligation to indemnify its directors and officers. To date, the Company has not incurred any costs and have not accrued any liabilities in the condensed consolidated financial statements as a result of these provisions.

Legal Proceedings

The Company is not a party to any litigation and does not have contingency reserves established for any litigation liabilities.

Employee Benefit Plan

The Company maintains a defined contribution 401(k) plan, under which employee contributions are voluntary and are determined on an individual basis, limited by the maximum amounts allowable under federal tax regulations. The Company provides an automatic matching contribution of employee contributions into the plan up to a maximum of 4% of employee deferral. The Company's matching contributions to employees were $0.3 million during the six months ended June 30, 2024 and 2023.

BIOAGE LABS, INC.
Notes to Condensed Consolidated Financial Statements

Leases

In August 2017, the Company entered into an agreement to lease approximately 6,436 square feet of office and lab space in Richmond California, which the Company uses for its corporate offices and research facility (the "Richmond Lease"). The Richmond lease had an initial term of three years but was amended in October 2017 and August 2019 to add additional space for a total of 18,829 square feet and to extend the term of the lease through February 2023. In January 2023, the Company entered into an amendment which extended the term of the lease through August 2024. In March 2024, the Company entered into an amendment which extended the term of the lease through August 2025. The Richmond Lease includes escalating rent payments but does not provide for any renewal options. The Company recognizes rent expense on a straight-line basis over the lease term. The Richmond lease does not provide a bargain purchase option nor does it transfer ownership at any point during the lease to the Company and is classified as an operating lease.

As of June 30, 2024, the remaining lease term was 1.2 years and the discount rate used to determine the operating leases liability was 12.5%.

Cash paid for amounts included in the measurement of operating lease liabilities was $0.2 million for the six months ended June 30, 2024 and 2023, respectively, and was included in net cash used in operating activities in the Company's statement of cash flows.

Future Minimum rental payments of $0.2 million will be made in each of 2024 and 2025. Rent expense was $0.2 million for each of the six months ended June 30, 2024 and 2023. Variable lease payments related to operating leases for the six months ended June 30, 2024 and 2023 were not material.

Note 9. Wellcome Leap Commercial Research Funding Agreement

In September 2023, the Company entered into a Commercial Research Funding Agreement with Wellcome Leap, Inc. (the "Wellcome Leap Agreement") in which Wellcome Leap was to fund certain research and development work performed by the Company. In connection with the Wellcome Leap Agreement, the Company entered into a statement of work in which the Company was to evaluate Azelaprag's efficacy at preventing muscle atrophy and frailty during hospitalization in chronic obstructive pulmonary disease ("COPD") patients through a Phase 2 clinical trial (the "COPD Trial").

Also, in September 2023, Wellcome Leap made a payment of $3.3 million to the Company to cover costs to be incurred related to the COPD Trial (the "Grant Funds"). As the Grant Funds are maintained in a separate bank account from the Company's other funds and are only to be expended on the COPD Trial, it was determined that the Grant Funds represented restricted cash and are classified as such in the consolidated balance sheet as of December 31, 2023.

In March 2024, the Company informed Wellcome Leap that it planned to terminate the COPD Trial due to concerns regarding commercial feasibility and on May 31, 2024, the Company and Wellcome Leap terminated the Wellcome Leap Agreement (the "Wellcome Leap Termination"). In connection with the Wellcome Leap Termination, the Company returned $2.4 million of unused Grant Funds received to Wellcome Leap in June 2024.

Note 10. Income Taxes

The Company estimates an annual effective tax rate of 0% for the year ending December 31, 2024 as the Company incurred losses for the six months ended June 30, 2024 and expects to continue to incur losses through the remainder of fiscal year ending December 31, 2024, resulting in an estimated net loss for both financial statement and tax purposes for the year ending December 31, 2024. Therefore, no federal, state or foreign income taxes are expected and none have been recorded at this time.

BIOAGE LABS, INC.
Notes to Condensed Consolidated Financial Statements

Due to the Company's history of losses since inception, there is not enough evidence at this time to support that the Company will generate future income of a sufficient amount and nature to utilize the benefits of its net deferred tax assets. Accordingly, the deferred tax assets have been reduced by a full valuation allowance, since the Company does not currently believe that realization of its deferred tax assets is more likely than not.

On June 30, 2024, the Company had no unrecognized tax benefits that would reduce the Company's effective tax rate if recognized.

Note 11. Net Loss Per Share Attributable to Common Stockholders

The following table sets forth the computation of the basic and diluted net loss per share attributable to common stockholders (in thousands except for share and per share data):

	Six Months Ended June 30,	
	2024	2023
Numerator:		
Net loss	$ (26,573)	$ (28,271)
Denominator:		
Weighted-average shares of common stock outstanding used to compute net loss per share attributable to common stockholders, basic and diluted	7,551,784	7,464,578
Net loss per share attributable to common stockholders, basic and diluted:	$ (3.52)	$ (3.79)

The Company's potentially dilutive securities have been excluded from the computation of diluted net loss per share attributable to common stockholders as the effect would be antidilutive. Therefore, the weighted- average number of shares of common stock outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same. Potentially dilutive securities that were not included in the diluted per share calculations because they would be anti-dilutive were as follows:

	June 30, 2024	June 30, 2023
Series A-1 redeemable convertible preferred stock	4,753,466	4,753,466
Series A-2 redeemable convertible preferred stock	2,948,071	2,948,071
Series A-3 redeemable convertible preferred stock	203,821	203,821
Series A-4 redeemable convertible preferred stock	27,643	27,643
Series B redeemable convertible preferred stock	7,455,241	7,455,241
Series C redeemable convertible preferred stock	16,076,886	16,076,886
Series D redeemable convertible preferred stock	49,713,402	—
Series D-1 redeemable convertible preferred stock	11,887,535	—
Stock options, issued and outstanding	20,183,532	10,509,998
Warrants to purchase common stock	141,436	141,436
Total	113,391,033	42,116,562

Note 12. Subsequent Events

The Company has evaluated subsequent events from June 30, 2024 through August 5, 2024, the date these consolidated financial statements were available to be issued, and has not identified any items requiring disclosure.

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Shares

Common Stock

Prospectus

Goldman Sachs & Co. LLC **Morgan Stanley** **Jefferies** **Citigroup**

, 2024

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution.

The following table sets forth all costs and expenses, other than underwriting discounts and commissions, paid or payable by the Registrant in connection with the sale of the common stock being registered. All amounts shown are estimates except for the SEC registration fee, the Financial Industry Regulatory Authority, Inc. (FINRA) filing fee and the Nasdaq Global Market (Nasdaq) listing fee:

	Amount Paid or to Be Paid
SEC registration fee	$ *
FINRA filing fee	*
Nasdaq listing fee	*
Printing and engraving expenses	*
Legal fees and expenses	*
Accounting fees and expenses	*
Blue Sky, qualification fees and expenses	*
Transfer agent and registrar fees and expenses	*
Miscellaneous expenses	*
Total	$ *

* To be completed by amendment.

Item 14. Indemnification of Directors and Officers.

Section 145 of the DGCL, authorizes a court to award, or a corporation's board of directors to grant, indemnity to directors and officers under certain circumstances and subject to certain limitations. The terms of Section 145 of the DGCL are sufficiently broad to permit indemnification under certain circumstances for liabilities, including reimbursement of expenses incurred, arising under the Securities Act.

As permitted by the DGCL, the registrant's restated certificate of incorporation to be effective immediately before the completion of this offering contains provisions that eliminate the personal liability of its directors and officers for monetary damages for any breach of fiduciary duties as a director or officer, except liability for the following:

- any breach of the director's or officer's duty of loyalty to the registrant or its stockholders;
- acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;
- with respect to directors, under Section 174 of the DGCL (regarding unlawful dividends and stock purchases); or
- any transaction from which the director or officer derived an improper personal benefit.

As permitted by the DGCL, the registrant's restated bylaws to be effective immediately before the completion of this offering, provide that;

- the registrant is required to indemnify its directors and officers to the fullest extent permitted by the DGCL, subject to limited exceptions;
- the registrant may indemnify its other employees and agents as set forth in the DGCL;

- the registrant is required to advance expenses, as incurred, to its directors and officers in connection with a legal proceeding to the fullest extent permitted by the DGCL, subject to limited exceptions; and
- the rights conferred in the restated bylaws are not exclusive.

Prior to the completion of this offering, the registrant intends to enter into indemnification agreements with each of its current directors and executive officers to provide these directors and executive officers additional contractual assurances regarding the scope of the indemnification set forth in the registrant's restated certificate of incorporation and restated bylaws and to provide additional procedural protections. There is no pending litigation or proceeding involving a director or executive officer of the registrant for which indemnification is sought. Reference is also made to the underwriting agreement to be filed as Exhibit 1.1 to this registration statement, which provides for the indemnification of executive officers, directors and controlling persons of the registrant against certain liabilities. The indemnification provisions in the registrant's restated certificate of incorporation, restated bylaws and the indemnification agreements entered into or to be entered into between the registrant and each of its directors and executive officers may be sufficiently broad to permit indemnification of the registrant's directors and executive officers for liabilities arising under the Securities Act.

The registrant has directors' and officers' liability insurance for securities matters.

Item 15. Recent Sales of Unregistered Securities.

The following lists set forth information regarding all securities sold or granted by the registrant from June 30, 2021 through the date of this prospectus that were not registered under the Securities Act, and the consideration, if any, received by the registrant for such securities:

(a) Equity Grants

Stock Option Grants. From June 30, 2021 through the date of this prospectus, the registrant has granted to its employees, directors, consultants and other service providers options to purchase an aggregate of shares of our common stock under the 2015 Plan, with exercise prices ranging from $ to $ per share. The issuances of the securities described above were deemed to be exempt from registration pursuant to Section 4(a)(2) of the Securities Act or Rule 701 promulgated under the Securities Act as transactions pursuant to compensatory benefit plans. The shares of our common stock issued upon the exercise of options are deemed to be restricted securities for purposes of the Securities Act.

(b) Preferred Stock

In two closings in February 2024, we sold an aggregate of 49,713,402 shares of our Series D Preferred Stock at a price per share of $3.4196 for total gross proceeds of approximately $170.00 million. Each share of our Series D Preferred Stock will automatically convert into shares of our common stock in connection with the completion of this offering. Pursuant to the IRA, holders of our Series D Preferred Stock are entitled to certain registration rights.

Pursuant to the Note Purchase Agreement dated as of February 10, 2023 in February 2023 and March 2023, we issued convertible promissory notes with an aggregate of $23.5 million, which were cancelled and converted in connection with the Series D Preferred Stock Financing into a total of 11,887,535 Series D-1 Preferred Stock pursuant to the Series D Preferred Stock Purchase Agreement dated as of February 1, 2024. These transactions were exempt from registration requirements of the Securities Act in reliance upon Section 4(a)(2) of the Securities Act or Regulation D promulgated under the Securities Act.

(c) Warrants to Purchase Common Stock

In May 2022, we issued warrants to SVB Financial Group, Innovation Credit Growth Fund IX, L.P. and Innovation Credit Fund VIII-A, L.P. to acquire 86,672 shares of our common stock with an exercise price of $2.30 in connection with the SVB Loan Agreement.

In May 2023, we issued warrants to SVB Financial Group, Innovation Credit Growth Fund IX, L.P., and Innovation Credit Fund VIII-A, L.P. to acquire 24,764 shares of our common stock with an exercise price of $2.30 in connection with the SVB Loan Agreement.

Unless otherwise stated, the sales of the above securities were deemed to be exempt from registration under the Securities Act in reliance on Section 3(a)(9), Section 4(a)(2) of the Securities Act (or Regulation D or Regulation S promulgated thereunder), or Rule 701 promulgated under Section 3(b) of the Securities Act, as transactions by an issuer not involving any public offering or pursuant to benefit plans and contracts relating to compensation as provided under Rule 701. The recipients of the securities in each of these transactions represented their intentions to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends were placed on the stock certificates issued in each of the foregoing transactions. None of the foregoing transactions involved any underwriters, underwriting discounts or commissions or any public offering, and the registrant believes each transaction was exempt from the registration requirements of the Securities Act as stated above. All recipients of the foregoing transactions either received adequate information about the registrant or had access, through their relationships with the registrant, to such information. Furthermore, the registrant affixed appropriate legends to the share certificates and instruments issued in each foregoing transaction setting forth that the securities had not been registered and the applicable restrictions on transfer.

Item 16. Exhibits and Financial Statement Schedules.

(a) Exhibits.

See the Exhibit Index attached to this registration statement, which Exhibit Index is incorporated herein by reference.

(b) Financial Statement Schedules.

Schedules not listed above have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

Item 17. Undertakings.

The undersigned registrant hereby undertakes to provide to the underwriters, at the closing specified in the underwriting agreement, certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser. Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

Exhibit Number	Description of Exhibit
1.1*	Form of Underwriting Agreement.
3.1**	Restated Certificate of Incorporation, as currently in effect.
3.2*	Form of Restated Certificate of Incorporation to be effective upon the completion of this offering.
3.3**	Amended and Restated Bylaws, as currently in effect.
3.4*	Form of Restated Bylaws, to be effective upon the completion of this offering.
4.1*	Form of Common Stock Certificate.
4.2**	Warrant to Purchase Common Stock, dated July 31, 2018, by and among the Registrant and Silicon Valley Bank.
4.3**	Form of 2022 Warrant to Purchase Common Stock.
4.4**	Amended and Restated Investors' Rights Agreement, dated February 1, 2024, by and among the Registrant and certain of its stockholders.
5.1*	Opinion of Fenwick & West LLP.
10.1*	Form of Indemnity Agreement.
10.2**	2015 Equity Incentive Plan, as amended, and forms of award agreements.
10.3*	2024 Equity Incentive Plan, to become effective on the date the registration statement is declared effective, and forms of award agreements.
10.4*	2024 Employee Stock Purchase Plan, to become effective on the date the registration statement is declared effective, and forms of award agreements.
10.5*	Form of Executive Officer Employment Agreement.
10.6*	Form of Change in Control and Severance Agreement, between the Registrant and each of its named executive officers.
10.7^**	Lease Agreement, by and between the Registrant and Erickson Properties LLC dated August 3, 2017, as amended.
10.8†^	Exclusive License Agreement by and between the Registrant and Amgen Inc. dated April 5, 2021, as amended.
10.9†^**	Material Transfer Agreement by and between the Registrant and Eli Lilly and Company dated October 25, 2023.
10.10**	Loan and Security Agreement, dated July 31, 2018, by and among the Registrant and Silicon Valley Bank.
21.1**	Subsidiaries of the Registrant.
23.1*	Consent of KPMG LLP.
23.2*	Consent of Fenwick & West LLP (included in Exhibit 5.1).
24.1*	Power of Attorney (included in the signature page to this registration statement).
107*	Calculation of Filing Fee Tables.

* To be filed by amendment.
** Previously Filed.
† The Registrant has omitted portions of the exhibit (indicated by "[*]") as permitted under Item 601(b)(10) of Regulation S-K.
^ The Registrant has omitted schedules and exhibits pursuant to Item 601(a)(5) of Regulation S-K. The Registrant agrees to furnish supplementally a copy of the omitted schedules and exhibits to the SEC upon request.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant has duly caused this registration statement on Form S-1 to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of San Diego, State of California, on the day of , 2024.

BIOAGE LABS, INC.

By: _____
Kristen Fortney, Ph.D.
Chief Executive Officer and President

SIGNATURES AND POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Kristen Fortney, Ph.D. and Dov Goldstein, M.D., and each one of them, as his or her true and lawful attorneys-in-fact, proxies and agents, each with full power of substitution and resubstitution and full power to act without the other, for him or her in any and all capacities, to sign any and all amendments to this registration statement (including post-effective amendments or any abbreviated registration statement and any amendments thereto filed pursuant to Rule 462(b) increasing the number of securities for which registration is sought), and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact, proxies and agents full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully for all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact, proxies and agents, or their or his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this registration statement on Form S-1 has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
Kristen Fortney, Ph.D.	Chief Executive Officer, President and Director (Principal Executive Officer)	, 2024
Dov Goldstein, M.D.	Chief Financial Officer (Principal Financial Officer)	, 2024
Shane Barton	Vice President of Finance (Principal Accounting Officer)	, 2024
Jason Coloma, Ph.D.	Director	, 2024
Michael Davidson, M.D.	Director	, 2024
Patrick Enright	Director	, 2024
James Healy, M.D., Ph.D.	Director	, 2024

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Signature	Title	Date
Rekha Hemrajani	Director	, 2024
Eric Morgen, M.D.	Director	, 2024
Vijay Pande, Ph.D.	Director	, 2024

Exhibit 10.8

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [*], HAS BEEN OMITTED BECAUSE IT IS NOT MATERIAL AND IS THE TYPE THAT BIOAGE LABS, INC. TREATS AS PRIVATE OR CONFIDENTIAL.

EXCLUSIVE LICENSE AGREEMENT

by and between

AMGEN INC.

and

BIOAGE LABS, INC.

Dated as of April 5, 2021

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Exhibit List

EXCLUSIVE LICENSE AGREEMENT

This EXCLUSIVE LICENSE AGREEMENT (this **"Agreement")** is entered into as of April 5, 2021 (the **"Effective Date")** by and between Amgen Inc., a Delaware corporation having an address at One Amgen Center Drive, Thousand Oaks, California 91320 **("Amgen"),** and **BioAge Labs, Inc.,** a Delaware corporation having an address at 1445A South 50th Street, Richmond, California 94804 **("BioAge").** BioAge and Amgen are sometimes referred to herein individually as a **"Party"** and collectively as the **"Parties".**

RECITALS

WHEREAS, Amgen possesses certain rights to patents and other intellectual property related to the Licensed Compound (as defined below); and

WHEREAS, BioAge desires to license from Amgen such patents and intellectual property rights, and to commercially develop, manufacture, use and distribute the Licensed Compound, and Amgen desires to grant such a license to BioAge in accordance with the terms and conditions of this Agreement; and

WHEREAS, in connection with the licenses and covenants granted in this Agreement, Amgen will be issued Series C Preferred Stock of BioAge pursuant to the terms of the Financing Agreements.

NOW, THEREFORE, in consideration of the premises and the mutual promises and covenants contained in this Agreement, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto agree as follows:

ARTICLE 1.
DEFINITIONS

All references to particular Exhibits, Articles or Sections shall mean the Exhibits to, and Articles and Sections of, this Agreement, unless otherwise specified. For the purposes of this Agreement and the Exhibits hereto, the following words and phrases shall have the following meanings:

Section 1.1 **"Abandoned Patent Right"** has the meaning set forth in Section 4.2.2 (Amgen Step-In Right).

Section 1.2 **"Agreement"** has the meaning set forth in the Preamble.

Section 1.3 **"Affiliate"** means, with respect to any Person, any other Person that, directly, or indirectly through one or more intermediaries, controls, is controlled by or is under common control with such Person, for as long as such control exists. For purposes of this Section, "control" means the direct or indirect ownership of more than fifty percent (50%) of the voting or economic interest of a Person, or the power, whether pursuant to contract, ownership of securities or otherwise, to direct the management and policies of a Person. For clarity, once a Person ceases to be an Affiliate of a Party, then, without any further action, such Person shall cease to have any rights, including license and sublicense rights, under this Agreement by reason of being an Affiliate of such Party.

Section 1.4 **"Amgen"** has the meaning set forth in the Preamble.

Section 1.5 **"Amgen Acquiree"** has the meaning set forth in Section 10.9 (Sale Transaction or Amgen Acquisition).

Section 1.6 **"Amgen Acquisition"** has the meaning set forth in Section 10.9 (Sale Transaction or Amgen Acquisition).

Section 1.7 **"Amgen Indemnified Parties"** has the meaning set forth in Section 7.1.2 (By BioAge).

Section 1.8 **"Anti-Corruption Laws"** means Laws, regulations, or orders prohibiting the provision of a financial or other advantage for a corrupt purpose or otherwise in connection with the improper performance of a relevant function, including without limitation, the U.S. Foreign Corrupt Practices Act (FCPA), as amended, the UK Bribery Act 2010, as amended, and any other applicable laws, rules and regulations relating to or concerning public or commercial bribery or corruption.

Section 1.9 **"Audited Party"** has the meaning set forth in Section 3.8 (Records and Audits).

Section 1.10 **"BioAge"** has the meaning set forth in the Preamble.

Section 1.11 **"BioAge Indemnified Parties"** has the meaning set forth in Section 7.1.1 (By Amgen).

Section 1.12 **"Calendar Quarter"** means a three-month period beginning on January, April, July or October 1st.

Section 1.13 **"Calendar Year"** means a one-year period beginning on January 1st and ending on December 31st.

Section 1.14 **"CDA"** has the meaning set forth in Section 8.4.

Section 1.15 **"Change of Control"** means (a) the closing of the sale, transfer, exclusive license or other disposition of all or substantially all of BioAge's assets or intellectual property, (b) the consummation of the merger or consolidation of BioAge with or into another entity (except a merger or consolidation in which the holders of capital stock of BioAge immediately prior to such merger or consolidation continue to hold at least fifty percent (50%) of the voting power of the capital stock of BioAge or the surviving or acquiring entity), (c) the closing of the transfer (whether by merger, consolidation or otherwise), in one transaction or a series of related transactions, to a person or group of affiliated persons (other than an underwriter of BioAge's securities), of BioAge's securities if, after such closing, such person or group of affiliated persons would hold fifty percent (50%) or more of the outstanding voting stock of BioAge (or the surviving or acquiring entity) or (d) a liquidation, dissolution or winding up of BioAge.

Section 1.16 **"Commercially Reasonable Efforts"** means [*].

Section 1.17 **"Confidential Information"** has the meaning set forth in Section 8.1.1 (Confidential Information).

Section 1.18 **"Consulting Support"** means any work or services to be performed [*]. Work performed by [*]. If BioAge [*].

Section 1.19 **"Control"** or **"Controlled"** means, with respect to any Know-How, material, Patent Right, or other intellectual property right, the possession (whether by ownership or license) by a Party or its Affiliate of the ability to grant to the other Party a license, sublicense or access as provided herein to such Know-How, material, Patent Right, or other intellectual property right, without violating Laws or the terms of any agreement or other arrangement with any Third Party, or being obligated to pay any royalties or other consideration therefor, in existence as of the time such Party or its Affiliates would first be required hereunder to grant the other Party such license, sublicense or access.

Section 1.20 **"Cover"** means (a) with respect to Know-How, such Know-How was used in the Exploitation of the product, and (b) with respect to a Patent Right, a Valid Claim would (absent a license thereunder or ownership thereof) be Infringed by the Exploitation of the ***product; provided, however,*** that in determining whether a Valid Claim that is a claim of a pending application would be Infringed, it shall be treated as if issued as then currently being prosecuted. Cognates of the word **"Cover"** shall have correlative meanings.

Section 1.21 **"Covered Individuals and Entities"** (or, in the singular, **"Covered Individual and Entity")** means any one or more of an HCP, HCI, Payor, Purchaser, Healthcare Industry Professional Society and Trade Association, and entities owned or operated by any one or more of an HCP, HCI, Payor, Purchaser, or Healthcare Industry Professional Societies or Trade Association.

Section 1.22 **"Deemed Liquidation Event"** has the meaning set forth in BioAge's Restated Certificate of Incorporation most recently filed with the Delaware Secretary of State that contains such a definition.

Section 1.23 **"Defending Party"** has the meaning set forth in Section 4.4.1.

Section 1.24 **"Designated Investment Document Terms"** means:

(a) [*]**;**

(b) [*];

(c) [*];

(d) [*]; and

(e) [*].

Section 1.25 **"Development Plan"** means that certain development plan for the development of the Products hereunder, attached hereto as Exhibit E, as such plan may be amended from time to time in accordance with Section 5.2 (Diligence).

Section 1.26 **"Disclosing Party"** has the meaning set forth in Section 8.1.1 (Confidential Information).

Section 1.27 **"Disclosure Laws"** has the meaning set forth in Section 10.6.

Section 1.28 **"Distracting Product"** means [*].

Section 1.29 **"Distracting Program"** means [*] of any Distracting Product.

Section 1.30 **"Distracting Transaction"** means any transaction entered into by BioAge or its Affiliates after the Effective Date whereby a Third Party that is engaged in a Distracting Program becomes an Affiliate of BioAge.

Section 1.31 **"Distracting Transaction Affiliates"** means those entities that are or would become Affiliates of BioAge by virtue of a Distracting Transaction.

Section 1.32 **"Divest"** means, with respect to any Distracting Program, the sale, exclusive license or other transfer of all of the right, title and interest in and to such Distracting Program, including technology, Know-How, intellectual property and other assets materially relating thereto, to an independent Third Party, without the retention or reservation of any rights or interest (other than solely an economic interest, or retention of ownership of intellectual property rights in the case of an exclusive license) in such Distracting Program by the relevant Party or its Affiliates.

Section 1.33 **"Dollars"** or **"$"** means U.S. Dollars.

Section 1.34 **"Effective Date"** has the meaning set forth in the Preamble.

Section 1.35 **"EMA"** means the European Medicines Agency or any successor entity thereto.

Section 1.36 **"Enforcing Party"** has the meaning set forth in Section 4.3.3 (Progress Reports).

Section 1.37 **"European Union"** means the countries of the European Union, as it is constituted as of the Effective Date and as it may be expanded from time to time thereafter, and the United Kingdom.

Section 1.38 **"Exploit"** means to make, import, use, sell, or offer for sale, including to research, develop, commercialize, register, hold, or keep (whether for disposal or otherwise), transport, distribute, promote, market, or otherwise dispose of, or to have performed any of the foregoing. Cognates of the word **"Exploit"** shall have correlative meanings.

Section 1.39 **"FDA"** means the United States Food and Drug Administration or any successor entity thereto.

Section 1.40 **"Financing Agreements"** means those agreements by and between BioAge and Amgen to effect grant of the Series C Preferred Stock of BioAge hereunder.

Section 1.41 **"First Commercial Sale"** means, with respect to a product in any country, the first sale for end use or consumption of such product in such country after Marketing Approval has been granted in such country. First Commercial Sale excludes any sale or other distribution of such product for use in a clinical trial or other development activity, promotional use (including samples) prior to Marketing Approval or for compassionate use or on a named patient basis.

Section 1.42 **"FTE Rate"** means [*]. The FTE Rate shall be increased by [*], beginning with [*].

Section 1.43 **"GAAP"** means the then current generally accepted accounting principles in the United States as established by the Financial Accounting Standards Board or any successor entity or other entity generally recognized as having the right to establish such principles in the United States, in each case consistently applied.

Section 1.44 **"Generic Product"** means, after a Marketing Approval of a Product in a given country, any other product designated for human use which (a) contains the same or a highly similar (e.g., salt or polymorph of the) active pharmaceutical ingredients as each of the compounds comprising the applicable Product, (b) is approved for use pursuant to a regulatory approval process governing approval of generic or interchangeable drugs based on the then-current standards for regulatory approval in such country, and (c) is sold in such country by any Third Party.

Section 1.45 **"Governmental Authority"** means any court, agency, department, authority or other instrumentality of any national, state, county, city or other political subdivision.

Section 1.46 **"Government Official"** means (a) any Person employed by or acting on behalf of a Governmental Authority, (b) any political party, party official or candidate, (c) any Person who holds or performs the duties of an appointment, office or position created by custom or convention, and (d) any Person who holds himself out to be the authorized intermediary of any of the foregoing.

Section 1.47 **"Healthcare Industry Professional Society and Trade Association"** means a non-profit or tax exempt healthcare industry organization seeking to further a particular profession, the interests of individuals engaged in that profession, or the public interest (examples of such include without limitation the American Society of Hematology, the North American Society for Dialysis and Transplantation, the American Society of Hypertension, the American Cancer Society and the American Society of Clinical Oncology).

Section 1.48 **"Healthcare Institution" or "HCI"** means a facility that provides health maintenance, or treats illness and injury, and can include without limitation any hospital, convalescent hospital, dialysis center, health clinic, nursing home, extended care facility, or other institution devoted to the care of sick, infirm, or aged persons, and is in a position to purchase or influence a purchasing decision for any human therapeutic product marketed, distributed, or sold or any service related thereto provided by or on behalf of Amgen or any of its Affiliates (each an **"Amgen Therapeutic Product").**

Section 1.49 **"Healthcare Professional" or "HCP"** means any person licensed to prescribe an Amgen Therapeutic Product, as well as anyone working for a person licensed to prescribe an Amgen Therapeutic Product and/or in a position to influence a purchasing decision, including without limitation physicians and other providers (e.g., nurses, pharmacists), dialysis providers, and other office personnel.

Section 1.50 **"Infringe" or "Infringement"** means any infringement as determined by Law, including, without limitation, direct infringement, contributory infringement or any inducement to infringe.

Section 1.51 **"Initiation"** means, with respect to a human clinical trial, the first dosing in the first patient in such clinical trial.

Section 1.52 **"International Trade Laws"** means all applicable United States laws, regulations, and orders pertaining to trade and economic sanctions, export controls, and customs, including, such laws, regulations, and orders administered and enforced by the U.S. Department of the Treasury, the U.S. Department of Commerce, the U.S. Department of State and the U.S. Customs and Border Protection agency, including but not limited to the sanctions administered and enforced by the Office of Foreign Assets Control (OFAC), the United States Export Administration Act of 1979, as amended, and the Export Control Reform Act of 2018, and implementing Export Administration Regulations (EAR); the Arms Export Control Act and implementing International Traffic in Arms Regulations (ITAR); and all comparable applicable export and import Laws outside the United States for each country where the Parties or their agents and representatives conduct business.

Section 1.53 **"IPO"** means a sale of the Company's capital stock to the public in an underwritten offering pursuant to a registration statement under the Securities Act of 1933, as amended.

Section 1.54 **"Issuing Party"** has the meaning set forth in Section 8.2.2 (Review).

Section 1.55 **"Know-How"** means techniques, technology, trade secrets, inventions (whether patentable or not), methods, data (both primary and summary), reports and results (including pharmacological, toxicological and clinical data and results), analytical and quality control data and results, regulatory documents, and other information.

Section 1.56 **"Law"** means, individually and collectively, any and all laws, ordinances, rules, directives, administrative circulars and regulations of any kind whatsoever of any Governmental Authority within the applicable jurisdiction, including, but not limited to, Anti-Corruption Laws, International Trade Laws, those concerning data privacy and protection, and healthcare compliance.

Section 1.57 **"Licensed Compound"** means Amgen's proprietary compound known as AMG 986, having the structure to be set forth on Exhibit C, or [*].

Section 1.58 **"Licensed Field"** means any and all diagnostic, preventative or therapeutic uses.

Section 1.59 **"Licensed Know-How"** means the Licensed Non-Manufacturing Know-How together with the Licensed Manufacturing Know-How, in each case, as set forth on Exhibit A.

Section 1.60 **"Licensed Manufacturing Know-How"** means all proprietary manufacturing process-related Know-How directly relating to the manufacture of the Licensed Compound which is both (a) Controlled by Amgen or its Affiliates and (b) is or was actually used by Amgen or its Affiliates in the manufacture of the Licensed Compound, in each case of (a) and (b) prior to the Effective Date.

Section 1.61 **"Licensed Materials"** means those certain materials set forth on Table 1 of Exhibit A, all to the extent Controlled by Amgen or its Affiliates as of the Effective Date.

Section 1.62 **"Licensed Non-Manufacturing Know-How"** means all Know-How which is both (a) Controlled by Amgen or its Affiliates and (b) is or was actually used by Amgen or its Affiliates in the development of the Licensed Compound, in each case of (a) and (b) prior to the Effective Date, which is necessary or useful to BioAge in the development, formulation, manufacture, use or sale of the Licensed Compound bulk and formulations thereof; ***provided, however,*** "Licensed Non-Manufacturing Know-How" excludes any Know-How relating to Amgen's or its Affiliates commercial manufacturing platform.

Section 1.63 **"Licensed Patents"** means the Patent Rights Controlled by Amgen or its Affiliates as of the Effective Date and set forth on Exhibit B. For further clarification, Licensed Patents includes any patent or pending patent application that claims priority to any of the United States provisional patent applications listed on the tables set forth on Exhibit B.

Section 1.64 **"Losses"** has the meaning set forth in Section 7.1.1 (By Amgen).

Section 1.65 **"Marketing Approval"** means all approvals, licenses, registrations or authorizations of the Regulatory Authority in a country, necessary for the manufacture, use, storage, import, marketing and sale of the Product in such country.

Section 1.66 **"Net Sales"** means, with respect to a certain time period, the gross invoiced sales prices charged for Products, Products sold by or for BioAge, its Affiliates and Sublicensees (the **"Selling Party")** in arm's length transactions to Third Parties during such time period, less the total of the following charges or expenses as determined in accordance with GAAP:

(a) [*];

(b) [*];

(c) [*];

(d) [*];

(e) [*];

(f) [*], and

(g) [*].

[*].

Upon any sale or other disposal of any Product that should be included within Net Sales for any consideration other than an exclusively monetary consideration on bona fide arm's length terms, then for purposes of calculating the Net Sales under this Agreement, such Product shall be deemed to be sold exclusively for money at the average sales price during the applicable reporting period generally achieved for such Product in the country in which such sale or other disposal occurred when such Product is sold alone and not with other products.

Where a Product is sold together with another pharmaceutically active ingredient for a single price (including any combination product including the Product) (a **"Bundle"),** then for the purposes of calculating the Net Sales under this Agreement, such Product shall be deemed to be sold for an amount equal to [*]. In the event that a Product or one or more of the other pharmaceuticals in the Bundle are not sold separately (in the same dosage form), the Parties will discuss in good faith to determine an equitable fair market price to apply to such Product or other pharmaceutical in the Bundle.

Section 1.67 **"Patent Rights"** means any provisional and non-provisional patents and patent applications, together with all additions, divisions, continuations, continuations-in-part, substitutions, and reissues claiming priority thereto, as well as any re-examinations, extensions, registrations, patent term extensions, supplemental protection certificates, renewals and the like with respect to any of the foregoing and all foreign counterparts thereof.

Section 1.68 **"Party"** has the meaning set forth in the Preamble.

Section 1.69 **"Payor"** means an organization, including without limitation its directors, officers, employees, contractors and agents, whether private or governmental (e.g., Centers for Medicare and Medicaid Services, Veterans Administration), that provides medical and/or pharmacy plans for covering and reimbursing patients and/or Healthcare Professionals from medical expenses incurred, including without limitation managed care organizations, pharmacy benefit managers, health maintenance organizations, other healthcare coverage providers, and any similar such organization.

Section 1.70 **"Person"** means any corporation, limited or general partnership, limited liability company, joint venture, trust, unincorporated association, governmental body, authority, bureau or agency, any other entity or body, or an individual.

Section 1.71 **"Personal Data" means** any information that relates to, describes or is capable of being associated with or linked to an individual, by direct or indirect means, including without limitation classes, categories and other types of information that may identify an individual as specified by applicable Law, which includes without limitation sensitive or special categories of information inclusive of personal health data.

Section 1.72 **"Phase 2 Clinical Trial"** means any human clinical trial of a Product conducted mainly to test the effectiveness of chemical or biologic agents or other types of interventions for purposes of identifying the appropriate dose for a Phase 3 Clinical Trial for a particular indication or indications that would satisfy the requirements of 21 CFR § 312.21(b) or its non-United States equivalents. A Phase 2/3 Clinical Trial shall be deemed to be a Phase 2 Clinical Trial with respect to the portion of that clinical trial that is regarded as its Phase 2 component, in accordance with the applicable protocol.

Section 1.73 **"Phase 3 Clinical Trial"** means any human clinical trial of a Product designed to: (a) establish that such Product is safe and efficacious for its intended use; (b) define warnings, precautions and adverse reactions that are associated with the Product in the dosage range to be prescribed; and (c) support Marketing Approval of such Product, that would satisfy the requirements of 21 CFR § 312.21(c) or its non-United States equivalents.

Section 1.74 **"Product"** means any pharmaceutical product containing a Licensed Compound as the active ingredient or in combination with one or more other active agents. For clarity, "Product" includes [*].

Section 1.75 **"Proper Conduct Practices"** means, in relation to any Person, such Person and each of its Representatives, not, directly or indirectly, (a) making, offering, authorizing, providing or paying anything of value in any form, whether in money, property, services or otherwise to any Governmental Authority, Government Official, or other Person charged with similar public or quasi-public

duties, or to any customer, supplier, or any other Person, or to any employee thereof, or failing to disclose fully any such payments in violation of the laws of any relevant jurisdiction to (i) obtain favorable treatment in obtaining or retaining business for it or any of its Affiliates, (ii) pay for favorable treatment for business secured, (iii) obtain special concessions or for special concessions already obtained, for or in respect of it or any of its Affiliates, in each case which would have been in violation of any Law, (iv) influence an act or decision of the recipient (including a decision not to act) in connection with the Person's or its Affiliate's business, (v) induce the recipient to use his or her influence to affect any government act or decision in connection with the Person's or its Affiliate's business, or (vi) induce the recipient to violate his or her duty of loyalty to his or her organization, or as a reward for having done so, (b) engaging in any transactions, establishing or maintaining any fund or assets in which it or any of its Affiliates shall have proprietary rights that have not been recorded in the books and records of it or any of its Affiliates, (c) making any unlawful payment to any agent, employee, officer or director of any Person with which it or any of its Affiliates does business for the purpose of influencing such agent, employee, officer or director to do business with it or any of its Affiliates, (d) violating any provision of applicable Anti-Corruption Laws, (e) making any payment in the nature of bribery, fraud, or any other unlawful payment under the Law of any jurisdiction where it or any of its Affiliates conducts business or is registered, or (f) if such Person or any of its Representatives is a Government Official, improperly using his or her position as a Government Official to influence the award of business or regulatory approvals to or for the benefit of such Person, its Representatives or any of their business operations, or failing to recuse himself or herself from any participation as a Government Official in decisions relating to such Person, its Representatives or any of their business operations.

Section 1.76 **"Purchaser"** means an individual or entity, including without limitation wholesalers, pharmacies, and group purchasing organizations, that purchase an Amgen Therapeutic Product to sell to members of the healthcare community or that are authorized to act as a purchasing agent for a group of individuals or entities who furnish healthcare services.

Section 1.77 **"Receiving Party"** has the meaning set forth in Section 8.1.1 (Confidential Information).

Section 1.78 **"Regulatory Authority"** means any Governmental Authority or other authority responsible for granting Marketing Approvals for the Product, including the FDA, European Commission/EMA and any corresponding national or regional regulatory authorities.

Section 1.79 **"Regulatory Exclusivity"** means, with respect to the Product, any exclusive marketing rights or data exclusivity rights conferred by the applicable Regulatory Authority with respect to the Product other than a Patent Right.

Section 1.80 **"Regulatory Filing"** means any all (a) submissions, material correspondence, notifications, registrations, licenses, authorizations, applications and other filings with any Governmental Authority with respect to the research, development, manufacture, distribution, pricing, reimbursement, marketing or sale of the Product and (b) Marketing Approvals for the Product.

Section 1.81 **"Release"** has the meaning set forth in Section 8.2.2 (Review).

Section 1.82 **"Representatives"** means, as to any Person, such Person's Affiliates and its and their successors, owners, controlling Persons, directors, officers, employees, agents, representatives, subcontractors, or other third party acting for or on its behalf.

Section 1.83 **"Restricted Period"** means the period beginning on the Effective Date and ending at 11:59 pm (US Pacific Time) on the [*] anniversary of the Effective Date.

Section 1.84 **"Reviewing Party"** has the meaning set forth in Section 8.2.2 (Review).

Section 1.85 **"ROW"** has the meaning set forth in Section 9.2.4 (Termination for Failure to Develop or Commercialize).

Section 1.86 **"Royalty Term"** has the meaning set forth in Section 3.3.1 (Royalty Rate; Royalty Term).

Section 1.87 **"Sale Transaction"** has the meaning set forth in Section 10.8 (Successors and Assigns).

Section 1.88 **"Sanctioned Country"** means Cuba, Iran, Syria, North Korea, and the Crimea Region of Ukraine, and any other country or region subject to comprehensive sanctions under applicable Law.

Section 1.89 **"Sanctioned Person"** means any natural or legal person (a) identified on the Specially Designated Nationals and Blocked Persons List administered by the U.S. Department of Treasury Office of Foreign Assets Control (OFAC), on the Entity List, the Unverified List, or the Denied Persons List administered by the U.S. Department of Commerce Bureau of Industry and Security **(BIS),** or on any equivalent lists maintained by the United Nations, (b) fifty percent (50%) or greater owned, directly or indirectly, in the aggregate, or otherwise controlled by a person or persons described in clause (a). or (c) that is organized, resident, or located in a Sanctioned Country.

Section 1.90 **"Sensitive Manufacturing Know-How"** means [*].

Section 1.91 **"Service Provider"** means any third party contractor providing services to BioAge in connection with a Product (including any contract manufacturer, contract research organization or contract laboratory service provider).

Section 1.92 **"Shares"** has the meaning set forth in Section 3.1.

Section 1.93 **"SPAC Transaction"** means a merger, acquisition or other business combination involving BioAge and a publicly traded special purpose acquisition company or other similar entity that does not constitute a Deemed Liquidation Event.

Section 1.94 **"Sublicensee(s)"** means any Person other than an Affiliate of BioAge to which BioAge has granted a sublicense under this Agreement.

Section 1.95 **"Sublicense Income"** means any payments or other value that BioAge receives from a Sublicensee or such Sublicensee's Affiliates in connection with a Product (including in connection with any sublicense of any Licensed Patent or any Licensed Know How), including without limitation, upfront fees, option fees, license fees, equity (except as set forth in clause (a) below), milestone payments and license maintenance fees, etc., but excluding the following payments: (a) payments made in consideration for the issuance of equity or debt securities of BioAge at fair market value, (b) payments specifically committed to the further research or development of Products, either in the relevant sublicense agreement or pursuant to a budget approved by BioAge's management, (c) earned royalties or profit sharing interest payments based on the sale of Products, or (d) reimbursements for patent expenses for filing, prosecuting or maintaining patent rights associated with Products. In addition, to the extent BioAge receives payment(s) from any Third Party for distribution rights, such payments shall be treated as Sublicense Income to the extent they are not payments for the sale of Product to such Third Party distributor. To the extent the payments are for the sale of Product to such Third Party distributor, the payments shall be treated as Net Sales. If BioAge receives non-monetary consideration for a sublicense, Sublicensee Income will be calculated based on the fair market value of that consideration. BioAge shall not shift compensation otherwise payable to BioAge from a Third Party with respect to the Product to another product or service for which consideration would not constitute Sublicense Income for the purpose of reducing BioAge's payment obligations with respect to Sublicense Income.

Section 1.96 **"Term"** has the meaning set forth in Section 9.1 (Term).

Section 1.97 **"Territory"** means the entire world.

Section 1.98 **"Third Party"** means a Person other than (a) Amgen or any of its Affiliates and (b) BioAge or any of its Affiliates.

Section 1.99 **"Third Party Acquirer"** has the meaning set forth in Section 10.9 (Sale Transaction or Amgen Acquisition).

Section 1.100 **"United States" or "U.S."** means the United States of America, including its territories and possessions (including the District of Columbia and Puerto Rico).

Section 1.101 **"Valid Claim"** means a claim of any issued and unexpired patent or patent application within the Licensed Patents and that has not been held invalid or unenforceable by a final decision of a court or governmental agency of competent jurisdiction, which decision can no longer be appealed or was not appealed within the time allowed; ***provided, however,*** that if a claim of a pending patent application within the Licensed Patents shall not have issued within [*] years after the earliest filing date from which such claim takes priority, such claim shall not constitute a Valid Claim for the purposes of this Agreement unless and until a Patent Right issues with such claim (from and after which time the same would be deemed a Valid Claim).

Section 1.102 **"VAT"** has the meaning set forth in Section 3.9.3 (VAT).

ARTICLE 2.
LICENSE GRANT

Section 2.1 Grant. Subject to the terms and conditions of this Agreement, upon the grant of the Shares pursuant to the Financing Agreements, Amgen shall grant and hereby grants to BioAge:

(a) an exclusive (even as to Amgen, but subject to Section 2.3 (Retained Rights and Limitations)), royalty bearing, sublicensable (but only in accordance with Section 2.2 (Sublicenses)), license under Amgen's rights in and to the Licensed Patents and

(b) a non-exclusive, royalty bearing, sublicensable (but only in accordance with Section 2.2 (Sublicenses)) license under Amgen's rights in and to the Licensed Know-How,

in each case (a) and (b), solely to Exploit Products in the Licensed Field in the Territory during the Term.

Notwithstanding the foregoing, the Licensed Know-How shall be sublicensable only in connection with the rights of BioAge with respect to Products and not with respect to any other products or services.

Section 2.2 Sublicenses. Subject to this Section 2.2 (Sublicense), BioAge shall be entitled, without the prior consent of Amgen, to grant one or more sublicenses, in full or in part, by a written agreement to Third Parties (with the right to sublicense through multiple tiers), ***provided, however,*** that as a condition precedent to and requirement of any such sublicense: (a) any such permitted sublicense shall be consistent with and subject to the terms and conditions of this Agreement; and (b) BioAge will continue to be responsible for full performance of BioAge's obligations under the Agreement and will be responsible for all actions of such Sublicensee as if such Sublicensee were BioAge hereunder. Notwithstanding the foregoing, in the event BioAge grants any such sublicenses to research, develop or commercialize the Product prior to the expiration of the Restricted Period, other than to Service Providers or to a Third Party distributor selling finished Product purchased from BioAge, BioAge shall (x) provide to Amgen a summary (in a form reasonably satisfactory to Amgen) of such sublicense transaction and (y) pay to Amgen an amount equal to [*] of the Sublicense Income in connection with such sublicense transaction.

Section 2.3 Retained Rights and Limitations. Notwithstanding the licenses granted to BioAge in this Article 2 (License Grant), Amgen retains a research-only right under Amgen's rights in and to the Licensed Patents solely for Amgen's internal research use.

Section 2.4 Transfer of Licensed Know-How and Licensed Materials.

2.4.1 Licensed Know-How and Licensed Materials. Amgen shall transfer to BioAge all Licensed Know-How and Licensed Materials listed on Exhibit A, in accordance with a schedule specified on Exhibit A or as mutually agreed by the Parties ***(provided,*** the Parties will use reasonable efforts to ensure such transfer is completed within [*] after the Effective Date); ***provided, however,*** that such transfer timeline may be reasonably extended for items that, despite diligent efforts by the Parties, are not practicable to transfer within such [*] period, in which case Amgen shall continue to [*] to transfer such items as promptly as practicable after such period but in any event within [*] after the Effective Date. The Licensed Know-How will be transferred in a customary electronic format and otherwise in the original paper format. The Parties acknowledge that there are extensive documents, materials and information related to the Licensed Compound, and that it is the intent of the Parties that the transfer of documents, materials and information hereunder be limited. Accordingly, Amgen shall not have any obligation to transfer to BioAge any Licensed Know-How or Licensed Materials other than those set forth on Exhibit A and the Parties agree to [*] to limit the number of shipments of Licensed Materials to the extent practicable. Notwithstanding the foregoing, if subsequent to the foregoing transfer, BioAge identifies additional Know-How that is not identified on Exhibit A, but is reasonably necessary for BioAge to Exploit the Product, then BioAge may request such Know-How from Amgen. If Amgen determines, in its sole discretion, that such request is reasonable, then Amgen will use commercially reasonable efforts to provide such additional Know-How to BioAge at BioAge's expense, at the FTE Rate. With respect to any clinical data and biological samples derived from Amgen clinical studies relating to the Licensed Compound that may be transferred to BioAge hereunder, BioAge shall ensure that its use of such data and samples are compliant with Law and the limitations set forth in informed consents governing the collection and use of such data and samples, including with respect to the destruction or ceasing the use thereof. Amgen will provide notice to BioAge when Amgen has completed the transfer of all Licensed Know-How and Licensed Materials listed in Exhibit A. Within [*] of receipt of such notice BioAge will confirm that such transfer is complete or will provide written notice, with reasonable specificity, to Amgen of any remaining Licensed Know-How or Licensed Materials that have not been transferred. In the event that BioAge is unable to accept any Licensed Materials in such [*] transfer period, Amgen reserves the right to charge BioAge for any further storage of such Licensed Materials at a rate reflecting Amgen's costs and expenses with respect to such continued storage; provided, however, that Amgen shall have no obligation to provide for such further storage of Licensed Materials for a time period later than [*] from the Effective Date, and shall be entitled to destroy any such Licensed Materials without liability to BioAge.

2.4.2 Consulting Support. Amgen shall provide, at its expense, Consulting Support with respect to the matters described in Section 2.4.1 in connection with the Exploitation of the Licensed Compound until the earlier of (a) Amgen has provided [*] total of Consulting Support or (b) the [*] anniversary of the Effective Date (or [*] if the transfer in Section 2.4.1 has not been completed at the [*] anniversary). If BioAge requires additional Consulting Support in excess of [*] in the aggregate and/or beyond such period set forth in the preceding clause (b) in connection with the Exploitation of the Products in the Territory, then [*], which shall be at BioAge's expense, at the FTE Rate.

2.4.3 Sensitive Manufacturing Know-How. With respect to Amgen's transfer of Sensitive Manufacturing Know-How, if any, the Parties agree that the following procedures shall apply:

(a) Upon BioAge's written request (and in any event prior to Amgen providing to BioAge any Sensitive Manufacturing Know-How, if any), the Parties shall enter into the supplemental confidentiality agreement in the form attached hereto on Exhibit D to ensure that Sensitive Manufacturing Know-How provided to BioAge shall be limited to specified BioAge employees or contractors or consultants that are pre-approved in writing by Amgen (such approval not to be unreasonably withheld or delayed), each who need such information for purposes of global Regulatory Filings and do not play any direct role in process development or manufacturing (such employees, contractors and consultants, the **"Clean Team,"** and such purpose, the **"Manufacturing Know-How Purpose")** and that such Sensitive Manufacturing Know-How shall be used solely for the Manufacturing Know-How Purpose. Prior to providing Sensitive Manufacturing Know-How to contractors and consultants of the Clean Team, the identity of such contractors and consultants shall be provided to Amgen, and BioAge shall enter into written agreements with such contractors and consultants containing confidentiality and non-use provisions no less restrictive than those contained in Section 8.1 (Confidential Information) **("Contractor Confidentiality Agreement"),** and BioAge shall provide such Contractor Confidentiality Agreement to Amgen to confirm compliance with the foregoing (provided, BioAge shall be entitled to redact other competitively sensitive information). Any act or omission of any such contractor or consultant that would be a breach of its Contractor Confidentiality Agreement shall be deemed a breach of this Agreement by BioAge (and treated as if BioAge breached Article 8). Upon the request of either Party, the Parties shall discuss in good faith and establish other reasonable arrangements, systems and protocols to ensure that Sensitive Manufacturing Know-How provided to BioAge will be disclosed or made available only to the Clean Team and will be used by such Clean Team solely for the Manufacturing Know-How Purpose.

(b) In the event any Regulatory Authority requests Sensitive Manufacturing Know-How, Amgen will provide to the Clean Team reasonable Consulting Support (at the FTE Rate) in connection with such request (for clarity, only with respect to requests relating to Sensitive Manufacturing Know-How).

(c) In the event of a BioAge Change of Control, BioAge shall ensure that the acquiror, successor or Sublicensee, as applicable, holds the same rights and obligations as BioAge in respect of Sensitive Manufacturing Know-How (including, without limitation, with respect to establishing and abiding by the supplemental confidentiality agreement described above). For clarity, any such acquirer, successor or Sublicensee shall, as a condition to such Change of Control, enter into a supplemental confidentiality agreement with Amgen in the form attached hereto on Exhibit D subject to any revisions Amgen may reasonably implement taking into account specific concerns arising with regard to the acquiror, successor or Sublicensee.

(d) Notwithstanding anything in this Agreement to the contrary, Amgen shall have no obligation under this Agreement to transfer to BioAge, its Affiliates or any Third Party any confidential or proprietary information or Know-How related to the manufacture of the Licensed Compound, except as expressly provided in Section 2.4.1, this Section 2.4.3 or Exhibit A.

2.4.4 No Warranties.

(a) BioAge acknowledges that any materials transferred by Amgen to BioAge under this Agreement are experimental in nature and may have unknown characteristics (including the hazardous and toxicological properties) and therefore agrees to use prudence and reasonable care in the use, handling, storage, transportation and disposition and containment of any such materials. Accordingly, no such materials, shall be used in any human application, including any clinical trial.

(b) ALL MATERIAL IS BEING SUPPLIED TO BIOAGE WITH NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. BIOAGE HEREBY ACKNOWLEDGES AND AGREES THAT ANY ANALYSIS OF THE REPORT OR RESULTS, OR OTHER DATA, PROVIDED BY AMGEN ARE PROVIDED "AS IS" WITH NO WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THEY ARE FREE FROM THE RIGHTFUL CLAIM OF ANY THIRD PARTY, BY WAY OF INFRINGEMENT OR THE LIKE.

Section 2.5 No Other Rights. BioAge acknowledges that the rights and licenses granted under this Article 2 (License Grant) and elsewhere in this Agreement are limited to the scope expressly granted. Accordingly, except for the rights expressly granted under this Agreement, no right, title, or interest of any nature whatsoever is granted whether by implication, estoppel, reliance, or otherwise, by Amgen to BioAge. All rights that are not specifically granted herein are reserved to Amgen. For clarity, the transfer of Licensed Know-How and Licensed Material under this Agreement shall constitute a transfer of possession together with a limited license to use such Licensed Know-How and Licensed Materials as contemplated under this agreement and shall not constitute a transfer in title in and to such Licensed Know-How and Licensed Materials.

Section 2.6 Restrictions. During the Term, BioAge shall not challenge the validity of any of the Licensed Patents. BioAge agrees (on behalf of itself and its Affiliates), and shall cause each of its Sublicensees and contract manufacturers to agree as a condition to the grant of a sublicense, (a) not to Exploit any Licensed Know-How or Licensed Patents for any products other than a Product and (b) not to Exploit any Sensitive Manufacturing Know-How other than for the manufacture of the Licensed Compound or a Product containing the Licensed Compound.

Section 2.7 Regulatory. Promptly following the Effective Date and acceptance of the transfer of the safety data/database by BioAge in accordance with Exhibit A, Amgen will transfer to BioAge the open Investigational New Drug (IND) for the Licensed Compound known as AMG- 986 and any other Regulatory Filings related to the Licensed Compounds or Product in the Territory. Except to the extent that Amgen is required under applicable Law to communicate with a Regulatory Authority with respect to a Licensed Compound or Product following such transfer, BioAge shall be responsible for all regulatory interactions and making all required Regulatory Filings related to the Licensed Compounds or Product.

ARTICLE 3.
UPFRONT, EQUITY, MILESTONES, ROYALTIES AND PAYMENTS

Section 3.1 Upfront Payment. In consideration of the rights granted herein to BioAge, BioAge shall make the following upfront payment to Amgen, in the form of a monetary payment and the issuance of certain equity in BioAge.

3.1.1 Within [*] following the Effective Date, BioAge shall pay to Amgen the amount of$1,000,000.

3.1.2 On the Effective Date, in accordance with the Financing Agreements, BioAge shall issue to Amgen 846,152 shares of Series C Preferred Stock of BioAge (the **"Shares"**).

Section 3.2 Milestone Payments.

3.2.1 Milestone Payments. As partial consideration for the rights granted to BioAge hereunder, BioAge shall pay Amgen the following non-creditable, non-refundable payments (described in the table below under the column "Milestone Payment" and each such payment, a **"Milestone Payment")** [*] following the date that each milestone (described in the table below under the column "Milestone") is achieved by BioAge, its Affiliates or Sublicensees:

	Milestone	Milestone Payment
1	[*]	[*]
2	[*]	[*]
3	[*]	[*]
4	[*]	[*]
5	[*]	[*]
6	[*]	[*]
7	[*]	[*]
8	[*]	[*]
9	[*]	[*]
10	[*]	[*]

BioAge will provide Amgen with prompt written notice of the accomplishment of each such Milestone and the corresponding Milestone Payment. Each Milestone Payment set forth in this Section 3.2 (Milestone Payments) is payable only once upon the first achievement of the respective milestone and no Milestone Payment shall be payable for subsequent or repeated achievements of the same milestone. In the event that a particular milestone event set forth above was not achieved by a Product, but a subsequent milestone event is achieved by a Product (i.e., [*]), the payment associated with earlier milestone(s) would nonetheless be owed to Amgen in full at the same time as BioAge's payment for achievement of the subsequent milestone event; provided that Milestone Payment #3 would only be due upon the earlier of achievement of milestone #3 or milestone #5 (i.e. [*]).

Section 3.3 Royalties.

3.3.1 Royalty Rate: Royalty Term. On a Product-by-Product basis, BioAge shall pay to Amgen the following tiered royalties on annual Net Sales of each Product sold by a Selling Party during the Royalty Term applicable to such Product:

(a) [*] on the portion of annual Net Sales of such Product less than [*];

(b) [*] on the portion of annual Net Sales of such Product that is equal to or greater than [*] but less than [*];

(c) [*] on the portion of annual Net Sales of such Product that is equal to or greater than [*]

Royalties will be payable on [*]; any such payments shall be made [*] after the end of the [*] during which the applicable Net Sales occurred. BioAge's obligation to pay royalties with respect to each Product in a particular country shall commence upon the First Commercial Sale of such Product in such country and shall expire on a country-by-country and Product-by-Product basis on the later of (a) the date on which the Exploitation of such Product is no longer Covered by a Valid Claim of a Licensed Patent in such country, (b) the loss of Regulatory Exclusivity for the Product in such country, or (c) the [*] anniversary of the First Commercial Sale of such Product in such country (the **"Royalty Term").**

3.3.2 Royalty Reductions. On a country-by-country basis, in the event that the Exploitation of a Product is not Covered by a Valid Claim of a Licensed Patent in such country and there are sales of a Generic Product in such country, then the royalty rates set forth in Section 3.3.1 (Royalty Rate; Royalty Term) with respect to Net Sales for such Product in such country shall be reduced by [*] (e.g., [*]), effective as of the date such Product is no longer Covered by a Valid Claim of a Licensed Patent in such country and for so long as such Generic Product remains available in such country (and, from and after the removal of such Generic Product from such country, the royalty rate shall revert to being paid in full) .

3.3.3 Third Party Royalties. If BioAge, its Affiliates or any Sublicensee is required by (a) a future order by a court of competent jurisdiction, (b) settlement agreement, (c) license or contract, or (d) other legally binding commitment to make royalty payments to a Third Party, in each case in exchange for a license or other right under Patent Rights held by such Third Party and such license or other rights are necessary for the Exploitation of any Licensed Compound in a given country, then BioAge shall be entitled to deduct from royalties due to Amgen under this Agreement with respect to Net Sales on all Products containing such Licensed Compound in a given Calendar Quarter in each such country an amount equal to [*] of the royalties actually paid to such Third Party in such Calendar Quarter as consideration for such license under such Patent Rights, up to a maximum amount of [*] of the royalties due to Amgen in each affected country in such Calendar Quarter.

3.3.4 Maximum Reduction. Notwithstanding anything to the contrary, the maximum aggregate reduction with respect to any Product in any Calendar Quarter during the applicable Royalty Term in any country pursuant to Section 3.3.2 (Royalty Reductions) and Section 3.3.3 (Third Party Royalties) shall be [*] (i.e., [*]).

3.3.5 Mutual Convenience of the Parties. The royalty and other payment obligations set forth hereunder have been agreed to by the Parties for the purpose of reflecting and advancing their mutual convenience, including the ease of calculating and paying royalties and other amounts to Amgen.

Section 3.4 Method of Payment. Unless otherwise agreed by the Parties, all payments due from BioAge to Amgen under this Agreement shall be paid in United States Dollars by wire transfer or electronic funds transfer of immediately available funds to the following account:

[*]

Section 3.5 Royalty Reports. After the First Commercial Sale of the first Product and until expiration of the last Royalty Term, BioAge shall prepare and deliver to Amgen royalty reports of the sale of the Products by the Selling Parties for each Calendar Quarter within [*] of the end of each such Calendar Quarter specifying in the aggregate and on the Product-by-Product and country-by-country basis: (a) total gross amounts for each Product sold or otherwise disposed of by a Selling Party, (b) amounts deducted by category in accordance with the definition of "Net Sales" in Article 1 (Definitions) from gross amounts to calculate Net Sales, (c) Net Sales, and (d) royalties payable.

Section 3.6 Currency Conversion. With respect to Net Sales invoiced in U.S. Dollars, such Net Sales invoiced shall be expressed in U.S. Dollars. With respect to Net Sales invoiced in a currency other than U.S. Dollars, such Net Sales invoiced shall be converted into the U.S. Dollar equivalent using a rate of exchange which corresponds to the rate used by the Selling Party in recording such receipt, for the respective reporting period, related to recording such Net Sales in its books and records that are maintained in accordance with GAAP. If a Selling Party is not required to perform such currency conversion for its GAAP reporting with respect to the applicable period, then for such period such Selling Party shall convert its amounts received incurred into U.S. Dollars using a rate of exchange which corresponds to the noon buying rate as published in the Wall Street Journal, Eastern U.S. Edition on the second to last business day of the Calendar Quarter (or such other publication as agreed-upon by the Parties). Any royalty amount shall be calculated based upon the U.S. Dollar equivalent calculated in accordance with the foregoing.

Section 3.7 Late Payments. In the event that any payment due hereunder is not made when due, the payment shall accrue interest beginning on the day following the due date thereof, calculated at the annual rate of the sum of (a) [*] plus (b) the prime rate effective for the date that payment was due, as published by the Wall Street Journal, Eastern U.S. Edition ,the interest being compounded on the last day of each Calendar Quarter; ***provided, however,*** that in no event shall said annual interest rate exceed the maximum rate permitted by Law. Each such payment when made shall be accompanied by all interest so accrued. Said interest and the payment and acceptance thereof shall not negate or waive the right of any Party to seek any other remedy, legal or equitable, to which it may be entitled because of the delinquency of any payment including, but not limited to termination of this Agreement as set forth in Article 10 (Term & Termination).

Section 3.8 Records and Audits.

3.8.1 BioAge will keep complete and accurate records of the underlying revenue and expense data relating to the calculations of Net Sales generated in the then current Calendar Year and payments required under this Agreement, and during the preceding [*] Calendar Years. Amgen will have the right, once annually at its own expense, to have a nationally recognized, independent, certified public accounting firm, selected by it and subject to BioAge's prior written consent (which shall not be unreasonably withheld), review any such records of BioAge and its Affiliates and Sublicensees (the **"Audited Party")** in the location(s) where such records are maintained by the Audited Party upon reasonable written notice (which shall be no less than [*] prior written notice) and during regular business hours and under obligations of strict confidence, for the sole purpose of verifying the basis and accuracy of payments made under Section 3.3 (Royalties) within the [*] period preceding the date of the request for review. No Calendar Year will be subject to audit under this Section more than once. BioAge will receive a copy of each such report concurrently with receipt by Amgen. Should such inspection lead to the discovery of a discrepancy to Amgen's detriment, BioAge will, within [*] after receipt of such report from the accounting firm, pay any undisputed amount of the discrepancy together with interest at the rate set forth in Section 3.7 (Late Payments). Amgen will pay the full cost of the review unless the underpayment of amounts due to Amgen is greater than [*] of the amount due for the entire period being examined, in which case BioAge will pay the cost charged by such accounting firm for such review. Should the audit lead to the discovery of a discrepancy to BioAge's detriment, BioAge may credit the amount of the discrepancy, without interest, against future payments payable to Amgen under this Agreement, and if there are no such payments payable, then Amgen shall pay to BioAge the amount of the discrepancy, without interest, within [*] of Amgen's receipt of the report.

3.8.2 Amgen will have the right, once annually at its own expense, to review (or have its designee review) any records of the Audited Party relevant to each Audited Party's compliance with Anti-Corruption Laws in the location(s) where such records are maintained by the Audited Party upon reasonable written notice (which shall be no less than [*] prior written notice) and during regular business hours and under obligations of strict confidence, for the sole purpose of verifying such compliance within the [*] period preceding the date of the request for review.

Section 3.9 Taxes.

3.9.1 Sales Tax. BioAge is responsible for the payment of any state or local, sales or use, or similar fees or taxes arising as a result of the transfer of Licensed Materials by Amgen to BioAge pursuant to Section 2.5 (Transfer of Licensed Know-How and Licensed Materials), and BioAge will remit such fees or taxes to Amgen, as the collection agent, upon invoice.

3.9.2 Withholding. In the event that any Law requires BioAge to withhold taxes with respect to any payment to be made by BioAge pursuant to this Agreement, BioAge will notify Amgen of such withholding requirement prior to making the payment to Amgen and provide such assistance to Amgen, including the provision of such standard documentation as may be required by a tax authority, as may be reasonably necessary in Amgen's efforts to claim an exemption from or reduction of such taxes. BioAge will, in accordance with such Law withhold taxes from the amount due, remit such taxes to the appropriate tax authority, and furnish Amgen with proof of payment of such taxes [*] following the payment. If taxes are paid to a tax authority, BioAge shall provide reasonable assistance to Amgen to obtain a refund of taxes withheld, or obtain a credit with respect to taxes paid. Notwithstanding this Section 3.9.2, if a withholding tax is imposed as a result of BioAge's residence outside the United States, exploitation of the rights granted hereunder outside the United States, or on a similar basis, and there is no applicable tax treaty that exempts the payment from withholding tax or reduces the withholding tax rate to 0%, then BioAge will pay to Amgen an additional amount, such that Amgen will receive the full amount of the payment as it would have received had there been no withholding tax imposed on the payment; provided that if Amgen subsequently receives any of such withheld amounts it will promptly pay such amounts to BioAge. Solely for purposes of the preceding sentence, the term United States does not include territories of the United States.

3.9.3 VAT. All payments due to Amgen from BioAge pursuant to this Agreement shall be paid exclusive of any value-added tax **("VAT")** (which, if applicable, shall be payable by BioAge upon receipt of a valid VAT invoice). If Amgen determines that it is required to report any such tax, BioAge shall promptly provide Amgen with applicable receipts and other documentation necessary or appropriate for such report. For clarity, this Section 3.9.3 (VAT) is not intended to limit BioAge's right to deduct value-added taxes in determining Net Sales.

3.9.4 Tax Treatment of Equity and Payments.

(a) Amgen and BioAge intend to treat the issuance to Amgen of the Shares and the payment of any Milestone Payments and any royalties pursuant to this Article 3 as consideration for the transfer of Licensed Patents and Licensed Know-How to BioAge for U.S. federal income Tax purposes (and applicable state, local or non-U.S. Tax purposes).

(b) Amgen and BioAge shall file all Tax returns, reports, schedules, information statements and other documents consistently with the understandings set forth in this Section 3.9.4, and shall take no contrary position on any such Tax return, or in any audit, claim, investigation or proceeding in respect of Taxes unless otherwise required pursuant to a final determination within the meaning of Section 1313 of the Code, or any analogous provision of applicable state, local or non-U.S. law.

ARTICLE 4.
PATENT PROSECUTION, MAINTENANCE, & INFRINGEMENT

Section 4.1 Intellectual Property Ownership.

4.1.1 Except to the extent expressly specified to the contrary in this Agreement: (a) each Party shall retain and own all right, title, and interest in and to all Patent Rights, trade secrets, proprietary rights and other intellectual property rights (collectively **"Inventions")** conceived or created solely by such Party, (b) the Parties shall jointly own all right, title, and interest in and to Inventions conceived or created jointly by the Parties pursuant to this Agreement **("Joint Inventions")** and, subject to the provisions of this Agreement, neither Party shall have any duty to account or obtain the consent of the other Party (such consent deemed given hereunder) in order to exploit, license or assign its respective rights in Joint Inventions, and (c) inventorship and authorship of any Invention or work of authorship conceived or created by either Party or jointly by the Parties pursuant to this Agreement, shall follow the rules of the U.S. Patent and Trademark Office and the Laws of the U.S. (without reference to any conflict of law principles).

4.1.2 Notwithstanding the foregoing, all right, title, and interest in and to Inventions exclusively related to Licensed Compound (and any associated Patent Rights) shall be owned exclusively by BioAge regardless of inventorship.

Section 4.2 Prosecution and Maintenance.

4.2.1 BioAge shall have the first right to file, prosecute and maintain all Patent Rights specified under Licensed Patents at BioAge's sole expense using outside counsel reasonably acceptable to Amgen. BioAge will use Commercially Reasonable Efforts to prepare, file, prosecute, defend and maintain all Patent Rights specified under Licensed Patents. Amgen shall reasonably cooperate with BioAge's requests for data, affidavits, and other information and assistance to support prosecution and maintenance of the Patent Rights in the Licensed Patents; ***provided, however,*** that BioAge shall reimburse Amgen for its reasonable, documented out-of-pocket expenses with respect to such cooperation. BioAge shall promptly upon receipt forward to Amgen copies of any office actions, communications, and correspondence relating to the Licensed Patents. Amgen shall have the right to comment on and to discuss prosecution and maintenance activities with BioAge, and BioAge shall consider the same in good faith and shall provide Amgen with copies of all proposed filings and correspondence to give Amgen the opportunity to review and comment.

4.2.2 Notwithstanding the foregoing, if BioAge declines to file, prosecute or maintain any Patent Rights, elects to allow any Patent Rights to lapse in any country, or elects to abandon any Patent Rights (in each case to the extent contained in the Licensed Patents) before all appeals within the respective patent office have been exhausted (each, an **"Abandoned Patent Right"),** then:

(a) BioAge shall provide Amgen with reasonable notice of such decision so as to permit Amgen to decide whether to file, prosecute or maintain such Abandoned Patent Rights and to take any necessary action (which notice shall, in any event, be given no later than [*] prior to the next deadline for any action that may be taken with respect to such Abandoned Patent Right with the U.S. Patent & Trademark Office or any foreign patent office).

(b) Amgen, at Amgen's expense, may assume control of the filing, prosecution and/or maintenance of such Abandoned Patent Rights.

(c) Amgen shall have the right to transfer the responsibility for such filing, prosecution and maintenance of such Abandoned Patent Rights to patent counsel (outside or internal) selected by Amgen.

(d) BioAge shall assist and cooperate with Amgen's reasonable requests to support prosecution and maintenance of such Abandoned Patent Rights; ***provided, however,*** that Amgen shall reimburse BioAge for its reasonable expenses with respect to such cooperation (including BioAge's employee's time at the FTE Rate).

(e) In the event a patent issues with respect to any such Abandoned Patent Rights, Amgen shall provide reasonable notice to BioAge thereof and such Abandoned Patent Right shall be excluded from the license granted by Amgen to BioAge under Section 2.1 (Grant), unless BioAge (i) reimburses Amgen for its reasonable, documented, internal and external costs and expenses related to the prosecution and maintenance of such Abandoned Patent Right [*] of notice of issuance of any such patent and (ii) assumes, in writing, the responsibility for the continued prosecution and maintenance of such Patent Rights in accordance with the provisions of Section 4.1 (Prosecution and Maintenance). For the avoidance of doubt, the Abandoned Patent Rights shall not be excluded from the license granted by Amgen to BioAge under Section 2.1 (Grant) unless and until after expiry of the [*] period referred to under (i) above and if BioAge elects not to exercise its rights under (i) and (ii) above.

Section 4.3 Enforcement.

4.3.1 BioAge Enforcement. Each Party will notify the other promptly in writing when any Infringement of a Licensed Patent by a Third Party is uncovered or reasonably suspected. BioAge shall have the first right to enforce any patent within the Licensed Patents against any Infringement or alleged Infringement thereof, and shall at all times keep Amgen informed as to the status thereof. BioAge may, at its own expense, institute

suit against any such infringer or alleged infringer and control and defend and settle such suit in a manner consistent with the terms and provisions hereof and recover any damages, awards or settlements resulting therefrom, subject to Section 4.5 (Recovery). Amgen shall reasonably cooperate in any such litigation (including joining or being named a necessary party thereto) at BioAge's expense. BioAge shall not enter into any settlement of any claim described in this Section 4.3.1 (BioAge Enforcement) that admits to the invalidity or unenforceability of the Licensed Patents, incurs any financial liability on the part of Amgen or requires an admission of liability, wrongdoing or fault on the part of Amgen, without Amgen's prior written consent, in each case, such consent not to be unreasonably withheld.

4.3.2 Amgen Enforcement. If BioAge elects not to enforce any patent within the Licensed Patents, then it shall so notify Amgen in writing within [*] of receiving notice that an Infringement exists (or such shorter period as may be necessary to prevent exhaustion of a statute of limitations (or laches) applicable to such Infringement), and Amgen may, in its sole judgement, and at its own expense, take steps to enforce any such patent and control, settle, and defend such suit in a manner consistent with the terms and provisions hereof, and recover any damages, awards or settlements resulting therefrom, subject to Section 4.5 (Recovery). BioAge shall reasonably cooperate in any such litigation (including joining or being named a necessary party thereto) at Amgen's expense. Amgen shall not enter into any settlement of any claim described in this Section 4.3.2 (Amgen Enforcement) that admits to the invalidity or unenforceability of the Licensed Patents, incurs any financial liability on the part of BioAge or requires an admission of liability, wrongdoing or fault on the part of BioAge without BioAge's prior written consent.

4.3.3 Progress Reports. The Party initiating or defending any such enforcement action (the **"Enforcing Party")** shall keep the other Party reasonably informed of the progress of any such enforcement action, and such other Party shall have the individual right to participate with counsel of its own choice at its own expense.

Section 4.4 Defense of Third Party Claims. If either (a) any Product Exploited by or under authority of BioAge becomes the subject of a Third Party's claim or assertion of Infringement of a patent relating to the manufacture, use, sale, offer for sale or importation of such Product in the Licensed Field in the Territory, or (b) a declaratory judgment action is brought naming either Party as a defendant and alleging invalidity or unenforceability of any of the Licensed Patents, the Party first having notice of the claim or assertion shall promptly notify the other Party, and the Parties shall promptly confer to consider the claim or assertion and the appropriate course of action. Subject to Article 8 (Indemnification), unless the Parties otherwise agree in writing, each Party shall have the right to defend itself against a suit that names it as a defendant (the **"Defending Party").** Neither Party shall enter into any settlement of any claim described in this Section 4.4 that admits to the invalidity or unenforceability of the Licensed Patents, incurs any financial liability on the part of the other Party, requires an admission of liability, wrongdoing or fault on the part of the other Party or, in the case that BioAge is the settling Party, without such other Party's prior written consent, in each case, such consent not to be unreasonably withheld. In any event, the other Party shall reasonably assist the Defending Party and cooperate in any such litigation at the Defending Party's request and expense.

Section 4.5 Recovery. Except as otherwise provided, the costs and expenses of the Party bringing suit under Section 4.3 (Enforcement) shall be borne by such Party, and any damages, settlements or other monetary awards recovered shall be shared as follows: (a) the amount of such recovery actually received by the Party controlling such action shall first be applied to the out-of-pocket costs of each Party in connection with such action; and then (b) the remainder of the recovery shall be shared as follows:

(a) If BioAge is the Enforcing Party, [*]; and

(b) If Amgen is the Enforcing Party, [*].

Section 4.6 Patent Term Extensions and Filings for Regulatory Exclusivity Periods. BioAge will advise Amgen when it is considering any patent term extension or supplementary protection certificates or their equivalent for the Licensed Patents. With respect to any patent listings required for any Regulatory Exclusivity for the Product, the Parties will mutually agree on which Licensed Patents to list.

Section 4.7 Patent Marking. BioAge will mark (including on packaging or a product website), and will cause all other Selling Parties to mark, the Product with all Licensed Patents in accordance with applicable Law, which marking obligation will continue for as long as (and only for as long as) required under applicable Law.

ARTICLE 5.
OBLIGATIONS OF THE PARTIES

Section 5.1 Responsibility. Following the Effective Date and at all times during the Term (except as expressly stated otherwise herein), BioAge shall be solely responsible for, and shall bear all costs associated with, the research, development and commercialization of the Product in the Territory, including regulatory, manufacturing, distribution, marketing and sales activities. Subject to the express written terms of this Agreement, all decisions concerning the development, marketing and sales of Product in the Territory including the clinical and regulatory strategy, design, sale, price and promotion of Product covered under this Agreement shall be within the sole discretion of BioAge.

Section 5.2 Diligence. BioAge shall (directly and/or through one or more Affiliates and/or Sublicensees) use Commercially Reasonable Efforts to develop [*] Product in accordance with the Development Plan and to commercialize the Product in each of the U.S., European Union, Japan and ROW. BioAge may update or revise the Development Plan from time to time; provided that Amgen shall have the right to comment on (but not direct) any updates or revisions.

Section 5.3 Reports.

5.3.1 Within [*] after the end of each Calendar Year, BioAge shall submit to Amgen a report providing the status of BioAge ‘s and its Affiliates’ and Sublicensees’ activities related to the development of and Marketing Approval for the Products during the [*], in each case in relation to the last updated Development Plan.

5.3.2 Within [*] prior to the beginning of each Calendar Year, BioAge shall submit to Amgen plans for future activities related to the commercialization of the Products for [*].

Section 5.4 Distracting Programs.

5.4.1 Distracting Programs. Except as set forth in Section 5.4.2 (Post-Effective Date Affiliates) and 5.4.3 (Termination or Divestiture), [*], BioAge shall not (and shall ensure its Affiliates and Sublicensees do not) directly or indirectly conduct, enable, or participate in any Distracting Program.

5.4.2 Post-Effective Date Affiliates. In the event that BioAge enters into a Distracting Transaction with a Third Party, then BioAge shall provide prompt written notice to Amgen. Until the provisions of Section 5.4.3 (Termination or Divestiture) are effectuated, BioAge shall ensure that information and materials relating to the Product or activities hereunder are not shared with or used for the benefit of, and are sequestered from, Distracting Transaction Affiliate(s).

5.4.3 [*]. The notice provided pursuant to Section 5.4.2 (Post-Effective Date Affiliates) shall include a notification as to whether BioAge intends to: (a) [*]; or (b) [*].

Section 5.5 Reasonable Restrictions. Each of the Parties acknowledges that the provisions of Section 5.4 (Distracting Programs) are reasonable and necessary to protect the legitimate interests of the other Party and to encourage the free sharing of information between the Parties with respect to the Product and each of the Parties agrees not to contest such limitations in any proceeding.

Section 5.6 Data Security. BioAge agrees to, and to cause its applicable Affiliates to, comply with the Information Security Requirements Schedule attached as Exhibit F.

Section 5.7 Product Lots. Subject to entering the Quality Agreement as set forth in this Section 5.7, the Parties shall reasonably cooperate and assist each other in transferring ownership of Product drug product and/or Product drug substance (such material, collectively, the **"Product Lots")** set forth in Exhibit A attached hereto as promptly as reasonably practicable following the Effective Date; provided, however, that neither Party shall be required to pay money to any Third Party, commence any litigation with, or offer or grant any accommodation (financial or otherwise) to any Third Party. Such Product Lots shall be delivered [*] (Incoterms 2020) Amgen, Thousand Oaks, California for shipment to a single location designated by BioAge. Any expense for shipment shall be borne by BioAge (including any import or export duties or taxes). Subject to the terms of this Section 5.7 and Section 6.2 (Additional AMGEN Warranties), Amgen transfers the Product Lots to BioAge "as is", and makes no other representation to BioAge in connection therewith. Within [*] of the Effective Date, the Parties will enter into a Quality Agreement with commercially reasonable terms governing the quality of the Product Lots to be supplied pursuant to this Section 5.7.

ARTICLE 6.
REPRESENTATIONS

Section 6.1 Mutual Representations and Warranties. Each of Amgen and BioAge represent and warrant that:

(a) it is duly organized and validly existing under the Law of the jurisdiction of its formation, and has full power and authority to enter into this Agreement and to carry out the provisions hereof;

(b) it is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder, and the individual executing this Agreement on its behalf has been duly authorized to do so by all requisite action;

(c) it shall comply with all applicable Law (including applicable Law relating to data protection and privacy), Proper Conduct Practices, and Anti-Corruption Laws in connection with the performance of its rights, duties and obligations under this Agreement; and

(d) this Agreement is legally binding upon it and enforceable in accordance with its terms. The execution, delivery and performance of this Agreement by it does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, nor violate any material applicable Law.

Section 6.2 Additional Amgen Warranties. Amgen warrants to BioAge that, as of the Effective Date:

(a) Amgen has full legal or beneficial title and ownership to the Licensed Patents listed on Exhibit B as is necessary to grant the licenses to BioAge to such Licensed Patents that Amgen grants pursuant to this Agreement;

(b) The patents and patent applications listed on Exhibit B represent all Patent Rights Controlled by Amgen or its Affiliates that Cover the Licensed Compounds;

(c) Amgen has no actual knowledge (without making any inquiry) of any fact or circumstance that would affect the validity or enforceability of the Licensed Patents;

(d) Amgen has the rights necessary to grant the licenses to BioAge to Licensed Know-How that Amgen grants pursuant to this Agreement;

(e) The Patent Rights included in the Licensed Patents are not subject to any liens or encumbrances and Amgen has not granted to any Third Party any rights or licenses under such Patent Rights or Licensed Know-How that would conflict with the licenses granted to BioAge hereunder. No patent application or registration within the Licensed Patents is the subject of any pending interference, opposition, cancellation or patent protest pursuant to 37 C.F.R. §1.291;

(f) No Third Party has made any claim or allegation to Amgen or its Affiliates in writing that a Third Party has any right or interest in or to the Licensed Patents listed on Exhibit B; and

(g) To the knowledge of Amgen, no claim or litigation that been brought or threatened in writing by any Third Party alleging that (i) the Licensed Patents are invalid or unenforceable or (ii) the manufacture, sale, offer for sale, or importation of the Product in the Licensed Field in the Territory infringes or misappropriates or would infringe or misappropriate any right of any Third Party;

Section 6.3 Disclaimer. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS ARTICLE 6 (REPRESENTATIONS), NEITHER PARTY MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, QUALITY, FITNESS FOR A PARTICULAR PURPOSE, NONINFRINGEMENT, OR VALIDITY OF PATENT CLAIMS. NOTHING IN THIS AGREEMENT SHALL BE CONSTRUED AS A REPRESENTATION MADE OR WARRANTY GIVEN BY EITHER PARTY THAT EITHER PARTY WILL BE SUCCESSFUL IN OBTAINING ANY PATENT RIGHTS, OR THAT ANY PATENTS WILL ISSUE BASED ON A PENDING APPLICATION. WITHOUT LIMITING THE RESPECTIVE RIGHTS AND OBLIGATIONS OF THE PARTIES EXPRESSLY SET FORTH HEREIN, EACH PARTY SPECIFICALLY DISCLAIMS ANY GUARANTEE THAT THE PRODUCTS WILL BE SUCCESSFUL, IN WHOLE OR IN PART.

Section 6.4 Additional BioAge Warranties. BioAge warrants to Amgen that, as of the Effective Date:

(a) Neither BioAge nor its directors, officers or employees have been debarred, excluded or the subject of debarment or exclusion proceedings by any Governmental Authority;

(b) Neither BioAge nor its officers or directors are Sanctioned Persons, nor are they owned fifty percent (50%) or more individually, or in the aggregate by, or Controlled by, any Sanctioned Person; and

(c) BioAge has established and maintains reasonable internal policies and controls, including codes of conduct and ethics and reasonable reporting requirements, intended to ensure compliance with Anti-Corruption Laws, International Trade Laws and other applicable Law, to the extent applicable to BioAge under the laws of the jurisdiction of its incorporation, including healthcare compliance, privacy laws and data protection laws.

Section 6.5 BioAge Covenants. BioAge covenants to Amgen that:

(a) it will conduct, and will cause its contractors to conduct, all preclinical and clinical studies for the Product and manufacturing of the Product, in accordance with (i) all U.S. Laws and the Laws of the country in which such clinical studies are conducted, and (ii) the known or published standards of the FDA and the Regulatory Authority in such country, including but not limited to good laboratory practice, good clinical practice, and current good manufacturing practices. Neither BioAge, nor any officer, employee or agent of BioAge, will knowingly make an untrue statement of a material fact to any Regulatory Authority with respect to the Product (whether in any submission to such Regulatory Authority or otherwise), and neither will knowingly fail to disclose a material fact required to be disclosed to any Regulatory Authority with respect to the Product;

(b) it (and its Affiliates) will not employ or otherwise use in any capacity the services of any Person debarred or excluded under United States Law, including under 21 U.S.C. § 335a and 42 U.S.C. § 1320a-7(a), or any foreign equivalent thereof, including any Person that has been: (i) debarred by the FDA (or subject to a similar sanction of a Regulatory Authority), or that is subject of an FDA debarment investigation or proceeding (or similar proceeding of a Regulatory Authority), or is otherwise ineligible to participate in federal healthcare programs or federal procurement or non-procurement programs; or (ii) has been convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended or otherwise declared ineligible;

(c) if, during the term of this Agreement, BioAge becomes aware that any Person employed or retained by it to perform any of its obligations under, or services related to, this Agreement: (i) comes under investigation by the FDA, or a similar Regulatory Authority, (ii) is debarred, excluded, suspended, disqualified or subject to a similar sanction of a Regulatory Authority, or (iii) engages in any conduct or activity that could lead to any of the aforementioned actions or similar sanctions of a Regulatory Authority, BioAge shall immediately notify Amgen;

(d) it shall comply with all applicable Law, International Trade Law, Proper Conduct Practices, and Anti-Corruption Laws in connection with the performance of its rights, duties and obligations under this Agreement;

(e) it shall provide Amgen with any information required by Amgen to comply with International Trade Laws with respect to this Agreement;

(f) it shall promptly provide Amgen with written notice upon receiving a formal notification that it is the target of a formal or informal request for information, subpoena, investigation, litigation, penalty, or claim from any Governmental Authority, or any Third Party, for violation or potential violation of any applicable Anti-Corruption Law, International Trade Laws or Proper Conduct Practices;

(g) prior to beginning any development or commercialization of any Product under this Agreement, each of its employees, agents, independent contractors or Affiliates involved in the development or commercialization of any Product shall be required to undergo compliance training with respect to Proper Conduct Practices and Anti-Corruption Laws;

(h) it shall use only legitimate and ethical business practices (including Proper Conduct Practices) in connection with activities conducted in connection with this Agreement whether directly, through the use of Representatives or otherwise, and shall not take any action that would subject any other Party to penalties under any applicable Law;

(i) it shall cause its Affiliates and its and their officers, directors, employees and agents to comply with this Agreement, including the covenants in this Section 6.5;

(j) it shall comply with all applicable (i) U.S. Laws prohibiting the re-export, directly or indirectly, of certain controlled U.S.-origin items without a license to parties located in certain countries or appearing on certain U.S. Government lists of restricted parties; (ii) U.S. Laws prohibiting participation in non-U.S. boycotts that the United States does not support; (iii) U.S. Laws prohibiting the sale of products to parties from any country subject to U.S. economic sanctions or who are identified on related U.S. Government lists of restricted parties; (iv) International Trade Laws, and (v) data privacy laws of the applicable jurisdiction, including the General Data Protection Regulation (Regulation (EU) 2016/679), and all data breach notification and information securities laws and regulations specific thereto;

(k) as of the Effective Date to and through the expiration or termination of this Agreement, (i) it, and, to the best of its knowledge, its Representatives, shall not, directly or indirectly, offer, pay, promise to pay, or authorize such offer, promise or payment, of anything of value, to any Person for the purposes of obtaining or retaining business through any improper advantage in connection with this Agreement, or that would otherwise violate any applicable Laws, rules and regulations concerning or relating to public or commercial bribery or corruption, (ii) that its books, accounts, records and invoices related to this Agreement or related to any work conducted for or on behalf of the other Party are and will be complete and accurate, and (iii) that Amgen may terminate this Agreement if (a) BioAge or BioAge's Representatives fails to comply with the Anti-Corruption Laws or with this provision, or (b) Amgen has a good faith belief that BioAge or BioAge's Representatives has violated, intends to violate, or has caused a violation of the Anti-Corruption Laws. Amgen may reasonably request from time to time that BioAge complete a compliance certification regarding the foregoing; Amgen may also terminate this agreement if BioAge (1) fails to complete a compliance certification, (2) fails to complete it truthfully and accurately, or (3) fails to comply with the terms of that certification; and

(l) if one or more Covered Individuals and Entities contributes to or performs any of BioAge obligations hereunder, payments made by or on behalf of BioAge to each such Covered Individual and Entity or other compensation or consideration received by each such Covered Individual and Entity on account of its contributions to or performance of any of BioAge's obligations hereunder shall (i) comply with all applicable Law, (ii) represent fair market value, (iii) not be determined in a manner that that takes into account the volume or value of any future business that might be generated between the Parties, and (iv) not be construed to require a Covered Individual or Entity to promote, purchase, prescribe, or otherwise recommend an Amgen Therapeutic Product being marketed or under development. BioAge agrees that Amgen shall have the right, upon notice to BioAge and without further agreement or acknowledgement of BioAge, to modify the terms of this Agreement as Amgen determines, in its reasonable discretion, is necessary or required to comply with Amgen's or, as applicable, one or more of its Affiliate's requirements for interactions with a Covered Individual and Entity (including without limitation conformance of the compensation to fair market value and imposition of additional reporting or documentation obligations).

ARTICLE 7.
INDEMNIFICATION

Section 7.1 Indemnity.

7.1.1 By Amgen. Amgen agrees to defend BioAge and its (and its Affiliates') directors, officers, employees and agents (the **"BioAge Indemnified Parties")** at Amgen's cost and expense, and will indemnify and hold BioAge and the other BioAge Indemnified Parties harmless from and against any claims, losses, costs, damages, fees or expenses (including legal fees and expenses) (collectively, **"Losses")** to the extent resulting from any Third Party claim (including product liability claims) arising out of or otherwise relating to (a) the negligence or willful misconduct of Amgen or its Affiliates in connection with its activities under this Agreement, (b) the breach of this Agreement or the representations and warranties made hereunder by Amgen, except, in the case of each of (a) or (b) of this Section 7.1.1 (By Amgen), to the extent such Losses result from clause (a), (b) or (c) of Section 7.1.2 (By BioAge). In the event of any such claim against the BioAge Indemnified Parties by a Third Party, the foregoing indemnity obligations shall be conditioned upon (x) BioAge promptly notifying Amgen in writing of the claim ***(provided, however,*** that any failure or delay to notify shall not excuse any obligations of Amgen except to the extent Amgen is actually materially prejudiced thereby) and (y) BioAge granting Amgen sole management and control, at Amgen's sole expense, of the defense of the claim and its settlement ***(provided, however,*** that Amgen shall not settle any such claim without the prior written consent of BioAge if such settlement does not include a complete release from liability or if such settlement would involve BioAge undertaking an obligation (including the payment of money by a BioAge Indemnified Party), would bind or impair a BioAge Indemnified Party, or includes any admission of wrongdoing or that any intellectual property or proprietary right of BioAge or this Agreement is invalid, narrowed in scope or unenforceable), and (z) the BioAge Indemnified Parties reasonably cooperating with Amgen (at Amgen's expense). The BioAge Indemnified Parties may, at their option and expense, be represented in any such action or proceeding by counsel of their own choosing.

7.1.2 By BioAge. BioAge agrees to defend Amgen and its (and its Affiliates') directors, officers, employees and agents (the **"Amgen Indemnified Parties")** at BioAge's cost and expense, and will indemnify and hold Amgen and the other Amgen Indemnified Parties harmless from and against any Losses to the extent resulting from any Third Party claim (including product liability claims) arising out of or otherwise relating to (a) the negligence or willful misconduct of BioAge, its Affiliates, or their respective Sublicensees in connection with its activities under this Agreement, (b) the breach of this Agreement or the representations, warranties and covenants made hereunder by BioAge, or (c) the Exploitation of the Product by or on behalf of BioAge, its Affiliates, or their respective Sublicensees (including from product liability and intellectual property infringement claims); except, in each case, to the extent such Losses result from clause (a) or (b) of Section 7.1.1 (By Amgen). In the event of any such claim against the Amgen Indemnified Parties by a Third Party, the foregoing indemnity obligations shall be conditioned upon (x) Amgen promptly notifying BioAge in writing of the claim ***(provided, however,*** that any failure or delay to notify shall not excuse any obligation of BioAge except to the extent BioAge is actually materially prejudiced thereby) and (y) Amgen granting BioAge shall sole management and control, at BioAge's sole expense, the defense of the claim and its settlement ***(provided, however,*** that BioAge shall not settle any such claim without the prior written consent of Amgen if such settlement does not include a complete release from liability or if such settlement would involve undertaking an obligation (including the payment of money by an Amgen Indemnified Party), would bind or impair an Amgen Indemnified Party, or includes any admission of wrongdoing or that any intellectual property or proprietary right of Amgen or this Agreement is invalid, narrowed in scope or unenforceable), and (z) the Amgen Indemnified Parties reasonably cooperating with BioAge (at BioAge's expense). The Amgen Indemnified Parties may, at their option and expense, be represented in any such action or proceeding by counsel of their own choosing.

Section 7.2 LIMITATION OF DAMAGES. IN NO EVENT SHALL EITHER PARTY BE LIABLE HEREUNDER TO THE OTHER PARTY FOR ANY PUNITIVE, INDIRECT, SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES (INCLUDING LOST REVENUE, LOST PROFITS, OR LOST SAVINGS) HOWEVER CAUSED AND UNDER ANY THEORY, EVEN IF IT HAS NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. THE LIMITATIONS SET FORTH IN THIS SECTION 7.2 (LIMITATION OF DAMAGES) SHALL NOT APPLY WITH RESPECT TO (A) ANY BREACH OF ARTICLE 8 (CONFIDENTIALITY) OR (B) THE INTENTIONAL MISCONDUCT OR GROSS NEGLIGENCE OF A PARTY. NOTHING IN THIS SECTION 7.2 (LIMITATION OF DAMAGES) IS INTENDED TO LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF A PARTY UNDER THIS ARTICLE 7 (INDEMNIFICATION) WITH RESPECT TO ANY DAMAGES PAID BY THE OTHER PARTY TO A THIRD PARTY IN CONNECTION WITH A THIRD-PARTY CLAIM.

Section 7.3 Insurance. At least [*] prior to the Initiation of the first clinical trial of a Product, BioAge shall at its own expense procure and maintain during the Term (and for [*] thereafter) clinical trial liability insurance coverage adequate to cover its obligations hereunder and which is/are consistent with normal business practices of prudent pharmaceutical companies. Additionally, at least [*] prior to First Commercial Sale of any Product in the Territory, BioAge shall at its own expense procure and maintain during the Term (and for [*] thereafter) product

liability insurance coverage adequate to cover its obligations hereunder and which is consistent with normal business practices of prudent pharmaceutical companies. Each insurance policy required by and procured by BioAge under this Section 7.3 (Insurance) shall name Amgen as an additional insured. Such insurance shall not be construed to create a limit of BioAge's liability with respect to its indemnification obligations under this Article 7 (Indemnification). BioAge shall provide Amgen with a certificate of insurance or other evidence of such insurance, upon request. BioAge shall provide Amgen with written notice at least [*] prior to the cancellation, non-renewal or a material change in such insurance which materially adversely affects the rights of Amgen hereunder, and [*] prior written notice of cancellation for non-payment of premiums. BioAge's insurance hereunder shall be primary with respect to the obligations for which BioAge is liable hereunder.

ARTICLE 8.
CONFIDENTIALITY

Section 8.1 Confidential Information.

8.1.1 Confidential Information. Each Party **("Disclosing Party")** may disclose to the other Party **("Receiving Party"),** and Receiving Party may acquire during the course and conduct of activities under this Agreement, certain proprietary or confidential information of Disclosing Party in connection with this Agreement. The term **"Confidential Information"** will mean (a) all Licensed Know-How, (b) all Licensed Materials, and (c) all ideas and information of any kind, whether in written, oral, graphical, machine-readable or other form, whether or not marked as confidential or proprietary, which are transferred, disclosed or made available by Disclosing Party or at the request of Receiving Party, including any of the foregoing of Third Parties. Without limiting the foregoing, Licensed Know-How and Licensed Materials will be considered Confidential Information of Amgen, and all research and development updates as well as financial and business disclosures from BioAge to Amgen will be considered Confidential Information of BioAge. During the Term, Amgen shall keep confidential all Licensed Know-How and Licensed Materials to the extent disclosure of such Confidential Information would negatively impact in any material way the Exploitation of the Product in the Territory by BioAge or its Affiliates or Sublicensees.

8.1.2 Restrictions. During the Term and for [*] thereafter, Receiving Party will keep all Disclosing Party's Confidential Information in confidence with the same degree of care with which Receiving Party holds its own confidential information (but in no event less than a commercially reasonable degree of care). Receiving Party will not use Disclosing Party's Confidential Information except in connection with the performance of its obligations and exercise of its rights under this Agreement. Receiving Party has the right to disclose Disclosing Party's Confidential Information without Disclosing Party's prior written consent, to the extent and only to the extent reasonably necessary, to Receiving Party's Affiliates and their employees, subcontractors, consultants or agents who have a need to know such Confidential Information in order to perform its obligations and exercise its rights under this Agreement and who are required to comply with the restrictions on use and disclosure in this Section 8.1.2 (Restrictions). Receiving Party will use diligent efforts to cause those entities and persons to comply with the restrictions on use and disclosure in this Section 8.1.2 (Restrictions). Receiving Party assumes responsibility for those entities and persons maintaining Disclosing Party's Confidential Information in confidence and using same only for the purposes described herein.

8.1.3 Exceptions. Receiving Party's obligation of nondisclosure and the limitations upon the right to use the Disclosing Party's Confidential Information will not apply to the extent that Receiving Party can demonstrate that the Disclosing Party's Confidential Information: (a) was known to Receiving Party or any of its Affiliates prior to the time of disclosure; (b) is or becomes public knowledge through no fault or omission of Receiving Party or any of its Affiliates; (c) is obtained by Receiving Party or any of its Affiliates from a Third Party under no obligation of confidentiality to Disclosing Party; or (d) has been independently developed by employees, subcontractors, consultants or agents of Receiving Party or any of its Affiliates without the use of Disclosing Party's Confidential Information, as evidenced by contemporaneous written records.

8.1.4 Permitted Disclosures. Without limiting Sections 2.4.3 and 8.1.2, Receiving Party may disclose Disclosing Party's Confidential Information to the extent (and only to the extent) such disclosure is reasonably necessary in the following instances:

(a) in order to comply with applicable law (including any securities law or regulation or the rules of a securities exchange) or with a legal or administrative proceeding;

(b) in connection with prosecuting or defending litigation, Marketing Approvals and other regulatory filings and communications, and filing, prosecuting and enforcing Patents in connection with Receiving Party's rights and obligations pursuant to this Agreement;

(c) in connection with exercising its rights hereunder, to its Affiliates; potential and future collaborators (including Sublicensees where BioAge is the Receiving Party); potential and permitted acquirers or assignees; and potential investment bankers, investors and lenders; and

(d) BioAge shall have the right to disclose [*].

provided, however, that (1) with respect to Sections 8.1.4(a) or 8.1.4(b), where reasonably possible, Receiving Party will notify Disclosing Party of Receiving Party's intent to make any disclosure pursuant thereto sufficiently prior to making such disclosure so as to allow Disclosing Party adequate time to take whatever action it may deem appropriate to protect the confidentiality of the information to be disclosed, and (2) with respect to Section 8.1.4(c), each of those named people and entities are required to comply with the restrictions on use and disclosure in Section 8.1.2 (Restrictions) (other than investment bankers, investors and lenders, which must be bound prior to disclosure by commercially reasonable obligations of confidentiality).

8.1.5 Privacy and Data Protection.

(a) Without limiting each Party's respective obligations elsewhere in the Agreement, each Party, as applicable, agrees that where a Party determines the purpose and means of processing Personal Data, such party is: (i) acting as a "controller" (as defined under the European Union General Data Protection Regulation (Regulation (EU) 2016/679 and implementation legislation adopted by any of the member states of the European Union ("GDPR") and other applicable Law) of such information; and (ii) shall comply with GDPR and all applicable data privacy and protection Law applicable to a controller, which shall include without limitation employing and maintaining appropriate Security (as defined below) to protect such data. "Security" means technological, physical and administrative controls, including, but not limited to, policies, procedures, organizational structures, hardware and software functions, as well as physical security measures, the purpose of which is, in whole or part, to ensure the confidentiality, integrity or availability of Personal Data.

(b) In the event of an actual or reasonably suspected breach or violation of Security concerning the Study Data ("Privacy Incident"), each Party shall notify the other of such incident without undue delay (but in no event later than [*] after discovery). In such event, each Party shall be responsible for fulfilling any reporting and notification obligations required under GDPR and other Law with regard to the data processing operations it carries out.

(c) The Parties hereby incorporate the EU Standard Contractual Clauses necessary to effectuate the compliant onward transfer of EU Personal Data outside of EU/EEA to third countries attached hereto as Exhibit H. In addition, the Parties agree to cooperate with each to effectuate the compliant transfer of Personal Data applicable to other jurisdictions, which may include executing additional data transfer agreements.

(d) The Parties shall notify each other without delay (but in no event later [*] after receipt) in the event a data subject asserts one of his/her rights under GDPR and applicable data privacy and protection laws. Any such notifications shall be made in a pseudonymous form using the subject's trial-specific identification number only. If necessary and appropriate, the Parties shall reasonably cooperate with each other by providing the necessary information to ensure full and effective implementation of the rights of the data subject. Notification required under this Section shall be made as follows:

Amgen: [*]

BioAge: [*]

(e) To the extent required under GDPR and Law, BioAge shall (i) make available to Amgen such information as is reasonably necessary to demonstrate BioAge's compliance with its obligations under this Agreement, GDPR and Law with respect to this Agreement and (ii) allow for and contribute to audits and inspections conducted by Amgen in accordance with the terms of this provision to demonstrate such compliance with BioAge's obligations set out in this Agreement, GDPR and Law. Should Amgen choose to exercise the right to conduct an audit or

inspection as described in (ii) above, Amgen shall designate an independent, qualified third-party that is reasonably acceptable to and approved by BioAge to perform such audit, at Amgen's cost and expense. The timing of such audit or inspection shall be agreed to by the Parties. BioAge will document the results of such inspections or audits and present them to Amgen for approval. If BioAge objects to Amgen's request for audit or inspection, it shall advise Amgen of its objections, the reasons for objecting, and reasonably work with Amgen to tailor the audit or inspection to address such objections, to the extent commercially reasonable

Section 8.2 Terms of this Agreement; Publicity.

8.2.1 Restrictions. The Parties agree that the terms of this Agreement will be treated as Confidential Information of both Parties, and thus may be disclosed only as permitted by Section 8.1.4 (Permitted Disclosures). Except as required by Law, each Party agrees not to issue any press release or public statement disclosing information relating to this Agreement or the transactions contemplated hereby or the terms hereof without the prior written consent of the other Party not to be unreasonably withheld (or as such consent may need to be obtained in accordance with Section 8.2.2 (Review) or 8.3.1 (Right to Publish)).

8.2.2 Review. In the event either Party (the **"Issuing Party")** desires to issue a press release or other public statement disclosing information relating to this Agreement or the transactions contemplated hereby or the terms hereof, the Issuing Party will provide the other Party (the **"Reviewing Party")** with a copy of the proposed press release or public statement (the **"Release").** The Issuing Party will specify with each such Release, taking into account the urgency of the matter being disclosed, a reasonable period of time within which the Receiving Party may provide any comments on such Release (but in no event less than [*]). If the Receiving Party provides any comments, the Parties will consult on such Release and work in good faith to prepare a mutually acceptable Release. Either Party may subsequently publicly disclose any information previously contained in any Release, provided that the other Party provided its written consent hereto as stated in 8.2.1 (Restrictions). For the avoidance of doubt (and notwithstanding anything contained in this Agreement to the contrary), BioAge, in its sole discretion, may make disclosures relating to the development or commercialization of the Product, including the results of research and any clinical trial conducted by BioAge or any health or safety matter related to the Product.

Section 8.3 Publications.

8.3.1 Right to Publish. Subject to the provisions of Sections 8.1 (Confidential Information), 8.2 (Terms of this Agreement; Publicity) and 8.3.2 (Review), BioAge shall have the right to publish with respect to the Products in publications based in the Territory, and to make scientific presentations on the Products in the Territory. Neither Party shall publish information concerning the manufacture of the Licensed Compound without the prior written consent of the other Party. The Parties acknowledge and agree that all BioAge publications pursuant to this section shall be developed by BioAge in accordance with

BioAge's publications policies and practices. In addition, authorship by BioAge of any publication arising from this Agreement will be undertaken in accordance with the International Committee of Medical Journal Editors (ICMJE) guidelines for authorship. Consistent with those guidelines, authorship will be based upon substantial contribution to the design, analysis, interpretation of data, drafting and/or critically revising any publication(s) derived from the Agreement, and authors must engage in the drafting of the publication or revise it critically for important intellectual content. BioAge agrees to maintain evidence of its compliance with the ICMJE guidelines for authorship, and that it will provide such evidence to Amgen upon request. Publications shall acknowledge use of any Amgen data, support, or other contributions as appropriate and consistent with medical journal guidelines.

8.3.2 Review. Except as required by Law or court order, for any proposed publication or presentation regarding the Product in the Territory, the Party desiring to make such publication: (a) shall transmit a copy of the proposed publication for review and comment to the other Party at least [*] prior to the submission of such publication to a Third Party; (b) shall postpone such publication for up to an additional [*] upon request of a Party to allow the consideration of appropriate patent applications or other protection to be filed; (c) upon request of the other Party (or applicable licensee) shall remove all Confidential Information of the other Party (or applicable licensee) (excluding, for clarity, anything permitted to be disclosed by BioAge pursuant to the last sentence of Section 8.2.2 (Review)); and (d) shall consider all reasonable comments made by the other Party (or its applicable licensee).

8.3.3 Amgen Publication. Amgen shall have the right to publish those publications in planning stage as of the Effective Date, including those listed in Exhibit G; ***provided, however,*** that any other publication regarding the Product or that discloses Confidential Information of BioAge shall require BioAge's prior written consent, such consent not to be unreasonably withheld, conditioned or delayed. The Parties acknowledge and agree that all Amgen publications pursuant to this section shall be developed by Amgen in accordance with Amgen's publications policies and practices.

Section 8.4 Relationship to the Confidentiality Agreements. Prior to the Effective Date, the Parties entered into a confidential disclosure agreement, [*] (the **"CDA").** Any Confidential Information previously disclosed by the Parties pursuant to the CDA shall now be Confidential Information for purposes of this Agreement and the Parties shall treat it as such in accordance with the terms hereof, and this Agreement supersedes the CDA with respect to the Parties.

Section 8.5 Attorney-Client Privilege. Neither Party is waiving, nor will be deemed to have waived or diminished, any of its attorney work product protections, attorney-client privileges or similar protections and privileges recognized under the applicable Law of any jurisdiction as a result of disclosing information pursuant to this Agreement, or any of its Confidential Information (including Confidential Information related to pending or threatened litigation) to the receiving Party, regardless of whether the disclosing Party has asserted, or is or may be entitled to assert, such privileges and protections. The Parties may become joint defendants in proceedings to which the information covered by such protections and privileges relates and may determine that they share a common legal interest in disclosure between them that is subject to such privileges and protections, and in such event, may enter into a joint defense agreement setting forth, among other things, the foregoing principles but are not obligated to do so.

ARTICLE 9.
TERM & TERMINATION

Section 9.1 Term. The term of this Agreement (the **"Term")** shall commence on the Effective Date, and unless terminated earlier as provided in this Article 9 (Term & Termination), shall continue in full force and effect until expiration of obligations to pay royalties under this Agreement for any Products in the Territory. Upon expiration of this Agreement, the licenses granted to BioAge by Amgen under this Agreement to Exploit the Product shall be fully paid-up, irrevocable and non-exclusive.

Section 9.2 Termination by Amgen.

9.2.1 Breach. Amgen will have the right to terminate this Agreement in the U.S., EU, and Japan, or in full upon delivery of written notice to BioAge in the event of any material breach by BioAge of (1) any terms and conditions of this Agreement with respect to the Exploitation in such country, region or Territory or (2) solely prior to the earliest to occur of [*], the Designated Investment Document Terms, ***provided, however,*** that such termination will not be effective if such breach has been cured within [*] after written notice thereof is given by Amgen to BioAge specifying in reasonable detail the nature of the alleged breach; ***provided further, however,*** that to the extent such material breach involves the material undisputed failure to make a payment when due, such breach must be cured within [*] after written notice thereof is given by Amgen to ***BioAge; provided further, however,*** that if the material breach is not reasonably capable of being cured within [*] cure period, and if BioAge (a) proposes within such [*] period a written plan, reasonably acceptable to Amgen, to cure such breach, and (b) makes good faith efforts to cure such default and to implement such written cure plan, then, until [*] receipt of notice of termination, Amgen may not terminate this Agreement for so long as BioAge is diligently pursuing such cure in accordance with such plan. Notwithstanding the foregoing, any breach by BioAge of Section 6.1 with respect to Proper Conduct Practices shall be deemed a material breach for which Amgen may terminate this Agreement immediately upon delivery of written notice without any opportunity for BioAge to cure such breach.

9.2.2 Termination for IP Challenge. Amgen will have the right to terminate this Agreement in full upon written notice to BioAge in the event that BioAge or any of its Affiliates or Sublicensees directly challenges in a legal or administrative proceeding the patentability, enforceability or validity of any Licensed Patents; ***provided, however,*** that Amgen will not have the right to terminate this Agreement under this Section 9.2.2 (Termination for IP Challenge) for any such challenge by any Sublicensee if (a) BioAge terminates such Sublicense within [*] of Amgen's notice to BioAge under this Section 9.2.2 (Termination for IP Challenge) or (b) such challenge is dismissed within [*] of Amgen's notice to BioAge under this Section 9.2.2 (Termination for IP Challenge) and not thereafter continued.

9.2.3 Termination for a BioAge Distracting Product. Amgen will have the right to terminate this Agreement in full upon written notice to BioAge in the event that BioAge violates Section 5.4.1 (Distracting Programs); ***provided, however,*** that such termination will not be effective if such violation has been cured [*] after written notice thereof is given by Amgen to BioAge.

9.2.4 Termination for Failure to Develop or Commercialize. In the event BioAge fails to perform any material development or commercialization activities with respect to the Products for a period of [*], and such failure is not due to reasons outside of BioAge's control (including, without limitation, a regulatory hold or force majeure event), then without limiting other available remedies, Amgen shall have the right to terminate this Agreement (1) in the U.S., European Union or Japan, with respect to the applicable country or region, or (2) in the remainder of the Territory excluding the U.S., European Union and Japan **("ROW"),** if no such development or commercialization activities occur anywhere in **ROW;** ***provided, however,*** that such termination will not be effective if such failure has been cured within [*] after written notice thereof is given by Amgen to BioAge regarding such failure.

Section 9.3 Termination by BioAge.

9.3.1 Breach. BioAge will have the right to terminate this Agreement in full upon delivery of written notice to Amgen in the event of any material breach by Amgen of any terms and conditions of this Agreement; ***provided, however,*** that such termination will not be effective if such breach has been cured within [*] after written notice thereof is given by BioAge to Amgen specifying the nature of the alleged breach; ***provided further, however,*** that if the material breach is not reasonably capable of being cured within the [*] cure period, and if Amgen (a) proposes within such [*] period a written plan, reasonably acceptable to BioAge, to cure such breach, and (b) makes good faith efforts to cure such default and to implement such written cure plan, then, until the first anniversary of receipt of notice of termination, BioAge may not terminate this Agreement for so long as Amgen is diligently pursuing such cure in accordance with such plan.

9.3.2 Discretionary Termination. BioAge will have the right to terminate this Agreement in full or on a country-by-country basis for convenience:

(a) In the time period prior to the initiation of clinical development for any Product, upon [*] prior written notice to Amgen

(b) In the time period after the initiation of clinical development for any Product, upon [*] prior written notice to Amgen

Following any such notice of termination, BioAge shall have no further obligation pursuant to Section 5.2 (Diligence) with respect to the terminated country(ies) (or the Territory if BioAge terminates this Agreement in full) to further Exploit any the Product, however, BioAge shall use its reasonable efforts to facilitate a smooth, orderly and prompt transition of any of the Product(s) Controlled by BioAge in the terminated country(ies) (or the Territory if BioAge terminates this Agreement in full) prior to the effective date of termination with respect to such country(ies) (or the Territory if BioAge terminates this Agreement in full) from BioAge to Amgen.

Section 9.4 Termination Upon Bankruptcy. Either Party may terminate this Agreement if, at any time, the other Party shall (a) file in any court or agency pursuant to any statute or regulation of any state, country or jurisdiction, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of that Party or of its assets, (b) propose a written agreement of composition or extension of its debts, (c) be served with an involuntary petition against it, filed in any insolvency proceeding, and such petition has not been dismissed within [*] after the filing thereof, (d) propose or be a party to any dissolution or liquidation, (e) make an assignment for the benefit of its creditors or (f) admit in writing its inability generally to meet its obligations as they fall due in the general course.

Section 9.5 Effects of Termination. Upon termination by Amgen under Section 9.2 (Termination by Amgen), or by BioAge Section 9.3.2 (Discretionary Termination) or by Amgen under Section 9.4 (Termination Upon Bankruptcy):

(a) BioAge will responsibly wind-down, in accordance with accepted pharmaceutical industry norms and ethical practices and all legal and regulatory requirements, any on-going clinical studies for which it has responsibility hereunder in which patient dosing has commenced or, if reasonably practicable and not adverse to patient safety and requested by Amgen, BioAge shall complete such trials and Amgen shall reimburse BioAge its reasonable, out-of-pocket costs and internal labor costs at the FTE Rate associated therewith. For the purpose of clarity, except as provided for above, BioAge may wind-down any ongoing clinical trials prior to the date of termination in accordance with accepted pharmaceutical industry norms and ethical practices and BioAge will be responsible for any costs associated with such wind-down.

(b) A termination of this Agreement will automatically terminate any sublicense granted by BioAge pursuant to Section 2.2 (Sublicenses) unless (1) Amgen has approved such sublicense in writing, such approval not to be unreasonably withheld, conditioned or delayed, (2) such Sublicensee is not in breach of such sublicense agreement, and (3) termination of this Agreement is not caused by any act or omission of such Sublicensee, in which case all rights under such sublicense shall be deemed to survive termination as long as Sublicensee complies with its obligations thereunder, and provided that in no event will Amgen be obligated to fulfill any of BioAge's obligations under such sublicense (other than the granting of rights under the Licensed Patents and Licensed Know-How). The Sublicensee of any such surviving sublicense shall continue to pay to Amgen the milestones and royalties that would have been due to Amgen under this Agreement based on such Sublicensee's activities had this Agreement not been terminated. For clarity, in the event that such Sublicensee fails to pay Amgen the applicable milestones and royalties due to Amgen based on such Sublicensee's activities, Amgen shall be entitled to terminate such Sublicensee's sublicense by providing written notice of termination which notice shall take effect [*] after it is received by such Sublicensee unless such Sublicensee has cured any such breach or default prior to expiration of the [*] period.

(c) All rights and licenses granted by Amgen to BioAge in Article 2 (License Grant) will terminate.

(d) Upon Amgen's request, all Marketing Approvals and other regulatory filings and communications owned (in whole or in part) or otherwise controlled by BioAge and its Affiliates, and (subject to Section 9.5(b)) Sublicensees, and all other documents, in all cases relating to or necessary to further Exploit any Product (and not with respect to any active pharmaceutical ingredients that are not a Licensed Compound that may be included in a Product), as such items exist as of the effective date of such termination (including all documents related to completed and ongoing clinical studies) will be assigned to Amgen to the extent practicable (or, if not so assigned, BioAge shall make the benefit of the foregoing reasonably available to Amgen), and BioAge will provide to Amgen one (1) copy of the foregoing and all documents contained in or referenced in any such items, together with the raw and summarized data for any clinical studies (and where reasonably available, electronic copies thereof). All expenses in relation to such assignment will be borne by Amgen. In the event of any failure to obtain assignment, BioAge hereby consents and grants to Amgen the right to access and reference (without any further action required on the part of BioAge, whose authorization to file this consent with any Regulatory Authority is hereby granted) any such item.

(e) Upon Amgen's election, BioAge shall and hereby does grant to Amgen and its Affiliates (i) an automatic, worldwide, royalty-bearing, perpetual and irrevocable exclusive license, with the right to grant sublicenses through multiple tiers, solely for use in Exploiting such Product, under Know-How and Patent Rights that are Controlled by BioAge or any of its Affiliates and Sublicensees prior to termination and that are solely related to a Product (and not with respect to any active pharmaceutical ingredients that are not a Licensed Compound that may be included in a Product) and which are necessary for Exploiting such Product and any improvement of any of the foregoing, and (ii) an automatic, worldwide, perpetual and irrevocable non-exclusive license, with the right to grant sublicenses through multiple tiers, solely for use in Exploiting the Product, under Know-How and Patent Rights that are Controlled by BioAge or any of its Affiliates and (subject to Section 9.5(b)) Sublicensees that are not solely related to such Product but that are necessary for Exploiting such Product and any improvement to any of the foregoing. For the purpose of clarity, upon Amgen's election at the time of termination, (1) such license shall be effective only as of and after the effective date of such termination and (2) Amgen will be obligated to pay royalties during the Royalty Term(s) as provided for in Section 3.3 (Royalties) whether the Net Sales are by Amgen its Affiliate or sublicensee; provided, all deductions and reductions contemplated in Section 3.3 will apply to such payments and the definition of Net Sales and Sections 3.4 (Method of Payment) -3.9 (Taxes)(inclusive) will apply mutatis mutandis to Amgen in connection with the

payment of such royalties and provided further that the royalty rates shall be [*] of the rates set forth in Section 3.3. Notwithstanding the foregoing, in the event that any of the foregoing Know-How or Patent Rights are not Controlled by BioAge (or any of its Affiliates and Sublicensees) due to the fact that such party would be obligated to make any payments to a Third Party in connection with the grant of the foregoing licenses, then Amgen shall have the right to assume such payment obligations and shall comply with other terms and conditions applicable to a sublicense under such agreement (to the extent allowed under the Third Party license agreement) and should it elect to do so, such Know-How and Patent Rights shall be included in such license grant.

(f) Upon Amgen's request, BioAge will assign (or, if applicable, will cause its Affiliates or (subject to Section 9.5(b)) Sublicensees to assign) to Amgen all of BioAge's (and such Affiliates' and Sublicensees') right, title and interest in and to any registered or unregistered trademarks or internet domain names that are specific to the Product(s), provided that such assignment is in accordance with BioAge's policy on trademarks (it being understood that the foregoing will not include any trademarks or internet domain names that contain the corporate or business name(s) of BioAge).

(g) If Amgen has elected the licenses under subclause (e) above, BioAge agrees (and shall cause its Affiliates and Sublicensees as a condition of the grant of the applicable Sublicense to so agree) to fully cooperate with Amgen and its designee(s) to facilitate a smooth, orderly and prompt transition of the Exploitation of the Product in the Territory to Amgen and/or its designee(s). Upon request by Amgen, BioAge shall transfer to Amgen some or all quantities of the Product in its possession. If BioAge is, at the time of such termination of this Agreement, party to any Third Party contracts with respect to the Product(s), then it shall provide Amgen notice of and (to the extent permitted to do so), copies thereof. BioAge shall assign to Amgen any such contracts requested by Amgen, to the extent relating to the Product(s) (and not with respect to any active pharmaceutical ingredients that are not a Licensed Compound that may be included in a Product) and to the extent it has the right under such contract(s) to do so (and shall use commercially reasonable efforts to obtain any required consents, which efforts shall not require making any payments or incurring any liabilities unless Amgen agrees to reimburse BioAge therefor (and BioAge shall inform Amgen of any such required payment or liability)). In addition, BioAge shall, at Amgen's cost and expense, (i) provide any cooperation reasonably requested by Amgen to ensure uninterrupted supply of the Product(s) (including BioAge's employees' time at the FTE Rate), and (ii) if BioAge manufactured the Product(s) at the time of termination, continue to provide for manufacturing of the Product for Amgen, at [*] of the fully-burdened manufacturing cost therefor, from the date of notice of such termination until the sooner to occur of such time as Amgen is able, using commercially reasonable efforts to do so, to secure an acceptable alternative commercial manufacturing source from which sufficient quantities of Product(s) may be procured and legally sold in the Territory or [*] from the effective date of termination of this Agreement.

BioAge shall duly execute and deliver, or cause to be duly executed and delivered, such instruments and shall do and cause to be done such activities and things, including the filings of such assignments, agreements, documents and instruments, as may be necessary under, or as Amgen may reasonably request in connection with, Amgen's rights under this Section 9.5 (Effects of Termination).

Section 9.6 Survival. In addition to the termination consequences set forth in Section 9.5 (Effects of Termination), the following provisions will survive termination or expiration of this Agreement: Articles 1 (Definitions), 7 (Indemnification), 8 (Confidentiality), and 10 (Miscellaneous) and Sections 2.7 (No Other Rights), 3.2 (Milestone Payments) (with respect to payment obligations accrued before such expiration or termination), 3.3 (Royalties) (with respect to sales made before such expiration or termination), 3.4 (Method of Payment) through 3.9 (Taxes) (inclusive) (with respect to Milestone Payments and periods with sales of the Product made before such expiration or termination), 4.3 (Enforcement) through 4.5 (Recovery) (inclusive) (with respect to any action initiated prior to such expiration or termination), 6.3 (Disclaimer), and this Section 9.6 (Survival). Termination or expiration of this Agreement are neither Party's exclusive remedy and will not relieve the Parties of any liability or obligation which accrued hereunder prior to the effective date of such termination or expiration nor preclude either Party from pursuing all rights and remedies it may have hereunder or at law or in equity with respect to any breach of this Agreement nor prejudice either Party's right to obtain performance of any obligation. All other rights and obligations will terminate upon expiration of this Agreement.

ARTICLE 10.
MISCELLANEOUS

Section 10.1 Entire Agreement; Amendment. This Agreement and all Exhibits attached to this Agreement and the Financing Agreements constitute the entire agreement between the Parties as to the subject matter hereof. All prior and contemporaneous negotiations, representations, warranties, agreements, statements, promises and understandings with respect to the subject matter of this Agreement are hereby superseded and merged into, extinguished by and completely expressed by this Agreement. None of the Parties shall be bound by or charged with any written or oral agreements, representations, warranties, statements, promises or understandings not specifically set forth in this Agreement. No amendment, supplement or other modification to any provision of this Agreement shall be binding unless in writing and signed by all Parties.

Section 10.2 Section 365(n) of the Bankruptcy Code. All rights and licenses granted under or pursuant to any section of this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code, licenses of rights to "intellectual property" as defined under Section 101(35A) of the U.S. Bankruptcy Code to the extent permitted thereunder. The Parties shall retain and may fully exercise all of their respective rights and elections under the U.S. Bankruptcy Code. Upon the bankruptcy of any Party, the non-bankrupt Party shall further be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property, and such, if not already in its possession, shall be promptly delivered to the non-bankrupt Party, unless the bankrupt Party elects to continue, and continues, to perform all of its obligations under this Agreement.

Section 10.3 Independent Contractors. The relationship between BioAge and Amgen created by this Agreement is solely that of independent contractors. This Agreement does not create any agency, distributorship, employee-employer, partnership, joint venture or similar business relationship between the Parties. Neither Party is a legal representative of the other Party, and neither Party can assume or create any obligation, representation, warranty or guarantee, express or implied, on behalf of the other Party for any purpose whatsoever. Each Party shall use its own discretion and shall have complete and authoritative control over its employees and the details of performing its obligations under this Agreement.

Section 10.4 Governing Law; Jurisdiction. This Agreement and its effect are subject to and shall be construed and enforced in accordance with the law of the State of New York, without regard to its conflicts of laws, except as to any issue which depends upon the validity, scope or enforceability of any Licensed Patent, which issue shall be determined in accordance with the laws of the country in which such patent was issued. Each of the Parties hereby irrevocably and unconditionally consents to submit to the exclusive jurisdiction of the courts of the State of New York for any matter arising out of or relating to this Agreement and the transactions contemplated hereby, and agrees not to commence any litigation relating thereto except in such courts. Each of the Parties hereby irrevocably and unconditionally waives any objection to the laying of venue of any matter arising out of this Agreement or the transactions contemplated hereby in the courts of the State of New York and hereby further irrevocably and unconditionally waives and agrees not to plead or claim in any such court that any such matter brought in any such court has been brought in an inconvenient forum. The Parties agree that a final judgment in any such matter shall be conclusive and may be enforced in other jurisdictions by suits on the judgment or in any other manner provided by law. Any proceeding brought by either Party under this Agreement shall be exclusively conducted in the English language.

Section 10.5 Notice. All notices or communication required or permitted to be given by either Party hereunder shall be deemed sufficiently given if mailed by registered mail or certified mail, return receipt requested, or sent by overnight courier, such as Federal Express, to the other Party at its respective address set forth below or to such other address as one Party shall give notice of to the other from time to time hereunder. Mailed notices shall be deemed to be received on the third (3rd) business day following the date of mailing. Notices sent by overnight courier shall be deemed received the following business day.

If to BioAge:	BioAge Labs, Inc. [*]
If to Amgen:	Amgen Inc. [*]
With a copy to:	[*]

Section 10.6 Compliance With Law; Severability. Nothing in this Agreement shall be construed to require the commission of any act contrary to Law. If any one or more provisions of this Agreement is held to be invalid, illegal or unenforceable, the affected provisions of this Agreement shall be curtailed and limited only to the extent necessary to bring it within the applicable legal requirements and the validity, legality and enforceability of the remaining provisions of this

Agreement shall not in any way be affected or impaired thereby. Notwithstanding anything to the contrary in this Agreement, each Party acknowledges and agrees that (a) the other Party is permitted to publicly disclose information regarding this Agreement to comply with applicable Laws (including without limitation the Physician Payment Sunshine Act and related requirements (collectively, **"Disclosure Laws")** and (b) this information may include without limitation payments, or other transfers of value, made on behalf or at the request of the other Party to physicians, teaching hospitals, and other persons or entities that are the subject of the Disclosure Laws. Each Party agrees to promptly respond to, and cooperate with, the reasonable requests of the other Party regarding collection of information regarding and compliance with Disclosure Laws. For the avoidance of doubt, BioAge will be responsible for reporting payments and other transfers of value **("POTV"),** including the Licensed Compound, that BioAge provides in connection with any clinical study to healthcare providers, teaching hospitals, and/or other persons or entities for whom POTV must be reported in accordance with reporting requirements under applicable Law. Further, each Party acknowledges and agrees that any payments made under this Agreement: (i) represent or, as applicable, will represent the fair market value of the rights granted hereunder, (ii) have been negotiated or, as applicable, will be negotiated at "arm's length", and (iii) have not been and will not be determined in any manner with regard to any implicit or explicit agreement to provide favorable procurement decisions or prescribing practices with regard to Amgen's products, or to the value or volume of any business or referrals generated between the Parties. The Parties further acknowledge and agree that no part of any payments provided under this Agreement is a prohibited payment for recommending or arranging for the referral of business or the ordering of items or services. Additionally, the Parties agree that neither this Agreement or any consideration paid hereunder is contingent upon BioAge's use or purchase of any Amgen products.

Section 10.7 Non-Use of Names. Amgen shall not use the name, trademark, logo, or physical likeness of BioAge or any of its officers, directors or employees, or any adaptation of any of them, in any advertising, promotional or sales literature, without such BioAge's prior written consent. Amgen shall require its Affiliates to comply with the foregoing. BioAge shall not use the name, trademark, logo, or physical likeness of Amgen or any of its officers, directors or employees, or any adaptation of any of them, in any advertising, promotional or sales literature, without Amgen's prior written consent. BioAge shall require its Affiliates and Sublicensees to comply with the foregoing in connection with each such Sublicensee's sublicense.

Section 10.8 Successors and Assigns. Neither this Agreement nor any of the rights or obligations created herein may be assigned by either Party, in whole or in part, without the prior written consent of the other Party, not to be unreasonably withheld or delayed except that either Party shall be free to assign this Agreement (a) to an Affiliate of such Party (for so long as such Affiliate remains an Affiliate) provided that such Party shall remain liable and responsible to the other Party for the performance and observance of all such duties and obligations by such Affiliate, or (b) in connection with any merger, consolidation or sale of such Party or sale of all or substantially all of the assets of the Party that relate to this Agreement (a **"Sale Transaction"),** without the prior consent of the non-assigning Party. This Agreement shall bind and inure to the benefit of the successors and permitted assigns of the Parties hereto. Any assignment of this Agreement in contravention of this Section 10.8 (Successors and Assigns) shall be null and void.

Section 10.9 Sale Transaction or Amgen Acquisition. In the event of (x) a Sale Transaction, or (y) the acquisition by Amgen of all or substantially all of the business of a Third Party (together with any entities that were Affiliates of such Third Party immediately prior to such acquisition, an **"Amgen Acquiree"),** whether by merger, sale of stock, sale of assets or otherwise (an **"Amgen Acquisition"),** intellectual property rights of the acquiring party in a Sale Transaction, if other than one of the Parties to this Agreement (together with any entities that were affiliates of such Third Party immediately prior to such Sale Transaction, a **"Third Party Acquirer"),** or the Amgen Acquiree, as applicable, shall not be included in the technology licensed hereunder or otherwise subject to this Agreement.

Section 10.10 Waivers. A Party's consent to or waiver, express or implied, of any other Party's breach of its obligations hereunder shall not be deemed to be or construed as a consent to or waiver of any other breach of the same or any other obligations of such breaching Party. A Party's failure to complain of any act, or failure to act, by the other Party, to declare the other Party in default, to insist upon the strict performance of any obligation or condition of this Agreement or to exercise any right or remedy consequent upon a breach thereof, no matter how long such failure continues, shall not constitute a waiver by such Party of its rights hereunder, of any such breach, or of any other obligation or condition. A Party's consent in any one instance shall not limit or waive the necessity to obtain such Party's consent in any future instance and in any event no consent or waiver shall be effective for any purpose hereunder unless such consent or waiver is in writing and signed by the Party granting such consent or waiver.

Section 10.11 No Third Party Beneficiaries. Except as expressly provided with respect to Amgen Indemnified Parties and BioAge Indemnified Parties in Article 7 (Indemnification), nothing in this Agreement shall be construed as giving any Person, other than the Parties hereto and their successors and permitted assigns, any right, remedy or claim under or in respect of this Agreement or any provision hereof.

Section 10.12 Headings; Exhibits. Article and Section headings used herein are for convenient reference only, and are not a part of this Agreement. All Exhibits are incorporated herein by this reference.

Section 10.13 Interpretation. Except where the context otherwise requires, wherever used, the singular shall include the plural, the plural the singular, the use of any gender shall be applicable to all genders and the word "or" is used in the inclusive sense (and/or). The term "including" as used herein shall mean including, without limiting the generality of any description preceding such term. The term "will" as used herein means shall. All references to a "business day" or "business days" in this Agreement means any day other than a day which is a Saturday, a Sunday or any day banks are authorized or required to be closed in the United States. The language in all parts of this Agreement shall be deemed to be the language mutually chosen by the Parties. The Parties and their counsel have cooperated in the drafting and preparation of this Agreement, and this Agreement therefore shall not be construed against any Party by virtue of its role as the drafter thereof.

Section 10.14 Equitable Relief. Each Party acknowledges that a breach by it of the provisions of this Agreement may not reasonably or adequately be compensated in damages in an action at law and that such a breach may cause the other Party irreparable injury and damage. By reason thereof, each Party agrees that the other Party is entitled to seek, in addition to any other remedies it may have under this Agreement or otherwise, preliminary and permanent injunctive and other equitable relief to prevent or curtail any breach of this Agreement by the other Party and is otherwise entitled to specific performance of the terms hereof; provided, however, that no specification in this Agreement of a specific legal or equitable remedy will be construed as a waiver or prohibition against the pursuing of other legal or equitable remedies in the event of such a breach.

Section 10.15 Force Majeure. Neither Party shall be held liable or responsible to the other Party, nor be deemed to have defaulted under or breached this Agreement, for failure or delay in fulfilling or performing any term of this Agreement to the extent, and for so long as, such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party, including fire, floods, embargoes, power shortage or failure, acts of war (whether war be declared or not), insurrections, riots, terrorism, civil commotions, strikes, a pandemic (including COVID19 related interruptions), lockouts or other labor disturbances, acts of God, or any acts, omissions, or delays in acting by any governmental authority or the other Party; ***provided, however,*** that the affected Party promptly notifies the other Party in writing (and continues to provide monthly status updates to the other Party for the duration of the effect); and ***provided further, however,*** that the affected Party shall use its commercially reasonable efforts to avoid or remove such causes of non-performance and to mitigate the effect of such occurrence, and shall continue performance with reasonable dispatch whenever such causes are removed. The Parties acknowledge and agree that as of the Execution Date, the activities of both Parties may be interrupted due to the COVID-19 pandemic and, as a result, each Party's performance of some or all of the activities relating to the transfer of Licensed Material and Licensed Know-How may be delayed. Further, as COVID-19 pandemic circumstances evolve, there may be additional delays or other circumstances for either Party that were not initially foreseeable. In light of the foregoing, the Parties agree to discuss in good faith an extension to timelines contemplated in this Agreement, as may be applicable.

Section 10.16 Further Assurances. Each Party shall execute, acknowledge, and deliver such further instructions, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

Section 10.17 Counterparts. This Agreement may be executed in counterparts by a single Party, each of which when taken together shall constitute one and the same agreement, and may be executed through the use of facsimiles or .pdf or other electronically transmitted documents.

[signature page follows]

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the date first set forth above.

BIOAGE LABS, INC.

By: /s/ Kristen Fortney
Name; Kristen Fortney
Title: CEO

AMGEN INC.

By: /s/ David M. Reese
Name: David M. Reese
Title: EVP, Research & Development

By: /s/ Peter H. Griffith
Name: Peter H. Griffith
Title: EVP & Chief Financial Officer

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the date first set forth above.

BIOAGE LABS, INC.

By: /s/ Kristen Fortney
Name; Kristen Fortney
Title: CEO

AMGEN INC.

By: /s/ David M. Reese
Name: David M. Reese
Title: EVP, Research & Development

By: /s/ Peter H. Griffith
Name: Peter H. Griffith
Title: EVP & Chief Financial Officer

EXHIBIT A

LICENSED KNOW-HOW

TECHNOLOGY TRANSFER

[*]

EXHIBIT B

LICENSED PATENTS

[*]

EXHIBIT C

LICENSED COMPOUND

[*]

EXHIBIT D

SUPPLEMENT AL CONFIDENTIALITY AGREEMENT

[*]

EXHIBIT E

DEVELOPMENT PLAN

[*]

EXHIBIT F

DATA SECURITY SCHEDULE

[*]

EXHIBIT G

PLANNED PUBLICATIONS

[*]

EXHIBIT H

Standard contractual clauses for the transfer of personal data from the Community to third countries (controller to controller transfers)

[*]

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [*], HAS BEEN OMITTED BECAUSE IT IS NOT MATERIAL AND IS THE TYPE THAT BIOAGE LABS, INC. TREATS AS PRIVATE OR CONFIDENTIAL.

AMENDMENT NO. 1

TO EXCLUSIVE LICENSE AGREEMENT

This Amendment No. 1 to the Exclusive License Agreement (this "Amendment") effective as of July 9, 2024 (the "Amendment Date"), is entered into between Amgen Inc. ("Amgen"), and BioAge Labs, Inc. ("BioAge").

WHEREAS, the parties previously entered into that certain Exclusive License Agreement dated as of April 5, 2021 (the "Agreement");

WHEREAS, the parties wish to amend the Agreement on the terms and conditions set forth herein.

NOW THEREFORE, capitalized terms not defined in this Amendment shall have the meaning ascribed in the Agreement, and the parties hereby agree as follows:

1. Amendment. Section 1.57 (Licensed Compound definition) is hereby amended to add the following to the end of the definition. [*].

2. Miscellaneous. This Amendment shall be effective for all purposes as of the Amendment Date. Except as expressly modified herein, the Agreement shall continue to remain in full force and effect in accordance with its terms. This Amendment may be executed in counterparts, each of which shall be deemed to be an original and together shall be deemed to be one and the same document.

IN WITNESS WHEREOF, the parties have caused this Amendment to be executed by their respective duly authorized representatives effective as of the Amendment Date.

AMGEN INC.	BIOAGE LABS, INC.
By: _____	By: _____
Name: _____	Name: Kristen Fortney
Title: _____	Title: CEO