Filed Pursuant to Rule 424(b)(4)
Registration No. 333-294690

**Prospectus**

# *39,062,500 Shares*

# *Common Stock*

This is Kailera Therapeutics, Inc.'s initial public offering. We are offering 39,062,500 shares of our common stock.

The public offering price is $16.00 per share. Prior to this offering, there has been no public market for our common stock. Our common stock has been approved for listing on the Nasdaq Global Select Market under the symbol "KLRA."

We are an "emerging growth company" and a "smaller reporting company" under the federal securities laws and are subject to reduced public company disclosure standards. See "Prospectus Summary—Implications of Being an Emerging Growth Company and a Smaller Reporting Company."

| | Per Share | Total |
|---|---|---|
| Public offering price | $ 16.00 | $625,000,000 |
| Underwriting discount and commissions(1) | $ 1.12 | $ 43,750,000 |
| Proceeds to Kailera Therapeutics, Inc., before expenses | $ 14.88 | $581,250,000 |

(1) See the section titled "Underwriting" for additional information regarding underwriting compensation.

We have received non-binding indications of interest from certain of our existing stockholders, including entities affiliated with Bain Capital Private Equity, Bain Capital Life Sciences and Qatar Investment Authority, to purchase up to an aggregate of approximately $225 million in shares of our common stock in this offering at the initial public offering price per share, on the same terms as the other purchasers in this offering. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters could determine to sell more, fewer or no shares to our existing stockholders, and our existing stockholders could determine to purchase more, fewer or no shares in this offering. The underwriters will receive the same underwriting discount and commissions on these shares as they will on any other shares sold to the public in this offering. The number of shares of common stock available for sale to the general public will be reduced to the extent that our existing stockholders purchase shares of common stock in the offering.

We have granted the underwriters an option for a period of 30 days from the date of this prospectus to purchase up to 5,859,375 additional shares of common stock from us at the initial public offering price, less the underwriting discounts and commissions.

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

**Neither the Securities and Exchange Commission nor any other regulatory body 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.**

The underwriters expect to deliver the shares against payment on or about April 20, 2026.

***Joint Book-Running Managers***

**J.P. Morgan** **Jefferies** **Leerink Partners** **TD Cowen** **Evercore ISI**

***Lead Manager***

**William Blair**

**The date of this prospectus is April 16, 2026.**

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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, any amendment or supplement to this prospectus, or in any free writing prospectus prepared by or on behalf of us or to which we have referred you. We and the underwriters take no 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 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 the United States**: Neither we nor 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 in the United States. Persons outside 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 common stock and the distribution of this prospectus outside the United States.

## Basis of presentation

Except where the context otherwise requires or where otherwise indicated, the terms “Kailera,” “we,” “us,” “our,” “our company,” “Company” and “our business” refer to Kailera Therapeutics, Inc. and its wholly owned subsidiaries, Kailera Securities Corporation and Kailera Therapeutics Australia PTY Limited.

The consolidated financial statements include the accounts of Kailera Therapeutics, Inc. Our financial statements have been prepared in accordance with generally accepted accounting principles in the United States, or GAAP. Our fiscal year ends on December 31 of each year. References to 2024 refer to the period from May 8, 2024 (inception) to December 31, 2024. Our most recent fiscal year ended on December 31, 2025.

Certain monetary amounts, percentages and other figures included in this prospectus have been subject to rounding adjustments. Percentage amounts included in this prospectus have not in all cases been calculated on the basis of such rounded figures, but on the basis of such amounts prior to rounding. For this reason, percentage amounts in this prospectus may vary from those obtained by performing the same calculations using the figures in our consolidated financial statements included elsewhere in this prospectus. Certain other amounts that appear in this prospectus may not sum due to rounding.

## Trademarks and tradenames

This prospectus includes our trademarks and trade names, including, without limitation, KAILERA, KAILERA THERAPEUTICS and our logo, which are our property and are protected under applicable intellectual property laws. This prospectus also contains trademarks, trade names and service marks of other companies, which are the property of their respective owners. Solely for convenience, trademarks, trade names and service marks referred to in this prospectus may appear without the ®, ™ or SM symbols, but such references are not intended to indicate, in any way, that we or the applicable owner will not assert, to the fullest extent permitted under applicable law, our or its rights or the right of any applicable licensor to these trademarks, trade names and service marks. We do not intend our use or display of other parties’ trademarks, trade names or service marks to imply, and such use or display should not be construed to imply, a relationship with, or endorsement or sponsorship of us by, these other parties.

## Industry and other market data

This prospectus contains industry, market and competitive position data from our own internal estimates and research as well as industry and general publications and research surveys and studies conducted by independent third parties. Industry publications, studies and surveys generally state that they have been obtained from sources believed to be reliable. Our internal data and estimates are based upon information obtained from trade and business organizations and other contacts in the markets in which we operate and our management’s understanding of industry conditions. Management is responsible for the accuracy of our internal company research and believes such information is reliable and the market definitions are appropriate. The industry in which we operate is subject to a high degree of uncertainty and risk 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 these expressed in the estimates made by the independent third parties and by us.

# Prospectus summary

*This summary highlights selected information and is qualified in its entirety by information contained elsewhere in this prospectus. This summary does not contain all of the information that may be important to you in making your investment decision. You should read this entire prospectus carefully, including the sections titled "Risk factors," "Management's discussion and analysis of financial condition and results of operations" and "Business" and our consolidated financial statements and the related notes included elsewhere in this prospectus, before making an investment decision. Some of the statements in this prospectus constitute forward-looking statements. See "Special note regarding forward-looking statements."*

## Overview

We are an advanced clinical-stage biotechnology company focused on elevating the next era of obesity care by advancing a diversified pipeline to provide options for people living with obesity no matter where they are in their treatment journey. Obesity is a chronic, progressive and debilitating disease that impacts over 1 billion people globally and requires long-term comprehensive treatment. Since obesity is the driving factor for more than 200 comorbidities and represents a significant contributor to increased morbidity and mortality, our vision is to deliver category-leading obesity management medications that give people the power to restore their health and transform their lives. With our obesity-first focus, we have built a diversified pipeline of product candidates specifically designed to address critical needs in the current therapeutic landscape with a lead product candidate that we believe offers the potential for the greatest weight loss.

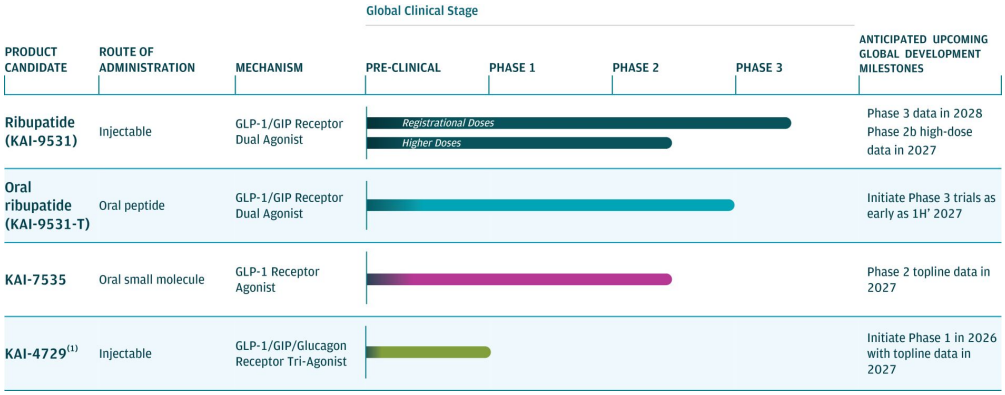
We are rapidly progressing four clinical-stage product candidates, leveraging multiple glucagon-like peptide-1, or GLP-1, based mechanisms of action and routes of administration. Our lead product candidate, ribupatide (also known as KAI-9531), is currently being evaluated in global Phase 3 trials as a once-weekly injectable GLP-1/glucose-dependent insulinotropic polypeptide, or GIP, receptor dual agonist peptide that we believe offers the potential for the greatest weight loss compared to all obesity management medications currently marketed or in development with a tolerability profile that is class-like or better. We are expanding our ribupatide franchise by developing a once-daily oral tablet formulation, oral ribupatide, based on the same peptide as injectable ribupatide, to provide a convenient oral option with the potential for highly differentiated tolerability with compelling weight loss among oral treatments. Additionally, we are advancing a second oral product candidate, KAI-7535, a once-daily small molecule GLP-1 receptor agonist with the potential to improve on the clinical profile of existing oral treatments. Finally, we are developing KAI-4729, a once-weekly injectable GLP-1/GIP/glucagon receptor tri-agonist, that leverages an incremental mechanism to potentially deliver compelling weight loss, improved liver fat reduction and a differentiated tolerability profile. KAI-4729 is based on a different peptide than injectable ribupatide and oral ribupatide.

Obesity is a chronic, complex disease characterized by the accumulation of excessive body fat, resulting in significant negative impacts on health and quality of life. The most severely impacted patient population, people with a body mass index, or BMI, of 35 $kg/m^2$ or greater, which we refer to as a BMI of 35+, represents the fastest growing and largest segment of this population, with half of U.S. adults with obesity expected to have a BMI of 35+ by 2030. While the approvals of GLP-1-based obesity management medications have changed the landscape of obesity management, there remains a critical need for medications offering greater weight loss, especially for those living with a higher BMI. For example, in the SURMOUNT-1 Phase 3 clinical trial, the majority of patients who had a baseline BMI of 35+ and were treated with tirzepatide, the most prescribed weight loss medicine today, were still living with obesity at the end of treatment. Both physicians and patients have identified expected weight loss as a primary treatment goal, with the magnitude of weight reduction serving as

a crucial driver in therapy selection. We believe that injectable treatments will remain foundational for patients needing significant weight reduction. Meanwhile, for patients with a lower BMI, lower incidences of gastrointestinal side effects may be needed to achieve optimal weight loss and treatment persistence, and we believe oral treatments can unlock adoption for those with more modest weight loss needs, while also supporting the chronic treatment journey of those living with higher BMIs.

## Our diversified GLP-1-based pipeline

We are advancing a diversified GLP-1-based pipeline of clinical-stage therapeutic candidates for the treatment of obesity. Our pipeline is informed by decades of experience with GLP-1-based therapies and substantial research efforts and clinical data. Our obesity-first approach seeks to capitalize on and improve upon proven science to advance product candidates which have the potential to maximize weight loss and address other critical needs in the current therapeutic landscape and to provide options, including oral options and alternative mechanisms, for people living with obesity no matter where they are in their treatment journey. We hold exclusive worldwide development and commercialization rights to all our product candidates outside of China, Hong Kong, Macau and Taiwan, or Greater China.




(1) Hengrui is conducting an ongoing Phase 1 clinical trial of HRS-4729 in China.

### *Ribupatide: Potential for the greatest weight loss*

Our lead product candidate, ribupatide (also known as KAI-9531 and being developed by Jiangsu Hengrui Pharmaceuticals Co., Ltd., or Hengrui, our collaboration partner discussed in greater detail below, in Greater China as HRS9531), is a once-weekly injectable GLP-1/GIP receptor dual agonist peptide that we believe offers the potential for a category-leading profile with the greatest weight loss compared to all obesity management medications currently marketed or in development and a tolerability profile that is class-like or better. We are currently evaluating ribupatide in a global Phase 3 clinical program, named the KaiNETIC program, comprised of three Phase 3 trials.

Based on the current clinical data and commercial success of tirzepatide, we believe GLP-1/GIP dual agonism will continue to be the foundational therapy for the treatment of obesity and overweight, with a proven mechanism of action that provides substantial weight loss and a favorable tolerability profile. However, there remains a critical unmet medical need for therapies that provide greater weight loss, especially for the growing population of people living with a BMI of 35+. For example, in the SURMOUNT-1 Phase 3 clinical trial, 68% of

participants who had a baseline BMI of 35+ and were treated with tirzepatide, the most prescribed weight loss medicine today, were still living with obesity at the end of 72 weeks of treatment.

Ribupatide was designed to have a clinical profile superior to tirzepatide, with modified potency on the GLP-1 and GIP receptors and *in vitro* studies demonstrating 3x GLP-1 receptor binding affinity and 0.5x GIP receptor binding affinity compared to tirzepatide, and a half-life of approximately seven days, roughly two days longer than tirzepatide, resulting in improved exposure through the full weekly dosing period. We believe this profile could result in the greatest weight loss compared to all obesity management medications currently marketed or in development with a tolerability profile that is class-like or better. However, we have not conducted head-to-head clinical trials of ribupatide or any of our other product candidates against currently approved products or those in development; all of our product candidates are still in clinical development in the United States, and it will take several years to develop and, if approved, commercialize them; and even if we are successful in obtaining regulatory approval, there can be no guarantee as to our product candidates' ability to outperform other therapies in terms of efficacy or tolerability.

Over 2,500 clinical trial participants have been dosed with ribupatide with treatment out to 52 weeks, including in multiple late-stage clinical trials conducted by Hengrui in China. Based on compelling clinical data evaluating doses up to 6 mg, Hengrui rapidly initiated a Phase 3 trial with 6 mg as the top dose. Concurrently, Hengrui evaluated an 8 mg dose in a Phase 2 trial to explore the potential for greater weight loss. These data have informed the doses being evaluated in our global Phase 3 clinical program discussed below.

With only 12 weeks of treatment at the 8 mg dose, ribupatide reduced weight by a mean of 23.6% from baseline, compared to a 1.8% reduction with placebo, when analyzed using the efficacy estimand, which reflects treatment effect assuming participants adhered to protocol treatment and excludes data collected after premature treatment discontinuations or use of other weight-loss therapies from the analysis. Using the treatment policy estimand, the primary estimand of the trial, which reflects treatment effect including the impact of premature discontinuations or use of other weight-loss therapies, the mean weight reduction was 22.8%, compared to a 1.7% reduction with placebo.

In the 48-week Phase 3 trial evaluating doses up to 6 mg, dose-dependent weight loss was observed at three different dose levels, including up to a mean reduction of 19.2% based on the efficacy estimand and a mean reduction of 17.7% based on the treatment policy estimand at the highest dose level of 6 mg, compared to a mean 1.4% reduction with placebo. Importantly, weight loss did not plateau in either trial, suggesting the potential for greater weight loss with longer treatment duration and higher doses. In both trials, ribupatide was found to be generally well-tolerated with most adverse events, or AEs, being mild or moderate, gastrointestinal, or GI-, related and consistent with the GLP-1-based class. Importantly, both trials showed that treatment-emergent AEs stabilized at doses of 3 mg and above, indicating the potential to continue dosing higher without a corresponding increase in GI-related AEs.

Based on the compelling results of the clinical program to date, we initiated our KaiNETIC global Phase 3 clinical program consisting of three Phase 3 trials to evaluate doses of 4 mg, 6 mg, 8 mg and 10 mg of ribupatide for the treatment of adults living with obesity or overweight. We believe that the range of doses being evaluated will enable personalized treatment to meet patients where they are in their treatment journey.

The first Phase 3 clinical trial, KaiNETIC-1, was initiated in December 2025 and we plan to enroll approximately 2,340 participants with a BMI of 30+ or a BMI of 27+ with a co-morbidity, excluding type 2 diabetes, or T2D. We anticipate reporting topline results from the KaiNETIC-1 trial in 2028. In the second trial, KaiNETIC-2, we plan to enroll 1,156 participants with a BMI of 27+ with T2D. In the third trial, KaiNETIC-3, we plan to enroll 1,200 adults with a BMI of 35+ and no T2D. Participants in these global, double-blind, randomized, placebo-controlled trials

will receive either placebo or ribupatide up to 10 mg administered over a period of 76 weeks. In addition, KaiNETIC-3 will include an arm that will be randomized to open-label 2.4 mg semaglutide. We initiated the global Phase 3 clinical trials of KaiNETIC-2 and -3 in January 2026 and December 2025, respectively, and expect to report topline results in 2028.

To evaluate the potential to achieve greater weight loss with higher doses of ribupatide, we have also initiated a Phase 2b clinical trial to evaluate higher doses of ribupatide in adults living with obesity. The randomized, double-blind, placebo-controlled Phase 2b trial is expected to enroll approximately 250 participants with a BMI of 35+ and no T2D. Participants will receive either placebo or doses up to 20 mg of ribupatide administered over a period of 48 weeks. We initiated the Phase 2b high-dose trial in March 2026 and expect to report topline results from this trial in 2027.

***Oral ribupatide: Potential for franchise expansion with an oral option providing highly differentiated tolerability and compelling weight loss***

We are expanding our ribupatide franchise to include a once-daily oral tablet formulation, oral ribupatide (also known as KAI-9531-T and being developed by Hengrui in Greater China as HRS9531-T). Based on initial Hengrui clinical data, we believe oral ribupatide has the potential for highly differentiated tolerability among oral treatments with compelling weight loss, representing an attractive clinical profile. Because it is an oral version of our extensively studied injectable ribupatide product candidate, we believe oral ribupatide may also have certain regulatory, development and commercial advantages, including increased speed to market and cost efficiencies.

In a Phase 2 clinical trial conducted by Hengrui in China evaluating doses up to 50 mg of oral ribupatide in 166 adults with obesity over 26 weeks, participants receiving oral ribupatide demonstrated a mean weight reduction from baseline of up to 12.1% at 26 weeks based on the efficacy estimand and up to 11.9% based on the treatment policy estimand, in each case with no observed plateau in weight loss, compared to 2.3% with placebo. Rates of vomiting (2.4% at 10 mg, 11.4% at 25 mg and 7.5% at 50 mg) and nausea (11.9% at 10 mg, 22.7% at 25 mg and 20.0% at 50 mg) were low, which we believe illustrates the potential of oral ribupatide to deliver highly differentiated tolerability with compelling weight loss among oral obesity treatments. Subject to discussions with the FDA and other regulatory agencies, we plan to initiate global Phase 3 trials of oral ribupatide as early as the first half of 2027, while Hengrui plans to advance oral ribupatide to a Phase 3 trial in China.

A next-generation formulation of oral ribupatide with enhanced bioavailability is also being evaluated in a Phase 1 clinical trial conducted by Hengrui in China.

***KAI-7535: Potential for competitive clinical profile in an oral small molecule***

We are advancing KAI-7535 (also being developed by Hengrui in Greater China as HRS-7535) as a once-daily oral small molecule GLP-1 receptor agonist with the potential to improve on the clinical profile of existing oral treatments. We believe that oral small molecule treatments will play an important role in the treatment of obesity worldwide driven by their convenience and improved scalability. As part of our approach to develop a pipeline that can benefit patients throughout their weight loss journey, we believe that KAI-7535 has the potential to offer a competitive weight loss and tolerability profile compared to other oral GLP-1 therapies.

In a Phase 2 clinical trial conducted by Hengrui in China evaluating doses ranging from 30 mg to 180 mg, treatment with 180 mg of HRS-7535 demonstrated a 9.5% (8.1% placebo-adjusted) mean weight reduction from baseline at Week 36 based on the efficacy estimand. Based on a *post-hoc*, exploratory analysis of patients with detectable drug concentrations at all post-baseline visits, treatment with 180 mg resulted in a 15.0% mean

weight reduction from baseline at Week 36. Treatment-emergent AEs reported in this trial were primarily mild or moderate in severity, and mainly GI-related, which is consistent with the oral GLP-1 class.

A Phase 3 clinical trial conducted by Hengrui is ongoing evaluating doses of 180 mg of HRS-7535, with two different titration schedules, in 556 adults with obesity or overweight in China over 50 weeks. Topline results are anticipated in 2026.

We initiated a double-blind, randomized, placebo-controlled Phase 2 trial of KAI-7535 in April 2026. This trial is expected to enroll approximately 320 participants with a BMI of 30+ or a BMI of 27+ with at least one co-morbidity (which may include T2D). Participants will receive either placebo or doses up to 360 mg of KAI-7535 administered over a period of 44 weeks. We expect to report topline results from this trial in 2027.

***KAI-4729: Potential for compelling weight loss, improved liver fat reduction and a differentiated tolerability profile***

We are advancing KAI-4729 (also being developed by Hengrui in Greater China as HRS-4729), a once-weekly injectable GLP-1/GIP/glucagon receptor tri-agonist, which was designed to improve upon existing tri-agonist profiles. We believe KAI-4729's combination of the proven GLP-1/GIP mechanism with the addition of glucagon agonism has the potential to result in greater weight reduction than currently marketed treatments with improved liver fat reduction and a differentiated efficacy and tolerability profile.

KAI-4729 was designed to have augmented potency on the GLP-1 receptor compared to reference drug retatrutide, a GLP-1/GIP/glucagon receptor tri-agonist in development by Eli Lilly. *In vitro* cell-based receptor potency data demonstrated 1.6x higher GLP-1 receptor binding affinity of KAI-4729 compared to reference drug retatrutide and similar potency on the GIP and glucagon receptors. This evaluation was conducted in an *in vitro* human cell-based receptor potency study and KAI-4729 may perform differently in *in vivo* studies. Additionally, results from testing of KAI-4729 compared to reference drug retatrutide in a nonclinical animal model of obesity showed the potential for greater weight loss.

A Phase 1 single ascending dose, or SAD, and multiple ascending dose, or MAD, trial of HRS-4729 conducted by Hengrui is ongoing in China.

We intend to initiate a Phase 1 clinical trial of KAI-4729 in 2026 and expect to report topline results from this trial in 2027.

## Our collaboration with Hengrui

Our pipeline was in-licensed through a strategic collaboration with Hengrui, a leading global innovative pharmaceutical company with robust research and development capabilities. We entered into a license and collaboration agreement with Hengrui which provides us with exclusive rights to the development and commercialization of our product candidates outside of Greater China, with Hengrui responsible for development and commercialization within Greater China. This collaboration provides us with access to broad and deep clinical data sets that inform and accelerate our global development plans based on data relating to dosing, titration, and patient populations enabling us to advance these global programs in a capital efficient manner. Moreover, Hengrui continues to generate additional data in obesity-related conditions that allow us to strategically evaluate value-creating opportunities for our product candidates. In addition to the four clinical candidates in our portfolio, we also have the right of first refusal on certain additional metabolic assets in development by Hengrui.

## Our team

Our leadership team and board of directors have significant experience discovering, developing and commercializing therapies, particularly for metabolic diseases. We believe the team we assembled has the experience needed to efficiently and effectively advance our pipeline, as well as to identify and capitalize upon the future opportunities which will arise in this large, growing market.

- **Ron Renaud**, **President and Chief Executive Officer** is a biotech leader with over 25 years of experience and a proven track record of leading companies through strategic growth, innovation and industry-defining milestones. Previous roles include:
    - President and Chief Executive Officer of Cerevel Therapeutics, prior to its acquisition by AbbVie
    - Chairman and Chief Executive Officer of Translate Bio, prior to its acquisition by Sanofi
    - Chief Financial Officer, Chief Business Officer and ultimately President and Chief Executive Officer of Idenix, prior to its acquisition by Merck
- **Scott Wasserman, M.D.**, **Chief Medical Officer** is a drug developer and cardiologist with more than two decades of experience driving global therapeutic innovation, regulatory strategy and successful drug approvals. Previous roles include:
    - Venture Partner at Frazier Life Sciences
    - Chief Executive Officer and co-founder of Latigo Biotherapeutics
    - Vice President, Global Development Therapeutic Area Head for Bone, Cardiovascular, Metabolic and Neuroscience at Amgen
- **Jamie Coleman**, **Chief Commercial Officer** is a commercial leader with nearly 25 years of experience driving global brand strategy, market leadership and revenue growth. Previous roles include:
    - Vice President, U.S. Brand Leader for Zepbound at Eli Lilly
    - Vice President, U.S. Brand Leader for Trulicity at Eli Lilly
- **Paul Burgess**, **Chief Operating Officer and Chief Business Officer** is a life sciences executive with over two decades of experience driving strategic growth, operations and cross-functional leadership. Previous roles include:
    - Chief Business Development and Strategic Operations Officer at Cerevel Therapeutics
    - Chief Operating Officer and Chief Legal Officer at Translate Bio
- **Douglas Pagán, Chief Financial Officer** is a financial executive with over two decades of experience driving organizational growth, operational excellence and long-term value creation. Previous roles include:
    - Chief Financial Officer and Chief Operating Officer at Atalanta Therapeutics
    - Chief Financial Officer and Chief Operating Officer at Jnana Therapeutics, prior to its acquisition by Otsuka Pharmaceutical
    - Chief Financial Officer at Dicerna Pharmaceuticals, prior to its acquisition by Novo Nordisk

- **Scott Akamine**, **Chief Legal Officer** is a legal executive with deep expertise in navigating complex regulatory and competitive environments to support strategic growth and corporate leadership. Previous roles include:
    - Chief Legal Officer and Corporate Secretary at Cerevel Therapeutics
    - General Counsel and Corporate Secretary of AEON Biopharma
- **Paula Cloghessy**, **Chief People Officer** is a human resources leader with over 20 years of experience building people-first cultures and guiding companies through transformative growth. Previous roles include:
    - Executive Vice President, Chief People Officer at Seres Therapeutics
    - Chief People Officer at Translate Bio

Since our inception, we have raised $900 million in proceeds from leading life science investors, including Bain Capital Life Sciences, Bain Capital Private Equity, RTW Investments, Atlas Venture and Canada Pension Plan Investment Board (CPP Investments). Prospective investors should not rely on the investment decisions of our existing investors, as these investors may have different risk tolerances and purchased their shares in financings that were conducted at a significant discount to the price offered to the public in this offering. See “Certain relationships and related party transactions” for more information.

## Our strategy

- Advance our lead product candidate, ribupatide, through currently ongoing global Phase 3 clinical development with the goal of demonstrating the greatest weight loss for people living with obesity.
- Accelerate clinical development of our oral therapies, oral ribupatide and KAI-7535, and our injectable tri-agonist, KAI-4729, to address critical needs in the current obesity landscape.
- Combine our team’s extensive drug development track record with Hengrui’s broad and deep clinical data to inform and accelerate our development strategy.
- Establish broad commercial reach and manufacturing scale to bring differentiated obesity treatments to market.

## Summary risk factors

There are a number of risks that you should understand before making an investment decision regarding this offering. You should carefully consider all of the information in this prospectus, including risks and uncertainties described in the sections titled “Management’s discussion and analysis of financial condition and results of operations” and “Risk factors,” before making a decision to invest in our common stock. If any of these risks actually occur, it could have a material adverse effect on our business, financial condition, and results of operations. In such case, the trading price of our common stock would likely decline, and you could lose all or part of your investment. These risks include, but are not limited to, the following:

- We are a clinical-stage biotechnology company with a limited operating history. We have incurred significant financial losses since our inception and anticipate that we will continue to incur significant financial losses for the foreseeable future.
- We have not generated any revenues to date and may never generate any revenue or become profitable or, if we achieve profitability, we may not be able to sustain it.

- Even if this offering is successful, we will require substantial additional capital to finance our operations, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our development programs or commercialization efforts.
- Raising additional capital 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.
- We depend heavily on the success of ribupatide and our other product candidates. If we are unable to successfully develop or commercialize ribupatide or any other product candidates, or experience significant delays in doing so, we may continue to incur significant financial losses.
- Clinical and nonclinical development involves a lengthy and expensive process with an uncertain outcome, and the results of prior clinical trials and studies involving our product candidates are not necessarily predictive of our future results. Our product candidates may not show favorable results in nonclinical studies or clinical trials or receive regulatory approval on a timely basis, if at all.
- Interim, topline and preliminary data from our clinical trials and nonclinical studies that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.
- We may find it difficult to enroll patients in our clinical trials. If we encounter difficulties or delays enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.
- Use of any of our current or future product candidates could be associated with side effects, adverse events or other properties or safety risks, which could delay or preclude regulatory approval, cause us to suspend or discontinue clinical trials, abandon any of our current or future product candidates, limit the commercial profile of an approved label or result in other significant negative consequences that could severely harm our business, financial condition, results of operations and prospects.
- We currently, and may in the future, conduct certain of our clinical trials for our product candidates outside of the United States. However, the FDA and foreign regulatory authorities may not accept data from such trials, which could materially harm our business.
- Our business is subject to the risks associated with having a collaboration partner located in China.
- If our product candidates are ultimately regulated as biologics rather than as drugs, we would be required to pursue approval under a different statutory framework than our current plans contemplate, which could delay development, increase costs, alter market exclusivity and competition dynamics, and adversely affect our business.
- We depend on our license agreement with, and the comprehensiveness of the intellectual property licensed from, Hengrui. Termination of the Hengrui License Agreement, and issues related to intellectual property we license from Hengrui, would have a material adverse effect on our business.
- We are dependent on Hengrui having accurately generated, collected, interpreted and reported data from certain nonclinical studies and clinical trials that were previously conducted for our product candidates.
- We rely on third parties to conduct our clinical trials and nonclinical studies. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements, or meet expected deadlines, any of our current or future product candidates and our ability to seek or obtain regulatory approval for or commercialize any of our current or future product candidates may be delayed.

- We rely on the use of third parties, including Hengrui, to manufacture our product candidates, which may increase the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable time and cost, which could delay, prevent or impair our development or commercialization efforts.
- We face significant competition from entities that have made substantial investments into developing novel treatments for patients with obesity, including large pharmaceutical companies with approved therapies in our current indications, and biopharmaceutical, specialty pharmaceutical and biotechnology companies developing novel treatments and technology platforms.
- The commercial success of any of our current or future product candidates will depend upon the degree of market acceptance of such product candidates by physicians, patients, healthcare payors and others in the medical community.
- If we or our current or future licensors are unable to obtain, maintain, defend and enforce patent or other intellectual property protection for any of our current or future product candidates or technology, or if the scope of the patent or other intellectual property protection obtained is not sufficiently broad, our competitors or other third parties could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize any of our current or future product candidates may be adversely affected.
- The trading price of the shares of our common stock could be highly volatile, and purchasers of our common stock could incur substantial losses.

## Implications of being an emerging growth company and a smaller reporting company

We are an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act of 2012, as amended, or the JOBS Act. An “emerging growth company” may take advantage of reduced reporting requirements that are otherwise applicable to public companies. These provisions include, but are not limited to:

- the option to present only two years of audited financial statements and only two years of related “Management’s discussion and analysis of financial condition and results of operations” 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, or the Sarbanes-Oxley Act;
- an exemption from compliance with the requirements of the Public Company Accounting Oversight Board regarding the communication of critical audit matters in the auditor’s report on the consolidated financial statements;
- reduced disclosure obligations regarding executive compensation 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 may take advantage of these provisions until the last day of our fiscal year following the fifth anniversary of the completion of this offering. However, if any of the following events occur prior to the end of such five-year period, (i) our annual gross revenue exceeds $1.235 billion, (ii) we issue more than $1.0 billion of non-convertible debt in any three-year period, or (iii) we become a “large accelerated filer” (as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended, or the Exchange Act), we will cease to be an emerging growth

company prior to the end of such five-year period. We will be deemed to be a “large accelerated filer” at such time that we (a) have an aggregate worldwide market value of common equity securities held by non-affiliates of $700.0 million or more as of the last business day of our most recently completed second fiscal quarter, (b) have been required to file annual and quarterly reports under the Exchange Act, for a period of at least 12 months, and (c) have filed at least one annual report pursuant to the Exchange Act. Even after we no longer qualify as an emerging growth company, we may still qualify as a “smaller reporting company,” which would allow us to take advantage of many of the same exemptions from disclosure requirements including reduced disclosure obligations regarding executive compensation in this prospectus and our periodic reports and proxy statements.

We have elected to take advantage of certain of the reduced disclosure obligations in the registration statement of which this prospectus forms 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. In particular, we have elected to use the extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date 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 consolidated financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates. If we were to subsequently elect instead to comply with these public company effective dates, such election would be irrevocable pursuant to the JOBS Act.

We are also a “smaller reporting company,” meaning that the market value of our shares 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 was 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 shares of our common 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 shares of our common 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. We may continue to be a smaller reporting company until the end of the fiscal year following the determination that we no longer meet the requirements necessary to be considered a smaller reporting company.

## Indications of interest

We have received non-binding indications of interest from certain of our existing stockholders, including entities affiliated with Bain Capital Private Equity, Bain Capital Life Sciences and Qatar Investment Authority, to purchase up to an aggregate of approximately $225 million in shares of our common stock in this offering at the initial public offering price per share, on the same terms as the other purchasers in this offering. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters could determine to sell more, fewer or no shares to our existing stockholders, and our existing stockholders could determine to purchase more, fewer or no shares in this offering. The underwriters will receive the same underwriting discount and commissions on these shares as they will on any other shares sold to the public in this offering. The number of shares of common stock available for sale to the general public will be reduced to the extent that our existing stockholders purchase shares of common stock in the offering.

## Corporate information

We were originally incorporated under the laws of the State of Delaware on May 8, 2024 under the name Hercules CM Newco, Inc. We changed our name to Kailera Therapeutics, Inc. on August 22, 2024. Our principal executive offices are located at 180 Third Avenue, 4th Floor, Waltham, Massachusetts 02451 and our telephone number is (781) 317-0290. Our website address is *www.kailera.com*. The information contained in, or accessible through, our website does not constitute a part of this prospectus. We have included our website address in this prospectus solely as an inactive textual reference.

## Channels for disclosure of information

Investors, the media and others should note that, following the effectiveness of the registration statement of which this prospectus forms a part, we intend to announce material information to the public through filings with the SEC, the investor relations page on our website (*www.kailera.com*), presentations on our website, press releases, public conference calls and webcasts.

The information disclosed by the foregoing channels could be deemed to be material information. As such, we encourage investors, the media and others to follow the channels listed above and to review the information disclosed through such channels.

Any updates to the list of disclosure channels through which we will announce information will be posted on the investor relations page on our website. The information contained in, or accessible through, our website does not constitute a part of this prospectus. We have included our website address in this prospectus solely as an inactive textual reference.

## The offering

| | |
|---|---|
| **Common stock offered by us** | 39,062,500 shares. |
| **Option to purchase additional shares** | We have granted the underwriters an option for a period of 30 days from the date of this prospectus to purchase up to 5,859,375 additional shares of our common stock from us at the initial public offering price, less the underwriting discounts and commissions. |
| **Common stock to be outstanding immediately after this offering** | 123,677,939 shares (or 129,537,314 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 $575.0 million (or approximately $662.1 million if the underwriters exercise their option to purchase additional shares of our common stock in full), based on the initial public offering price of $16.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.<br><br>We intend to use the net proceeds of this offering to fund the development of ribupatide, oral ribupatide, KAI-7535, and the remainder to fund other research and development activities, including development of KAI-4729, and 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 carefully read the section titled “Risk factors” and the other information included in this prospectus for a discussion of factors you should consider carefully before deciding to invest in our common stock. |
| **Nasdaq Global Select Market symbol** | “KLRA” |

The number of shares of our common stock to be outstanding after this offering is based on 84,615,439 shares of our common stock outstanding as of December 31, 2025, after giving effect to the conversion of all outstanding shares of our convertible preferred stock into 84,596,391 shares of our common stock upon the closing of this offering, and excludes:

- 13,470,409 shares of our common stock issuable upon the exercise of outstanding stock options granted under the Kailera Therapeutics, Inc. 2024 Equity Incentive Plan, or the 2024 Plan, as of December 31, 2025, at a weighted average exercise price of $6.20 per share;
- 1,572,649 shares of our common stock issuable upon the exercise of outstanding options granted under the 2024 Plan subsequent to December 31, 2025, at a weighted average exercise price of $10.65 per share;
- 4,142,000 shares of our common stock issuable upon the exercise of stock options granted in connection with this offering, or the IPO Grants, under our 2026 Incentive Award Plan, or the 2026 Plan, which became

effective in connection with this offering, to certain of our executive officers, directors and employees, at an exercise price per share equal to the initial public offering price in this offering;

- 14,011,037 shares of our common stock reserved for future issuance under the 2026 Plan (which number includes the IPO Grants), plus any automatic increases in the number of shares reserved for future issuance pursuant to the terms of the 2026 Plan; and
- 1,295,482 shares of our common stock reserved for future issuance under our 2026 Employee Stock Purchase Plan, or the ESPP, plus any automatic increases in the number of shares reserved for future issuance pursuant to the terms of the ESPP.

Unless otherwise indicated or the context otherwise requires, this prospectus reflects and assumes the following:

- the conversion of all outstanding shares of our preferred stock into 84,596,391 shares of our common stock upon the closing of this offering;
- no exercise of the outstanding stock options described above;
- no exercise by the underwriters of their option to purchase additional shares of our common stock; and
- the filing and effectiveness of our amended and restated certificate of incorporation, which will occur immediately after the completion of this offering, the form of which is filed as an exhibit to the registration statement of which this prospectus is a part.

## Summary consolidated financial data

The following tables set forth our summary financial data as of, and for the periods ended on, the dates indicated. We have derived the statements of operations data for the period from May 8, 2024 (inception) to December 31, 2024 and for the year ended December 31, 2025 and the summary balance sheet data as of December 31, 2025 from our audited financial statements included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results that should be expected for any future period.

You should read the following summary financial data together with the more detailed information contained in the section titled "Management's discussion and analysis of financial condition and results of operations" and our financial statements and the related notes included elsewhere in this prospectus.

| (in thousands) | Period from May 8, 2024 (date of inception) to December 31, 2024 | Year ended December 31, 2025 |
|---|---|---|
| **Statements of operations and comprehensive loss data:** | | |
| Operating expenses: | | |
| Research and development | $ 6,975 | $ 109,113 |
| Acquired in-process research and development as part of the acquisition of the Hengrui License | 214,070 | — |
| General and administrative | 9,371 | 49,227 |
| Total operating expenses | 230,416 | 158,340 |
| Loss from operations | (230,416) | (158,340) |
| Other income | | |
| Interest income | 2,508 | 11,048 |
| Other income (expense), net | 8,195 | (1,663) |
| Total other income | 10,703 | 9,385 |
| Net loss | $ (219,713) | $ (148,955) |
| Other comprehensive income | | |
| Unrealized gain | — | 229 |
| Comprehensive loss | $ (219,713) | $ (148,726) |
| Net loss per common share attributable to common stockholders—basic and diluted(1) | $ (219,713) | $ (949) |
| Weighted-average common stock outstanding—basic and diluted | 1 | 157 |
| Pro forma net loss per common share attributable to common stockholders—basic and diluted (unaudited)(2) | | $ (3.05) |
| Pro forma weighted-average common stock outstanding—basic and diluted (unaudited)(2) | | 48,830 |

(1) See Note 12 to our audited financial statements included elsewhere in this prospectus for an explanation of the method used to calculate basic and diluted net loss per common share.

(2) Unaudited pro forma net loss per common share attributable to common stockholders, basic and diluted, is calculated giving effect to the conversion of all outstanding shares of our convertible preferred stock into shares of our common stock. Unaudited pro forma net loss per share attributable to common stockholders does not include the shares expected to be sold and related proceeds to be received in this offering. Unaudited pro forma net loss per share attributable to common stockholders for the year ended December 31, 2025 was calculated using the weighted-average number of shares of common stock outstanding, including the pro forma effect of the conversion of all outstanding shares of our convertible preferred stock into 84,596,391 shares of our common stock, as if such conversion had occurred at the beginning of the period, or their issuance dates, if later.

| (in thousands) | As of December 31, 2025 | | |
|---|---|---|---|
| | Actual | Pro forma(2) | Pro forma as adjusted(3) |
| **Balance Sheet Data:** | | | |
| Cash and cash equivalents | $ 160,267 | $ 160,267 | $ 735,217 |
| Marketable securities | 385,789 | 385,789 | 385,789 |
| Working capital(1) | 511,132 | 511,132 | 1,086,082 |
| Long-term marketable securities | 106,672 | 106,672 | 106,672 |
| Total assets | 692,294 | 692,294 | 1,267,244 |
| Total liabilities | 56,388 | 56,388 | 56,388 |
| Convertible preferred stock | 992,364 | — | — |
| Additional paid-in capital | 11,981 | 1,004,345 | 1,579,295 |
| Accumulated deficit | (368,668) | (368,668) | (368,668) |
| Total stockholders' (deficit) equity | (356,458) | 635,906 | 1,210,856 |

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

(2) The pro forma balance sheet data gives effect to (i) the conversion of all outstanding shares of our preferred stock into an aggregate of 84,596,391 shares of our common stock upon the closing of this offering and (ii) the filing and effectiveness of our amended and restated certificate of incorporation.

(3) Reflects the pro forma adjustments described in footnote (2) and the issuance and sale of 39,062,500 shares of our common stock in this offering at the initial public offering price of $16.00 per share, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

# Risk factors

*Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below and the other information in this prospectus, including our financial statements and the related notes and the section titled "Management's discussion and analysis of financial condition and results of operations," before making an investment in our common stock. Our business, financial condition, results of operations, or prospects could be materially and adversely affected if any of these risks occurs, and as a result, the market price of our common stock could decline and you could lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operation. This prospectus also contains forward-looking statements that involve risks and uncertainties. See "Special note regarding forward-looking statements." Our actual results could differ materially and adversely from those anticipated in these forward-looking statements as a result of certain factors, including those set forth below.*

## Risks Related to Our Limited Operating History, Financial Position and Capital Requirements

***We are a clinical-stage biotechnology company with a limited operating history. We have incurred significant financial losses since our inception and anticipate that we will continue to incur significant financial losses for the foreseeable future.***

We are a clinical-stage biotechnology company with a limited operating history. We were formed in May 2024 and our operations to date have been limited to pre-commercial activities. All of our current product candidates were initially discovered and initially developed for the Chinese Market by Jiangsu Hengrui Pharmaceuticals Co., Ltd., or Hengrui, which we licensed pursuant to a license and collaboration agreement with Hengrui, or the Hengrui License Agreement, shortly after our formation. We have not yet demonstrated an ability to complete large-scale clinical trials, obtain regulatory approvals, generate revenues, manufacture any product on a commercial scale, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization.

To date, we have focused primarily on organizing and staffing our company, business planning, establishing our intellectual property portfolio, raising capital, conducting nonclinical studies and, more recently, clinical trials, and providing general and administrative support for these operations. We have no products approved for commercial sale and have not generated any revenue from product sales to date.

Since our inception, we have not generated revenue from any sources, including from product sales, are not profitable and have incurred significant operating losses and negative cash flows from our operations. Net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital. Our net losses totaled $149.0 million and $219.7 million for the year ended December 31, 2025 and the period from May 8, 2024 (inception) to December 31, 2024, respectively. As of December 31, 2025 and December 31, 2024, we had an accumulated deficit of $368.7 million and $219.7 million, respectively. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of, and seek regulatory approvals for, our product candidates.

We anticipate that our expenses will increase substantially if, and as, we:

- advance global clinical trials for ribupatide and oral ribupatide;
- continue the development of our other product candidates, including an ongoing Phase 2 clinical trial for KAI-7535 and initiating a Phase 1 trial for KAI-4729;

- advance our manufacturing strategy to support global scale and long-term continuity;
- seek to in-license or acquire additional product candidates and technologies;
- seek regulatory and marketing approvals for any product candidates that successfully complete clinical trials, if any;
- hire and retain additional personnel, such as clinical, quality control, commercial and scientific personnel;
- establish a sales, marketing and distribution infrastructure to commercialize any product candidates for which we may obtain marketing approval;
- advance our earlier-stage product candidates into clinical development;
- expand our infrastructure and facilities to accommodate our growing employee base;
- maintain, expand and protect our intellectual property portfolio;
- make milestone, royalty or other payments due under the Hengrui License Agreement and any future license or collaboration agreements;
- make milestone, royalty, interest or other payments due under any future financing or other arrangements with third parties; and
- add operational, legal, compliance, financial and management information systems and personnel to support our operations as a public company.

Pharmaceutical product development entails substantial upfront capital expenditures and significant risks that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval, secure market access and reimbursement and become commercially viable, and therefore any investment in us is highly speculative. Accordingly, before making an investment in us, you should consider our prospects, factoring in the costs, uncertainties, delays and difficulties frequently encountered by clinical-stage biotechnology companies such as ours. Any predictions you make about our future success or viability may not be as accurate as they would otherwise be if we had a longer operating history or a history of successfully developing and commercializing pharmaceutical products.

As a young business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will need to transition at some point from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

In addition, our expenses could increase beyond our expectations if we are required by the U.S. Food and Drug Administration, or FDA, or other regulatory authorities to perform clinical trials in addition to those that we currently expect, or if there are any delays in establishing appropriate manufacturing arrangements for, or in completing, our clinical trials or the development of any of our product candidates.

***We have not generated any revenues to date and may never generate any revenue or become profitable or, if we achieve profitability, we may not be able to sustain it.***

To generate revenue and 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 and obtaining regulatory approval for one or more of our current or future product candidates, and manufacturing, marketing, and selling any products for which we may obtain regulatory approval. We are in the preliminary stages of only a few of these activities. We may never succeed in these activities and, even if we do, we may never generate

revenue that is significant enough to achieve profitability. In addition, we have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the pharmaceutical industry. Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve 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 a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our development programs or commercialization efforts.***

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts to continue the clinical and nonclinical development of our product candidates, particularly given the capital-intensive nature of obesity clinical trials. We will need to raise additional capital to complete our currently planned clinical trials and any future clinical trials. Other unanticipated costs may arise in the course of our development efforts. If we are able to gain marketing approval for product candidates that we develop, we will require significant additional amounts of funding in order to launch and commercialize such product candidates and will also be required to make certain milestone and royalty payments under the Hengrui License Agreement. We cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of any product candidate we develop, and we may need substantial additional funding to complete the development and commercialization of our product candidates.

As of December 31, 2025, we had $652.7 million in cash, cash equivalents and marketable securities. Based on our current business plans, we believe that the net proceeds from this offering, together with our existing cash, cash equivalents and marketable securities, will be sufficient to fund our operating expenses and capital expenditure requirements into the second quarter of 2028. 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, requiring us to seek additional funds sooner than planned, through public or private equity or debt financings or other sources, such as strategic collaborations. Our failure to raise capital or enter into such other arrangements when needed would have a negative impact on our financial condition and could force us to delay, limit, reduce or terminate clinical trials, our research and development programs or other operations, or lead us to grant rights to third parties to develop and market product candidates that we would otherwise prefer to develop and market ourselves. In addition, we may seek additional capital opportunistically due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. Attempting to secure additional financing may divert our management from our day-to-day activities. See “Management’s discussion and analysis of financial condition and results of operations—Liquidity and capital resources.”

Our future capital requirements will depend on, and could increase significantly because of many factors including:

- the scope, progress, results and costs of researching and developing our current product candidates, as well as other additional product candidates we may develop and pursue in the future;
- the timing of, and the costs involved in, obtaining marketing approvals for our product candidates and any other additional product candidates we may develop and pursue in the future;

- the number of future product candidates that we may pursue and their development requirements;
- subject to receipt of regulatory approval, the costs of commercialization activities for our product candidates, to the extent such costs are not the responsibility of any future collaborators, including the costs and timing of establishing product sales, marketing, distribution and manufacturing capabilities;
- subject to receipt of regulatory approval, revenue, if any, received from commercial sales of our product candidates or any other additional product candidates we may develop and pursue in the future;
- the achievement of milestones that trigger payments to Hengrui under the Hengrui License Agreement;
- the royalty payments due to Hengrui under the Hengrui License Agreement;
- the extent to which we license or acquire rights to other products, product candidates or technologies;
- our ability to establish collaboration arrangements for the development of our product candidates on favorable terms, if at all;
- our headcount growth and associated costs as we expand our research and development and market development and pre-commercial planning activities;
- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights, including enforcing and defending intellectual property related claims; and
- the costs of operating as a public company.

We cannot be certain that additional funding will be available on acceptable terms, or at all. For instance, the trading prices for other biopharmaceutical companies have been highly volatile. We may face difficulties raising capital through sales of our equity or debt securities or such sales may be on unfavorable terms. Similarly, adverse market or macroeconomic conditions or market volatility resulting from global economic developments, political unrest, high inflation, rising interest rates, future public health epidemics or other factors, could materially and adversely affect our ability to consummate an equity or debt financing on favorable terms, or at all.

Furthermore, upon the closing of this offering, we expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we will be forced to delay, reduce, or eliminate programs, and may be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition, results of operations and prospects.

***Raising additional capital 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.***

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations through a combination of equity offerings, debt financings, royalty financings or other capital sources, including potential future collaborations, licenses, or other similar arrangements. 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, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences and anti-dilution protections that could adversely affect your rights as a stockholder. Debt financing and 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, that could adversely impact our ability to conduct our business. If we raise

additional funds through government and other third-party funding, royalty financings, collaboration agreements, strategic alliances, licensing arrangements or marketing and distribution arrangements, we may have to relinquish valuable rights to our future revenue streams, research programs or drug candidates, or grant licenses on terms that may not be favorable to us. We do not currently have any committed external source of funds. 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 products or product candidates that we would otherwise prefer to develop and market ourselves, obtain funds through arrangements with collaborators on terms unfavorable to us or pursue other strategies, all of which could adversely affect your holdings or you as a stockholder.

***Our ability to use net operating loss carryforwards and other tax attributes may be limited in connection with this offering or other ownership changes.***

We have incurred substantial losses during our history, do not expect to become profitable in the near future and may never achieve profitability. As of December 31, 2025, we had $54.6 million in gross U.S. federal net operating loss, or NOL, carryforwards and $40.3 million in gross state NOL carryforwards, which may be available to offset our future taxable income, if any. Our NOL carryforwards and other tax attributes are subject to expiration, review and possible adjustment by the Internal Revenue Service, or IRS, and state tax authorities.

In addition, under Section 382 of the U.S. Internal Revenue Code of 1986, as amended, or the Code, our federal NOL carryforwards may be or become subject to an annual limitation in the event we have had or have in the future an “ownership change.” For these purposes, an “ownership change” generally occurs if one or more stockholders or groups of stockholders who own at least 5% of a company’s stock increase their ownership by more than 50 percentage points over their lowest ownership percentage within a rolling three-year period. Similar rules may apply under state tax laws. Although we believe there have been one or more ownership changes resulting from past transactions, we have not determined the amount of the cumulative change in our ownership resulting from this offering or other transactions, or any resulting limitations on our ability to utilize our NOL carryforwards and other tax attributes. However, we believe that our ability to utilize our NOL carryforwards and other tax attributes to offset future taxable income or tax liabilities may be limited as a result of ownership changes, including potential changes in connection with this offering. If we earn taxable income, such limitations could result in increased future income tax liability to us and our future cash flows could be adversely affected.

We have recorded a full valuation allowance related to our NOL carryforwards and other deferred tax assets due to the uncertainty of the ultimate realization of the future benefits of those assets.

## Risks Related to the Development and Regulatory Approval of Our Product Candidates

***We depend heavily on the success of ribupatide and our other product candidates. If we are unable to successfully develop or commercialize ribupatide or any other product candidates, or experience significant delays in doing so, we may continue to incur significant financial losses.***

We have invested, and plan to continue to invest, a significant portion of our efforts and financial resources in the development of ribupatide, which is currently in a Phase 3 program. Our ability to generate product revenues, which may not occur for several years, if ever, will depend heavily on the successful development and commercialization of ribupatide and our other product candidates. The success of our product candidates depends on a number of factors, including, but not limited to, the following:

- successful patient enrollment in, and completion, of global clinical trials;
- our ability to demonstrate to the satisfaction of the FDA or any comparable foreign regulatory authority that the applicable product candidate’s risk-benefit ratio for its proposed indication is acceptable;

- receipt of authorizations to conduct clinical trials and future marketing approvals from applicable regulatory authorities in all the countries where we intend to conduct clinical trials or seek marketing approval;
- our ability to meet any required post-regulatory approval commitments to applicable regulatory authorities and other post-marketing requirements;
- establishing supply chain and commercial manufacturing arrangements with third-party manufacturers;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity;
- protecting our rights in our intellectual property portfolio;
- establishing sales, marketing and distribution capabilities;
- launching commercial sales of ribupatide and our other product candidates, if and when approved, whether alone or in collaboration with others;
- acceptance of ribupatide and our product candidates, if and when approved, by patients, the medical community and third-party payors;
- obtaining timely and adequate coverage and reimbursement from payors;
- ensuring no disruption in supply or lack of sufficient quantities of ribupatide and our other product candidates;
- effectively competing with other therapies; and
- maintaining an acceptable safety profile of ribupatide and our other product candidates during development and following approval.

Risks and uncertainties related to these factors could cause us to experience significant delays or an inability to successfully commercialize ribupatide and our other product candidates, which would materially harm our business.

***The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.***

We are not permitted to commercialize, market, promote or sell any product candidate in the United States without obtaining regulatory approval from the FDA. Foreign regulatory authorities impose similar requirements. The time required to obtain approval by the FDA and comparable foreign authorities is inherently unpredictable, but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. For instance, jurisdictions outside of the United States, such as Australia, Canada, the United Kingdom, or UK, the European Union, or EU, or Japan, may have different requirements for regulatory approval, which may require us to conduct additional clinical, nonclinical or chemistry, manufacturing and control studies. To date, we have not submitted a New Drug Application, or NDA, to the FDA or similar drug approval submissions to comparable foreign regulatory authorities for any product candidate. We must complete additional nonclinical studies and clinical trials to demonstrate the safety and efficacy of our product candidates in humans before we will be able to seek or obtain approvals for our product candidates.

Our current and future product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities, such as those in Australia or Japan, may disagree as to the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from clinical trials or nonclinical studies;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA to the FDA or similar submissions to foreign regulatory authorities or to obtain regulatory approval in the United States, the EU or elsewhere;
- the FDA, European Medicines Agency, or EMA, or comparable foreign regulatory authorities may find deficiencies with or fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process as well as the unpredictability of clinical trial results may result in our failing to obtain regulatory approval to market any product candidate we develop, which would substantially harm our business, results of operations and prospects. The FDA and other comparable foreign authorities have substantial discretion in the approval process and determining when or whether regulatory approval will be granted for any product candidate that we develop. Even if we believe the data collected from future clinical trials of our product candidates are promising, such data may not be sufficient to support approval by the FDA or any other regulatory authority. In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

In addition, the FDA's and other regulatory authorities' policies with respect to clinical trials may change and additional government regulations may be enacted. For instance, the regulatory landscape related to clinical trials in the EU recently evolved. The EU Clinical Trials Regulation, or CTR, which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. While the EU Clinical Trials Directive required a separate clinical trial application, or CTA, to be submitted in each member state in which the clinical trial takes place, to both the competent national health authority and an independent ethics committee, the CTR introduces a centralized process and only requires the submission of a single application for multi-center trials. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each member state, leading to a single decision per member state. The assessment procedure of the CTA has been harmonized as well, including a joint assessment by all member states concerned, and a separate assessment by each member state with respect to specific requirements related to

its own territory, including ethics rules. Each member state's decision is communicated to the sponsor via the centralized EU portal. Once the CTA is approved, clinical study development may proceed. The CTR transition period ended on January 31, 2025, and all clinical trials (and related applications) are now fully subject to the provisions of the CTR. Compliance with the CTR requirements by us and our third-party service providers, such as contract research organizations, or CROs, may impact our development plans.

In addition, FDA and foreign regulatory authorities may change their approval policies and new regulations may be enacted. For instance, the EU pharmaceutical legislation has been undergoing a complete review in the context of the Pharmaceutical Strategy for Europe initiative, launched by the European Commission in November 2020. The European Commission introduced legislative proposals in April 2023 that, if adopted, will replace the current regulatory framework in the EU for all medicines (including those for rare diseases and for children). The proposed changes were since discussed and negotiated by the European Parliament and the Council of the EU as part of the EU ordinary legislative process. In April 2024, the European Parliament adopted its position on the legislative proposals and, in June 2025, the Council of the EU adopted its position. A provisional agreement on the text was reached on December 11, 2025. Following positive votes by member states and the European Parliament on the provisional agreement in March 2026, the proposed revisions (affecting the duration of regulatory data protection and market protection, including for orphan medicinal products, revising the eligibility for expedited pathways, etc.) must now be formally adopted by the Ministers of Health in the Employment, Social Policy, Health and Consumer Affairs Council, or EPSCO, and the European Parliament Plenary, currently anticipated in the second half of 2026. The proposed changes are not expected to become applicable before 2028 but may have a significant impact on the pharmaceutical industry and our business in the long term.

Furthermore, on April 28, 2025, the UK adopted an amendment to the Medicines for Human Use (Clinical Trials) Regulations 2004 intended to support a more streamlined and flexible regulation of clinical trials, removing unnecessary administrative burdens on trial sponsors, whilst protecting the interests of trial participants. It also intends to bring the UK regulatory framework for clinical trials, which is still based on the EU Clinical Trials Directive, into closer alignment with the (EU) CTR. The amendment will become applicable on April 28, 2026 following a one-year transition period. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our development plans may be adversely impacted.

***The FDA or comparable foreign regulatory authorities may disagree with our regulatory plan for our product candidates.***

In order to obtain FDA approval of our product candidates, we must, among other things, demonstrate substantial evidence of the effectiveness of such product candidates. FDA has generally considered this demonstration to require data gathered from two or more adequate and well-controlled clinical trials of the product candidate in the relevant patient population, or in some cases, one adequate and well-controlled trial plus other confirmatory evidence. Adequate and well-controlled clinical trials typically involve a large number of patients, have significant costs and take years to complete. The FDA or other regulatory authorities may disagree with us about whether a clinical trial is adequate and well-controlled or may request that we conduct additional clinical trials prior to granting any regulatory approval. In addition, there is no assurance that the doses, endpoints and trial designs that we intend to use for our planned clinical trials, including those that we have developed based on feedback from the FDA or other regulatory agencies or those that have been used for the approval of similar drugs, will be acceptable for future approvals. For example, while we have designed our Phase 3 program for ribupatide after receiving input and feedback from the FDA and other regulatory agencies, there can be no assurance that the design of our planned clinical trials will be satisfactory to such agencies or that such agencies will not require us to modify our trials or conduct additional testing, or that completing these trials will result in regulatory approval. For instance, in connection with their review of our KaiNETIC

Phase 3 program, regulatory agencies, particularly those outside of the U.S., may disagree with elements of our clinical trial design, including dose selection and control arms, and utilization of data collected outside of the applicable territory. While we plan to initiate global Phase 3 trials of oral ribupatide as early as the first half of 2027, our plans are subject to discussions with regulatory agencies, including the FDA. We are not currently planning to conduct a global Phase 2 dose-ranging trial or Phase 1 pharmacokinetic bridging trial for oral ribupatide prior to commencing global Phase 3 clinical trials. The FDA and other regulatory agencies may disagree with our clinical development strategy or the designs of our proposed Phase 3 trials for oral ribupatide, including but not limited to dose selection, sample size and utilization of data collected outside of the applicable territory. Even if our Phase 3 clinical trials achieve their primary endpoint, there can be no assurance that the FDA and other regulatory agencies will find them sufficient to support approval.

Our clinical trial results may not support approval of our product candidates. In addition, our product candidates could fail to receive regulatory approval, or regulatory approval could be delayed, for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may not file or accept our NDAs or marketing application for substantive review;
- the FDA or comparable foreign regulatory authorities may disagree with the dosing regimen, design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that our product candidates are safe and effective for any of their proposed indications;
- the results of our clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that our product candidates' clinical and other benefits outweigh their safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from our nonclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to the satisfaction of the FDA or comparable foreign regulatory authorities to support the submission of an NDA or other comparable submission in foreign jurisdictions or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may find deficiencies with or fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA, EMA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

***Clinical and nonclinical development involves a lengthy and expensive process with an uncertain outcome, and the results of prior clinical trials and studies involving our product candidates are not necessarily predictive of our future results. Our product candidates may not show favorable results in nonclinical studies or clinical trials or receive regulatory approval on a timely basis, if at all.***

Pharmaceutical development is expensive and can take many years to complete, and its outcome is inherently uncertain. We cannot guarantee that any clinical trials or nonclinical studies will be conducted as planned, including whether we are able to meet expected timeframes for data readouts, or completed on schedule, if at all, and failure can occur at any time during the trial or study process, including due to factors that are beyond our control.

Any of our current or future product candidates in later stages of clinical trials may fail to show the desired characteristics despite having progressed through nonclinical studies and initial clinical trials. The results from nonclinical studies or clinical trials of any of our current and future product candidates, or a competitor's product candidate in the same class, may not predict the results of later clinical trials of any of our current or future product candidates. It is not uncommon to observe results in clinical trials that are unexpected based on nonclinical studies and early clinical trials, and many product candidates fail in later stage clinical trials despite very promising early results. In addition, we do not know whether ribupatide will demonstrate weight loss similar to that seen in clinical trials conducted in China by Hengrui. In particular, most of the ribupatide clinical data that has been generated to date has been in Chinese patient cohorts based on a maximum dose of 8 mg, however, in our ongoing Phase 3 program of ribupatide, we intend to study a dosing regimen of up to 10 mg in populations outside of China. We have limited information as to whether the new dosing regimen will result in a favorable balance between weight loss and tolerability profile and cannot guarantee that we will not need to further optimize the ribupatide dosing regimen in the future. A number of companies in the biopharmaceutical and biotechnology industries have suffered significant setbacks in clinical development even after achieving promising results in earlier studies. Such setbacks have occurred and may occur for many reasons, including, but not limited to: clinical sites and investigators may deviate from clinical trial protocols, whether due to lack of training or otherwise, and we may fail to detect any such deviations in a timely manner; patients may fail to adhere to any required clinical trial procedures, including any requirements for post-treatment follow-up; our product candidates may fail to demonstrate safety, purity or potency (or efficacy) in certain patient subpopulations, which has not been observed in earlier trials due to limited sample size, lack of analysis or otherwise; or our clinical trials may not adequately represent the patient populations we intend to treat, whether due to limitations in our trial designs or otherwise, such as where one patient subgroup is overrepresented in the clinical trial. There can be no assurance that we will not suffer similar setbacks despite the data we observed in earlier or ongoing studies. For example, if a higher-than-expected number of patients drop out of clinical trials prior to completion either as a result of their failure to lose weight on placebo or as a result of side effects on an active arm, we may experience difficulties completing trials with adequate numbers of patients to generate sufficient data to support a marketing application. Moreover, nonclinical and clinical data may be susceptible to varying interpretations and analyses. Because injectable ribupatide and oral ribupatide are based on the same peptide, if injectable ribupatide does not show safety or efficacy in clinical trials, it may negatively impact the development of oral ribupatide, and vice versa. Based upon negative or inconclusive results, we or any current or any future collaborator may decide, or regulators may require us, to conduct additional nonclinical studies or clinical trials, which would cause us to incur additional operating expenses and delays and may not be sufficient to support regulatory approval on a timely basis or at all.

Clinical testing is expensive, difficult to design and implement, can take many years to complete and is inherently uncertain as to outcome. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. The clinical development of our initial and potential additional product candidates is susceptible to the risk of failure inherent at any stage of development, including failure to demonstrate efficacy in a clinical trial or across a broad population of patients, the occurrence of adverse events that are severe or medically or commercially unacceptable, failure to comply with protocols or applicable regulatory requirements and determination by the FDA or any comparable foreign regulatory authority that a product candidate may not continue development or is not approvable. It is possible that even if any of our product candidates have a beneficial effect, that effect will not be detected during clinical evaluation as a result of one or more of a variety of factors, including the size, duration, design, measurements, conduct or analysis of our clinical trials. Conversely, as a result of the same factors, our clinical trials may indicate an apparent positive effect of such product candidate that is greater than the actual positive effect, if any. Similarly, in our clinical trials we may fail to detect toxicity of, or intolerability caused by, such product candidate, or mistakenly believe that our product candidates are toxic or not well tolerated when that is not in

fact the case. Serious adverse events or other adverse events, as well as tolerability issues, could hinder or prevent market acceptance of the product candidate at issue.

For the foregoing reasons, we cannot be certain that our ongoing and planned clinical trials and nonclinical studies will be successful. Any safety concerns observed in any one of our clinical trials in our targeted indications could limit the prospects for regulatory approval of our product candidates in those and other indications, which could have a material adverse effect on our business, financial condition and results of operations.

***Interim, topline and preliminary data from our clinical trials and nonclinical studies that we announce or publish from time to time may change as more patient data become available and 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 interim, topline or preliminary data from our clinical trials and nonclinical studies, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We may 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 interim, topline or preliminary results that we report may differ from future results of the same studies or trials, or different conclusions or considerations may qualify such results once additional data have been received and fully evaluated. Topline and preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the topline or preliminary data we previously published. As a result, topline and preliminary data should be viewed with caution until the final data are available. Interim data from clinical trials are further 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 differences between interim, topline or preliminary data and final data could significantly harm our business prospects. In addition, clinical trials with smaller sample sizes can be disproportionately influenced by various biases associated with clinical trial conduct, which limits the ability to generalize the results across a broader population, making the clinical trial results less likely to be replicated than clinical trials with a larger number of patients. For example, in our planned global Phase 3 trials for oral ribupatide, we plan to enroll a larger number of participants than were enrolled in the Phase 2 clinical trial conducted by Hengrui and may not be able to replicate the weight loss seen in the prior Hengrui Phase 2 trial. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock.

In addition, others, including regulatory authorities, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product, and our company in general. Moreover, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is 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 drug, product candidate or our business. If the interim, topline or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for and commercialize any of our current or future product candidates may be harmed, which could harm our business, financial condition, results of operations and prospects.

***Any difficulties or delays in the commencement or completion, or the termination or suspension, of our current or planned clinical trials or nonclinical studies could result in increased costs to us, delay or limit our ability to receive approval for and commercialize any product candidates and generate revenue.***

Before obtaining approval from regulatory authorities for the sale of any of our current or future product candidates, we must conduct extensive nonclinical studies and clinical trials to demonstrate the safety and efficacy (for small molecule drugs) or safety, purity, and potency (for biologics) of our product candidates. In addition, before we can initiate clinical development for any future nonclinical product candidates, we must submit the results of nonclinical studies to the FDA or comparable foreign regulatory authorities along with other information, including information about product candidate chemistry, manufacturing, and controls, and our proposed clinical trial protocol, as part of an Investigational New Drug, or IND, application, or similar regulatory submission to foreign regulatory authorities for clinical trials outside of the United States. The FDA or comparable foreign regulatory authorities may require us to conduct additional nonclinical studies for any future product candidates before it allows us to initiate clinical trials under any IND or similar foreign regulatory submission, which may lead to delays or increase the costs of developing future product candidates. Moreover, issues may arise that could cause regulatory authorities to suspend or terminate our ongoing or planned clinical trials. Any such delays in the commencement or completion, or the termination or suspension, of our ongoing and planned clinical trials or nonclinical studies could significantly affect our product development timelines and product development costs. We do not know whether our planned clinical trials or nonclinical studies will begin on time or if our ongoing or future trials or studies will be completed on schedule, if at all. The commencement, data readouts and completion of clinical trials and nonclinical studies can be delayed for a number of reasons, including delays related to:

- inability to obtain animals or materials to initiate and generate sufficient nonclinical, toxicology, or other *in vitro* data to support the initiation or continuation of clinical trials;
- non-acceptance of nonclinical or clinical data generated in China by Hengrui;
- obtaining authorization from regulatory authorities to commence a clinical trial or reaching a consensus with regulatory authorities on trial design;
- the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical trials;
- changes in regulatory requirements, policies, and guidelines;
- any failure or delay in reaching an agreement with contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- delays in identifying, recruiting, and training suitable clinical investigators;
- obtaining approval from one or more institutional review boards, or IRBs, or ethics committees, or ECs, at clinical trial sites;
- IRBs/ECs refusing to approve, suspending, or terminating the trial at an investigational site, precluding enrollment of additional patients, or withdrawing their approval of the trial;
- changes to the clinical trial protocol;
- clinical sites deviating from the trial protocol or dropping out of a trial;
- failure by our CROs to perform in accordance with Good Clinical Practice, or GCP, requirements or applicable regulatory requirements or guidelines in other countries;

- obtaining sufficient quantities of any of our current or future product candidates, including in respect of any combination product candidates, and related raw materials or obtaining sufficient quantities of other materials needed for use in clinical trials and nonclinical studies;
- patients failing to enroll or remain in our trials at the rate we expect, or failing to return for post-treatment follow-up;
- patients choosing alternative treatments for the indications for which we are developing any of our current or future product candidates, or participating in competing clinical trials;
- lack of adequate funding to continue the clinical trials or nonclinical studies or costs being greater than we anticipate;
- patients experiencing severe or serious unexpected drug-related adverse effects;
- occurrence of serious adverse events in trials of the same class of agents conducted by other companies that could be considered similar to any of our current or future product candidates;
- selection of clinical endpoints that require prolonged periods of clinical observation or extended analysis of the resulting data;
- transfer of manufacturing processes to larger-scale facilities operated by third-party manufacturers, delays or failure by our third-party manufacturers or us to make any necessary changes to such manufacturing process, or failure of such third-party manufacturers to produce clinical trial materials in accordance with current Good Manufacturing Practices, or cGMPs, regulations or other applicable requirements;
- third parties being unwilling or unable to satisfy their contractual obligations in a timely manner;
- third-party actions claiming infringement by our product candidates in clinical trials outside the United States and obtaining injunctions interfering with our progress; and
- business interruptions resulting from geo-political actions, including war and terrorism, natural disasters including earthquakes, typhoons, floods, and wildfires, or disease.

Clinical trials must be conducted in accordance with the FDA and other applicable regulatory authorities' legal requirements, regulations or guidelines, and are subject to oversight by these governmental agencies and ECs or IRBs at the medical institutions where the clinical trials are conducted. We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by a data safety monitoring board for such trial or by the FDA or comparable foreign regulatory authorities. Such authorities may impose such a suspension, including a clinical hold, or termination due to a number of factors, including, among other reasons, failure to conduct the clinical trial in accordance with GCP and other regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or comparable foreign 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 drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial.

Further, we and Hengrui are currently conducting, and we, Hengrui and any future collaborators may in the future conduct, clinical trials in foreign countries, which presents additional risks that may delay completion of our clinical trials. For example, Hengrui is currently conducting clinical trials in China. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocols as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign

regulatory schemes, and political and economic risks relevant to such foreign countries, including war. See “Risk factors—We currently, and may in the future, conduct certain of our clinical trials for our product candidates outside of the United States. However, the FDA and foreign regulatory authorities may not accept data from such trials, which could materially harm our business.”

Moreover, principal investigators for our clinical trials have served and may in the future serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA or comparable foreign regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or comparable foreign regulatory authority, as the case may be, and may ultimately lead to the denial of regulatory approval of any of our current or future product candidates.

Many of the factors that cause, or lead to, the 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. Any delays to our clinical trials that occur as a result could shorten any period during which we may have the exclusive right to commercialize any of our current or future product candidates. In such cases, our competitors may be able to bring products to market before we do, and the commercial viability of any of our current or future product candidates could be significantly reduced. Any of these occurrences may harm our business, financial condition, results of operations and prospects.

***As an organization, we have never completed late-stage clinical trials or submitted a NDA, and may be unable to do so for any of our product candidates.***

We will need to successfully complete clinical development, including late-stage clinical trials, in order to obtain FDA or comparable regulatory authority approval to market ribupatide or any future product candidates. Carrying out late-stage clinical trials and the submission of a successful NDA is a complicated process. As an organization, we are in the process of conducting Phase 3 clinical trials for ribupatide and have not yet completed any late-stage clinical trials for ribupatide or any other current and future product candidates. We have limited experience as a company in preparing, submitting and prosecuting regulatory filings and have not previously submitted a NDA or other comparable foreign regulatory submission for any product candidate. We also plan to conduct a number of clinical trials for multiple product candidates in parallel over the next several years. This may be a difficult process to manage with our limited resources. In addition, we have had limited interactions with the FDA and cannot be certain how the FDA or comparable foreign regulatory authorities will require such trials to be designed. Consequently, we may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that supports a successful regulatory submission and approval of any of our product candidates. We may require more time and incur greater costs than our competitors and may not succeed in obtaining regulatory approvals of product candidates that we develop. Failure to commence or complete, or delays in, our planned clinical trials, could prevent us from or delay us in submitting NDAs for and commercializing our product candidates.

***Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay.***

As product candidates proceed through nonclinical studies to late-stage clinical trials towards potential approval and commercialization, it is common that various aspects of the development program, such as the vendors used to manufacture drug product or manufacturing methods and formulation, are altered along the way in an effort to optimize processes and results. For instance, we are seeking to develop alternative synthesis strategies for certain of our peptide product candidates and conduct formulation development on certain of our

oral product candidates. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the materials manufactured using altered processes.

In addition, when we make formulation or manufacturing changes to any of our current or future product candidates, we may need to conduct additional nonclinical studies or clinical trials to bridge our current versions of any of our current or future product candidates to earlier versions. If we are unable to conduct such studies or trials, or if we otherwise fail to adequately bridge the current versions of our product candidates to earlier versions, then we may be unable to utilize any data we have gathered from studies or trials that evaluated such earlier versions in our planned regulatory submissions, and we could be required to perform additional testing, which could delay our programs. For example, in future studies of ribupatide, we currently plan to utilize materials produced by a different third-party manufacturer than the third-party manufacturer that produced ribupatide in prior studies and that are formulated as autoinjectors and/or multi-use pens rather than the pre-filled syringes used in prior studies of ribupatide, and we may be unable to demonstrate full comparability between lots produced by our current manufacturer and any future supplier. As a result, we may be required to gather additional data before we are able to submit a marketing application for ribupatide or any of our other current or future product candidates, if ever. Any delay of clinical trials, the repetition of one or more clinical trials, increases in clinical trial costs or delays in approval of our product candidates could jeopardize our ability to commence sales and generate revenue, if approved.

***We may find it difficult to enroll patients in our clinical trials. If we encounter difficulties or delays enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.***

Successful and timely completion of clinical trials will require that we identify and enroll a specified and sufficient number of eligible patients to participate and remain in the trial until its conclusion for each of our clinical trials. We may not be able to initiate or continue certain clinical trials if we are unable to identify and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or comparable foreign regulatory authorities outside the United States. Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors, including the size and characteristics of the patient population, the process for identifying patients, the proximity and availability of clinical trial sites for prospective patients, the inclusion and exclusion criteria for the trial, the design of the clinical trial, our ability to recruit clinical trial investigators with the appropriate competencies and experience, and competing clinical trials and clinicians' and patients' perceptions as to the potential advantages and risks of the product candidates being studied in relation to other available therapies, including any new products that may be approved for the indications we are investigating as well as any product candidates under development. We will be required to identify and enroll a sufficient number of patients for each of our clinical trials, obtain and maintain patient consent for each patient enrolled, and monitor such patients adequately during and after treatment. Potential patients for any planned clinical trials may not be adequately diagnosed or identified with the diseases which we are targeting, which could adversely impact the outcomes of our trials and could have safety concerns for the potential patients. Potential patients for any planned clinical trials may also not meet the entry criteria for such trials.

Additionally, other pharmaceutical companies targeting obesity are recruiting clinical trial patients from these patient populations, which may make it more difficult to fully enroll our clinical trials. Our clinical trials will compete with marketed products that are available for use in the same disease areas as our product candidates, and other clinical trials for investigational product candidates in the same disease areas as our product candidates. This competition could reduce the number and types of patients available to us, because some patients who might have opted to enroll in our clinical trials may instead opt to receive an approved therapy or enroll in a trial being conducted by one of our competitors. The timing of our clinical trials depends, in part, on the speed at which we can recruit patients to participate in our trials, as well as completion of

required follow-up periods. Moreover, the changing clinical trial landscape in obesity, with increased availability of marketed or compounded obesity management medications that are contraindicated in our clinical trials, may make patient recruitment and retention more difficult. The eligibility criteria of our clinical trials, once established, may further limit the pool of available trial participants. If patients are unwilling or unable to participate in our trials for any reason, including the existence of concurrent clinical trials for similar target populations, the availability of approved therapies, or the fact that enrolling in our trials may prevent patients from taking a different product, or we otherwise have difficulty enrolling a sufficient number of patients, the timeline for recruiting patients, conducting trials and obtaining regulatory approval of any of our current or future product candidates may be delayed. Our inability to enroll a sufficient number of patients for any of our future clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether.

In addition, we rely on, and will continue to rely on, CROs and clinical trial sites to ensure proper and timely conduct of our clinical trials and nonclinical studies. Though we have entered into agreements governing their services, we have limited influence over their actual performance. We cannot be certain that our assumptions used in determining expected clinical trial timelines are correct or that we will not experience delays or difficulties in enrollment, or be required by the FDA or other regulatory authority to increase our enrollment, which would result in the delay of completion of such trials beyond our expected timelines.

***Use of any of our current or future product candidates could be associated with side effects, adverse events or other properties or safety risks, which could delay or preclude regulatory approval, cause us to suspend or discontinue clinical trials, abandon any of our current or future product candidates, limit the commercial profile of an approved label or result in other significant negative consequences that could severely harm our business, financial condition, results of operations and prospects.***

Results of our, Hengrui's or any future collaborators' clinical trials could reveal a high and unacceptable severity and prevalence of expected or unexpected side effects or unexpected characteristics. Undesirable side effects caused by our product candidates when used alone or in combination with approved or investigational drugs could cause us or regulatory authorities or IRBs to interrupt, delay or halt clinical trials and could result in a more restrictive label, or lead to the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. For example, in clinical trials of ribupatide conducted to date, drug-related adverse events including nausea, vomiting, diarrhea and alopecia have been observed. These and any other drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trials, lead to poor data, or result in potential product liability claims. Any of these occurrences may harm our business, financial condition, results of operations and prospects significantly.

Moreover, if any of our current or future product candidates are associated with undesirable side effects in clinical trials or demonstrate characteristics that are unexpected, we may elect to abandon their development or limit their development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective, which may limit the commercial expectations for such product candidate if approved. Additionally, adverse developments in clinical trials of product candidates conducted by others or adverse events associated with commercial products offered by others may cause the FDA or other regulatory oversight bodies to suspend or terminate our clinical trials or change the requirements for approval of any of our product candidates, or otherwise adversely affect the clinical and commercial development of our product candidates.

We may also be required to modify our development and clinical trial plans based on findings in our ongoing clinical trials or concerns of the FDA or other regulatory authorities.

It is possible that as we, Hengrui or any future collaborators test any of our current or future product candidates in larger, longer and more extensive clinical trials, including with different dosing regimens, or as

the use of these product candidates becomes more widespread following any regulatory approval, more illnesses, injuries, discomforts and other adverse events than were observed in earlier trials, as well as new conditions that did not occur or went undetected in previous trials, may be discovered. If such side effects become known later in development or upon approval, if any, such findings may harm our business, financial condition, results of operations and prospects significantly.

In addition, we may study any of our current or future product candidates in combination with other therapies, which may exacerbate adverse events associated with such product candidate. If significant adverse events or other side effects are observed in any of our ongoing or planned clinical trials, we may have difficulty recruiting patients to the clinical trials, or we may be required to abandon the trials or our development efforts of that product candidate altogether. We, the FDA, other comparable foreign regulatory authorities or an IRB may suspend clinical trials of a product candidate at any time for various reasons, including a belief that subjects 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 due to tolerability concerns as compared to other available therapies. Any of these developments could materially harm our business, financial condition and prospects.

Additionally, if any of our product candidates receives regulatory approval, and we or others later identify undesirable side effects caused by such product, a number of potentially significant negative consequences could result. For example, the FDA could require us to adopt a Risk Evaluation and Mitigation Strategy, or REMS, to ensure that the benefits of treatment with such product candidate outweigh the risks for each potential patient, which may include, among other things, a communication plan to health care practitioners, patient education, extensive patient monitoring or distribution systems and processes that are highly controlled, restrictive and more costly than what is typical for the industry. We, Hengrui or our future collaborators may also be required to adopt a REMS or engage in similar actions, such as patient education, certification of health care professionals or specific monitoring, if we or others later identify undesirable side effects caused by any product that we develop alone. Other potentially significant negative consequences associated with adverse events include:

- IRBs, ECs, or safety monitoring committees may recommend that enrollment or dosing be placed on hold or that additional safety measures be implemented for ongoing clinical trials;
- we may be required to suspend marketing of a product, or we may decide to remove such product from the marketplace;
- regulatory authorities may withdraw or change their approvals of a product;
- regulatory authorities may require additional warnings or contraindications on the label or limit access of a product to selective specialized centers with additional safety reporting and with requirements that patients be geographically close to these centers for all or part of their treatment;
- we may be required to create a medication guide outlining the risks of a product for patients, or to conduct post-marketing studies;
- we may be required to change the way a product is dosed, distributed, or administered, or conduct additional clinical trials;
- we may be subject to limitations on how we may promote the product;
- we could be subject to fines, injunctions, or the imposition of criminal or civil penalties, or be sued and held liable for harm caused to subjects or patients; and
- a product may become less competitive, and our reputation may suffer.

Any of these events could diminish the usage or otherwise limit the commercial success of our product candidates and prevent us from achieving or maintaining market acceptance of our product candidates, if approved by the FDA or other regulatory authorities.

If any of our current or future product candidates receive regulatory approval, they may be subject to stringent labeling requirements, including the potential imposition of a boxed warning. A boxed warning, also known as a "Black Box" warning, is ordinarily used to highlight for prescribers one of the following situations: (1) There is an adverse reaction so serious in proportion to the potential benefit from the drug (e.g., a fatal, life threatening or permanently disabling adverse reaction) that it is essential that it be considered in assessing the risks and benefits of using the drug; (2) or there is a serious adverse reaction that can be prevented or reduced in frequency or severity by appropriate use of the drug (e.g., patient selection, careful monitoring, avoiding certain concomitant therapy, addition of another drug or managing patients in a specific manner, avoiding use in a specific clinical situation); or (3) FDA approved the drug with restrictions to ensure safe use because the FDA concluded that the drug can be safely used only if distribution or use is restricted.

The FDA has required the full prescribing information of approved GLP-1 obesity management medications, such as Wegovy and Zepbound, to carry a boxed warning regarding the risk of thyroid C-cell tumors. The boxed warnings state that semaglutide and tirzepatide, the active ingredients in Wegovy and Zepbound, respectively, cause thyroid C-cell tumors in rodents, but that it is unknown whether Wegovy and Zepbound cause thyroid C-cell tumors in humans. The boxed warnings for both drugs also indicate that they are contraindicated in patients with a personal or family history of medullary thyroid carcinoma or in patients with multiple endocrine neoplasia syndrome type 2. We expect that the label of our GLP-1 monotherapy or any future GLP-1 combination product candidates we may develop, if approved, may carry similar warnings.

If the FDA requires us to include a boxed warning in the prescribing information of any of our current or future product candidates, the inclusion of the boxed warning could adversely affect the market acceptance and commercial success of any of our current or future product candidates. The inclusion of a boxed warning could diminish the usage or otherwise limit the commercial success of our product candidates and prevent us from achieving or maintaining market acceptance of our product candidates, if approved by the FDA or other regulatory authorities.

Further, competitors who are developing products in the obesity management medication field or that utilize a similar mechanism of action as us may experience problems with their products that could indicate or result in class-wide problems or additional requirements that would potentially harm our business. For example, in January 2024, the FDA announced that it was evaluating reports of suicidal thoughts or actions in patients treated with GLP-1 receptor agonists. While the FDA ultimately did not find any association between use of GLP-1 receptor agonists and the occurrence of suicidal thoughts or actions, it did recommend that physicians prescribing GLP-1 receptor agonists should monitor their patients for and advise patients using GLP-1 receptor agonists to report new or worsening depression, suicidal thoughts, or any unusual changes in mood or behavior. Were an association between GLP-1 receptor agonists and suicidal thoughts or actions to be found in the future as additional data become available or other class-wide issues to arise, the FDA may impose additional requirements for product candidates seeking approval or impose labeling requirements the inclusion of which could adversely affect the market acceptance and commercial success of any of our current or future product candidates.

***We currently, and may in the future, conduct certain of our clinical trials for our product candidates outside of the United States. However, the FDA and foreign regulatory authorities may not accept data from such trials, which could materially harm our business.***

We and Hengrui are currently conducting, and we, Hengrui and any future collaborators may in the future conduct clinical trials for any of our current or future product candidates outside the United States. The

acceptance of study data from clinical trials conducted outside the United States or another jurisdiction by the FDA or comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. For example, in cases where data from foreign clinical trials are intended to serve as the sole basis for regulatory approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless the data are applicable to the U.S. population and U.S. medical practice; the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations; and the data may be considered valid without the need for an on-site inspection by the FDA, or if the FDA considers such inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means.

In addition, even where the foreign study data are not intended to serve as the sole basis for approval, if the relevant study was not conducted pursuant to an IND, the FDA will not accept the data as support for a marketing application unless the study was conducted in accordance with GCP requirements and the FDA is able to validate the data from the study through an onsite inspection if deemed necessary. Many foreign regulatory authorities have similar requirements for clinical data gathered outside of their respective jurisdictions. For instance, for nonclinical studies submitted to the European Medicines Agency, or EMA, particularly those supporting marketing applications in Europe, China-based testing facilities must adhere to the Organisation for Economic Co-operation and Development, or OECD, Principles of GLP and be part of the OECD Mutual Acceptance of Data system for data to be accepted. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. For example, the data generated by Hengrui on our product candidates in China may not be acceptable to the FDA or other regulatory authorities. If the FDA or any comparable foreign regulatory authority does not accept such data from our clinical trials of any of our current or future product candidates, we would need to conduct additional trials, which could be costly and time-consuming, and which may not ultimately support approval in the applicable jurisdiction. Conducting clinical trials outside the United States also exposes us to additional risks, including risks associated with:

- foreign regulatory requirements;
- compliance with foreign manufacturing, customs, shipment, and storage requirements;
- inconsistent standards for reporting and evaluating clinical data and adverse events;
- diminished protection of intellectual property in some countries; and
- public health concerns or political instability, civil unrest, war or similar events that may jeopardize our ability to commence, conduct or complete a clinical trial and evaluate resulting data.

***Our future growth may depend, 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 depend, in part, on our ability to develop and commercialize any of our current or future product candidates in foreign markets. We are not permitted to market or promote any of our current or future product candidates before we receive regulatory approval from applicable regulatory authorities in foreign markets, and we may never receive such regulatory approvals for any of our current or future product candidates. To obtain separate regulatory approval in many other countries we must comply with numerous and varying regulatory requirements regarding safety and efficacy and governing, among other things, clinical trials, commercial sales, pricing and distribution of any of our current or future product candidates. Approval procedures may be more onerous than those in the United States and may require that we conduct additional nonclinical studies or clinical trials. If we obtain regulatory approval of any of our current or future product

candidates and ultimately commercialize our products in foreign markets, we would be subject to additional risks and uncertainties, including:

- different regulatory requirements for approval of drugs in foreign countries;
- reduced protection for intellectual property rights;
- the existence of additional third-party patent rights of potential relevance to our business;
- compliance with export control and import laws and regulations and changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- foreign reimbursement, pricing, and insurance regimes;
- workforce uncertainty in countries where labor unrest is common;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, public health pandemics or epidemics, or natural disasters including earthquakes, typhoons, floods and fires.

***Our business is subject to the risks associated with having a collaboration partner located in China.***

As a result of our collaboration with Hengrui, located in China, our results of operations, financial condition, and prospects are subject to a significant degree to economic, political, and legal developments in China including government control over capital investments or changes in tax regulations that are applicable to us. China's economy differs from the economies of most developed countries in many respects, including with respect to the amount of government involvement, level of development, growth rate and control of foreign exchange, and allocation of resources. Since we collaborate with an entity located in China, our business is subject to the risks associated with having a collaboration partner located in China, including:

- adverse political and economic conditions, particularly those potentially negatively affecting the trade relationship between the United States and China;
- trade protection measures, such as tariff increases, and import and export licensing and control requirements;
- potentially negative consequences from changes in tax laws;
- difficulties associated with the Chinese legal system, including increased costs and uncertainties associated with enforcing contractual obligations in China;
- historically lower protection of intellectual property rights;
- requirements relating to China's data security rules and regulations;
- requirements relating to China personal information protection laws;

- changes and volatility in currency exchange rates;
- workforce uncertainty;
- unexpected or unfavorable changes in regulatory requirements; and
- difficulties in managing foreign relationships and operations generally.

We are exposed to the possibility of product supply disruption and increased costs in the event of changes in the policies of the U.S. or Chinese governments, political unrest or unstable economic conditions in China. New legislation, regulations or court decisions may impede, delay, limit, or increase the cost of manufacturing our therapeutic candidates. Such events could result in our clinical or commercial supply of drug being interrupted or limited, which could harm our business.

***Changes in U.S. and international trade policies, particularly with respect to China, may adversely impact our business and operating results.***

The U.S. government has recently made statements and taken certain actions that may lead to potential changes to U.S. and international trade policies, including imposing several rounds of tariffs and export control restrictions affecting certain products manufactured in China, and most recently, proposing legislation that, if enacted would restrict trade with certain Chinese companies that provide biopharmaceutical research, development, and manufacturing services. Recently both China and the United States have each imposed tariffs indicating the potential for further trade barriers. In addition, in the past the U.S. Commerce Department has implemented export controls adding numerous Chinese entities to its “unverified list,” which requires U.S. exporters to go through more procedures before exporting goods to such entities. It is unknown whether and to what extent new tariffs, export controls, trade restrictions, or other new laws or regulations will be adopted, or the effect that any such actions would have on us or our industry. Sustained uncertainty about, or the further escalation of, trade and political tensions between the United States and China could result in a disadvantageous research and manufacturing environment in China, particularly for U.S. based companies, including retaliatory restrictions that hinder or potentially inhibit our ability to rely on manufacturing partners and other service providers that operate in China. For example, proposed legislation has been introduced in Congress that could prohibit, among other things, the use of U.S. government executive agency contract, grant, or loan funding to procure or obtain, or enter into, extend or renew contracts involving the use of certain equipment or services produced or provided by certain Chinese companies which could cause us to reevaluate our relationship with our certain of our existing manufacturing partners, including Hengrui.

In addition to Hengrui, some of our other suppliers, vendors and service providers are located in China. Trade tensions and conflicts between the United States and China have been escalating in recent years and, as such, we are exposed to the possibility of supply disruptions and increased costs and expenses in the event of changes to the laws, rules, regulations and policies of the governments of the United States or China, or due to geopolitical unrest and unstable economic conditions. 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 their supply of material to us. Additionally, third parties may voluntarily require compliance or supply chain requirements that go above and beyond potential legislation to address perceived risk of “pass through,” which would make it difficult for us to operate our business.

For example, the U.S. BIOSECURE Act, which was enacted in December 2025, prohibits federal agencies from procuring or using any biotechnology equipment or services from “biotechnology companies of concern”, or entering into, extending, or renewing any contracts with entities that use such biotechnology equipment or services from “biotechnology companies of concern”. Congress has interpreted a “biotechnology company of

concern" as an entity that is under the control of a foreign adversary and that poses a risk to national security based on its research or multiomic data collection (e.g., collection of genomic information). While the U.S. BIOSECURE Act has a grandfathering period of five years for existing contracts, and has carveouts for manufacture of drugs for supply under Medicaid and Medicare Part B, subject to the Secretary of Veteran Affairs' discretion, the impact of the U.S. BIOSECURE Act on the biotechnology industry is uncertain.

It is possible some of our contractual counterparties, including Hengrui, could be impacted by the legislation described above.

Any unfavorable government policies on international trade, such as export controls, capital controls or tariffs, may increase the cost of manufacturing our product candidates and materials, affect the demand for our drug products (if and once approved), the competitive position of our product candidates, and import or export of raw materials and finished product candidate used in our, Hengrui's and our future collaborators' nonclinical studies and clinical trials, particularly with respect to any product candidates and materials that we import from China, including pursuant to the Hengrui License Agreement. If any new tariffs, export controls, legislation and/or regulations are implemented, or if existing trade agreements are renegotiated or, in particular, if either the U.S. or Chinese government takes retaliatory trade actions due to the recent trade tension, such changes could have an adverse effect on our business, financial condition and results of operations.

***Even if we or our collaborators obtain approval for any of our product candidates in one jurisdiction, we may never obtain approval for or commercialize such candidates in any other jurisdiction, which would limit our ability to realize their full market potential.***

In order to market any products in any particular jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a country-by-country basis regarding safety and efficacy. Approval by the FDA in the United States does not ensure approval by regulatory authorities in other countries or jurisdictions. However, the failure to obtain approval in one jurisdiction may negatively impact our ability to obtain approval elsewhere. For example, ribupatide (being developed as HRS9531 by Hengrui) is currently the subject of a pending NDA in China that has been submitted by Hengrui. If Hengrui fails to obtain approval for ribupatide in China, it could negatively impact our ability to obtain approval in the United States or any other jurisdiction. In addition, regulatory approval in one country does not guarantee regulatory approval in any other country.

Approval processes vary among countries and can involve additional product testing and validation, as well as additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and increased costs for us and require additional nonclinical studies or clinical trials which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. We do not have any product candidates approved for sale in any jurisdiction, including in international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of any product we develop will be unrealized.

***If our product candidates are ultimately regulated as biologics rather than as drugs, we would be required to pursue approval under a different statutory framework than our current plans contemplate, which could delay development, increase costs, alter market exclusivity and competition dynamics, and adversely affect our business.***

We are currently developing our product candidates with the expectation of seeking FDA approval through NDAs. There is, however, ongoing litigation challenging whether certain similar products should be regulated as drugs or biologics. The outcome of this litigation could affect how products with attributes comparable to our

product candidates are classified. If that litigation, or related FDA actions, result in a determination that product candidates like ours must be regulated as biologics, we could be required to pursue approval via biologics license applications, or BLAs, under the Public Health Service Act.

A change in classification would subject our programs to a different and potentially more burdensome regulatory framework. Among other things, the biologics pathway can entail distinct and complex chemistry, manufacturing, and controls requirements, including expectations around process validation, comparability, and lot-to-lot consistency; expanded facility inspections; differences in quality system requirements; product-specific potency assays; and, potentially, additional nonclinical or clinical data to support a demonstration of safety, purity, and potency. Reclassification could necessitate redesign of our manufacturing processes (for example, to align with biologics quality standards), redevelopment or revalidation of analytical methods, new or supplemental bridging studies, and changes to our clinical development plans. It could also require us to engage different specialized contract manufacturers or to build or qualify new internal capabilities. Any of these changes could materially delay our timelines and substantially increase our costs.

Market entry and competition dynamics would also differ. If approved as biologics, our product candidates' period of reference product exclusivity, biosimilar and interchangeable product competition, and related patent litigation procedures would be governed by the Biologics Price Competition and Innovation Act rather than the generic drug framework under the Drug Price Competition and Patent Term Restoration Act of 1984. While biologics may be eligible for a different statutory regulatory exclusivity period than drugs, the biosimilar and interchangeability standards, naming conventions, and substitution rules are distinct from those applicable to generic drugs approved under abbreviated new drug applications. These differences could change the timing, nature, and intensity of post-approval competition, and affect our pricing and market access strategies.

We have designed our development, regulatory, and manufacturing strategies based on our current understanding that our product candidates will be regulated as drugs subject to the NDA pathway. If FDA were to require that we instead pursue BLAs, we may experience substantial delays to our development programs; incur significant, unplanned costs; need to repeat or augment nonclinical or clinical studies; requalify or replace manufacturing sites and suppliers; and modify our commercial plans. We may also face uncertainty while the scope and implications of any reclassification are implemented by FDA, including how existing guidance, review practices, and user fee commitments apply. Any of these outcomes could adversely affect our ability to obtain timely approval, our competitive position, our potential market opportunity, and our business, financial condition, and results of operations.

***Additional time may be required to obtain marketing authorizations for any product candidates that we develop as drug-device combination products.***

We expect our current injectable product candidates will be regulated as combination products, as our therapeutic candidates will be administered by the patient using a disposable injector device (pre-filled syringe, autoinjector and/or multi-use pen) marketed together with the therapeutic candidate, if approved. Development of a product candidate as a combination product candidate requires close coordination within the FDA and within comparable regulatory agencies for review of each of the drug and device components that comprise the product and would typically be reviewed by different centers within the FDA if offered for use as standalone products. For example, the FDA's review of a marketing application for a drug-device combination that has a primary mode of action as a drug would likely be subject to a NDA with the Center for Drug Evaluation and Research as the lead center, with coordination with the Center for Devices and Radiological Health for the review of the device component. Although the FDA and comparable foreign agencies have or may have systems in place for the review and approval of such combination products, we may experience additional delays in the development and commercialization of such product candidates due to regulatory timing constraints and uncertainties in the product development and approval process. Furthermore, regulatory bodies like the FDA may require a human factors study, also

sometimes referred to as a usability study, to evaluate how people interact with drug-device combination products in real-world settings to ensure they can be used safely and effectively, and the requirement to conduct a human factors study may delay or prevent approval of a drug-device combination product. Moreover, although we anticipate that the device component of any combination product candidates we develop will be reviewed within the usual time frames expected for the marketing authorization application for underlying therapeutic candidate, and that no separate marketing application for the device components of such product candidates will be required in the United States, the FDA or comparable regulatory authorities may delay approval or require us to conduct additional studies with the device, which may delay the approval of the combination product.

The EU regulates medical devices and medicinal products separately, through different legislative instruments, and the applicable requirements will vary depending on the type of drug-device combination product. For instance, drug-delivery products intended to administer a medicinal product where the medicinal product and the device form a single integral product are regulated as medicinal products in the EU. In such a case, the marketing authorization application must include—where available—the results of the assessment of the conformity of the device part with the EU Medical Devices Regulation contained in the manufacturer's EU declaration of conformity of the device or the relevant certificate issued by a notified body. If the marketing authorization application does not include the results of the conformity assessment and where for the conformity assessment of the device, if used separately, the involvement of a notified body is required, the EMA or the EU member state competent authority must require the applicant to provide a notified body opinion on the conformity of the device. By contrast, in case of drug-delivery products intended to administer a medicinal product where the device and the medicinal product do not form a single integral product (but are e.g. co-packaged), the medicinal product is regulated in accordance with the rules for medicinal products described above while the device part is regulated as a medical device and will have to comply with all the requirements set forth by the Medical Devices Regulation.

***Even if we receive regulatory approval for any product candidate, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense, and we may be subject to penalties if we fail to comply with regulatory requirements.***

For any regulatory approvals that we may receive for our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, sampling, import, export and recordkeeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities, as well as ongoing compliance with cGMPs and GCPs for any clinical trials. The holder of an NDA also must submit supplemental applications and obtain prior approval for certain changes to the approved product, product labeling, or manufacturing process.

Manufacturers of drug products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA and other regulatory authorities for compliance with cGMPs and other applicable regulations and standards. Accordingly, we will need to continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production, and quality control. Manufacturers and other parties involved in the supply chain must also meet chain of distribution requirements and build electronic, interoperable systems for product tracking and tracing and for notifying the FDA of counterfeit, diverted, stolen, and intentionally adulterated products or other products that are otherwise unfit for distribution in the United States.

In addition, any regulatory approvals we may receive will require the submission of periodic reports to regulatory authorities and ongoing surveillance to monitor the safety and efficacy of the product. Such approvals may also contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, and may include burdensome post-approval study or risk management

requirements. For example, the FDA may require a REMS as a condition of approval of our product candidates, which could include requirements for a medication guide, physician training and communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools.

If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facilities where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. This may also result in revisions to the approved labeling to add new safety information, imposition of post-marketing studies or clinical trials to assess new safety risks, or imposition of distribution restrictions or other restrictions under a REMS program. In addition, failure to comply with FDA and other comparable foreign regulatory requirements may subject our company to administrative or judicially imposed sanctions, including:

- restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market or voluntary or mandatory product recalls;
- restrictions on product distribution or use, or requirements to conduct post-marketing studies or clinical trials;
- fines, restitutions, disgorgement of profits or revenues, warning letters, untitled letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications submitted, or suspension or revocation of approvals;
- revisions to the labeling, including limitations of use or requirements for additional warnings, contraindications, or other safety information, including boxed warnings;
- product seizures or detentions, or refusal to permit the import or export of our products; and
- injunctions or the imposition of civil or criminal penalties.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be promulgated that could prevent, limit or delay marketing authorization of any product candidates we develop. The U.S. Supreme Court's July 2024 decision to overturn prior established case law giving deference to regulatory agencies' interpretations of ambiguous statutory language has introduced uncertainty regarding the extent to which the FDA's regulations, policies and decisions may become subject to increasing legal challenges, delays, and/or changes. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action and we may not achieve or sustain profitability.

***The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.***

The FDA and other regulatory agencies strictly regulate marketing, labeling, advertising, and the promotional claims that may be made about prescription products, such as any of our current or future product candidates,

if approved. In particular, a product may not be promoted for uses that are not approved by the FDA or other regulatory agencies as reflected in the product's approved labeling. If we receive regulatory approval for any of our current or future product candidates, physicians may prescribe, in their independent professional medical judgment, legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Physicians may believe that such off-label uses are the best treatment for some patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. Companies may share truthful and not misleading information that is otherwise consistent with a product's FDA-approved labeling, but the FDA does, however, restrict a manufacturer's communications about off-label use of their products. Similar requirements apply in foreign jurisdictions. If we are found to have promoted such off-label uses, we may become subject to significant liability. The U.S. federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The government has also required companies to enter into consent decrees or imposed permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of any of our current or future product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

***Disruptions at the FDA, the SEC, and other government agencies caused by funding shortages or staffing limitations could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner, or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could have a negative impact on our business.***

The ability of the FDA or foreign 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, and statutory, regulatory, and policy changes. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also prolong the time necessary for new drugs or biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, in recent years and in the past year, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC, and other government employees and stop critical activities. In addition, the current U.S. Presidential administration has issued certain policies and Executive Orders directed towards reducing the employee headcount and costs associated with U.S. administrative agencies, including the FDA, and it remains unclear the degree to which these efforts may limit or otherwise adversely affect the FDA's ability to conduct routine activities. If a prolonged government shutdown were to occur, or if funding shortages or staffing limitations hinder or prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly affect the ability of the FDA to review and process our regulatory submissions in a timely manner, which could have a material adverse effect on our business.

## Risks Related to Our Reliance on Third Parties

***We depend on our license agreement with, and the comprehensiveness of the intellectual property licensed from, Hengrui. Termination of the Hengrui License Agreement, and issues related to intellectual property we license from Hengrui, would have a material adverse effect on our business.***

We depend on the patents, know-how and other intellectual property licensed from Hengrui through the Hengrui License Agreement for the development and, if approved, commercialization of our product

candidates. If the Hengrui License Agreement is terminated, or found to be unenforceable, it could result in the loss of significant rights and could harm our ability to commercialize our product candidates.

The Hengrui License Agreement imposes certain obligations on us, including obligations to use commercially reasonable efforts to develop and commercialize licensed products in our territory, obligations to achieve certain regulatory milestone obligations within specified timelines, and obligations to pay Hengrui milestone payments, royalties and other fees. If we are unable to meet our obligations, our rights under the License Agreement may be reduced or terminated.

Our rights to our product candidates are subject to the Hengrui License Agreement, which may be terminated in certain circumstances, including in the event of an uncured material breach by us (such as an uncured payment default) or Hengrui. Without rights to the patents and know-how licensed under the Hengrui License Agreement, we may be unable to continue to develop, manufacture or commercialize our product candidates.

Additionally, our ability to realize the full potential of the Hengrui License Agreement may be severely limited by factors involving intellectual property rights, including:

- whether and to what extent our technology and processes may infringe on intellectual property rights of third parties that are not subject to the Hengrui License Agreement;
- whether third parties are entitled to compensation or equitable relief, such as an injunction, for our use of the third parties' intellectual property without their authorization;
- our right to sublicense patent and other intellectual property rights to third parties under collaborative development relationships;
- our compliance with our obligations with respect to the use of the licensed technology in relation to our development and commercialization of product candidates; and
- ownership of specific intellectual property arising under the Hengrui License Agreement.

These issues, if they arise, could reduce or eliminate our rights to the relevant intellectual property or technology, increase what we believe to be our financial or other obligations under the relevant agreement, or increase our costs to develop, manufacture and commercialize products under the Hengrui License Agreement. For a more complete description of the Hengrui License Agreement, see "Business—Hengrui License and Collaboration Agreement."

***We are dependent on Hengrui having accurately generated, collected, interpreted and reported data from certain nonclinical studies and clinical trials that were previously conducted for our product candidates.***

We have licensed the rights to substantially all of our current product candidates from Hengrui, for which they undertook prior research and development, including nonclinical studies and clinical trials, primarily in China. We had no involvement with or control over the nonclinical and clinical development of any of our product candidates prior to our entry into the Hengrui License Agreement. In addition, we had no involvement in the development of third-party agents used as comparators or background therapies in such studies. Therefore, we are dependent on these third parties having conducted their research and development in accordance with the applicable protocols, legal and regulatory requirements, and scientific standards; having accurately reported the results of all nonclinical studies and clinical trials conducted with respect to such product candidates and having correctly collected and interpreted the data from these studies and trials. These risks also apply to any additional product candidates that we may acquire or license in the future. To date, we have not completed a comprehensive audit of the data that was generated by Hengrui with respect to our current product candidates. If we were to discover that data previously generated by Hengrui or another third-party was materially inaccurate or that their research and

development activities were carried out in a noncompliant manner, we would be unable to rely on such data for our own clinical development, regulatory approval or commercialization purposes, adversely impacting the development of the implicated product candidate(s).

***We rely on third parties to conduct our clinical trials and nonclinical studies. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements, or meet expected deadlines, any of our current or future product candidates and our ability to seek or obtain regulatory approval for or commercialize any of our current or future product candidates may be delayed.***

We are dependent on third parties to conduct our clinical trials and nonclinical studies. Specifically, we rely on, and intend to continue to rely on, medical institutions, clinical investigators, CROs and consultants to conduct our nonclinical studies and clinical trials in accordance with our clinical protocols and applicable regulatory requirements. These CROs, investigators and other third parties play a significant role in the conduct and timing of these trials and subsequent collection and analysis of data. In particular, we have licensed our pipeline from Hengrui, which has conducted and is conducting multiple nonclinical studies and clinical trials of our product candidates in China. We intend to leverage the clinical capabilities and data generated by Hengrui to inform and support our global development programs. While we have and will have agreements governing the activities of our third-party contractors, including Hengrui, we have limited influence over their actual performance, and we have no control over the data generated by Hengrui on our product candidates. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards and requirements, and our reliance on our CROs and other third parties does not relieve us of our regulatory responsibilities. In addition, we and our CROs are required to comply with GLP requirements, as applicable, for certain nonclinical studies, as well as GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for any of our current and future clinical trials of product candidates. Regulatory authorities enforce these requirements through periodic inspections of laboratories conducting GLP studies, trial sponsors, principal investigators and trial sites. If we, our investigators, or any of our CROs or trial sites fail to comply with applicable GLP or GCP or other requirements, the clinical data generated in our nonclinical studies or clinical trials may be deemed unreliable, the statistical analysis and robustness of our datasets could be compromised, and the FDA or comparable foreign regulatory authorities may require us to perform additional nonclinical studies or clinical trials before approving our marketing applications, if ever. Further, our clinical trials must be conducted with investigational products produced in accordance with cGMP regulations. Failure to comply with these regulations may require us to repeat clinical trials, which would delay the development and regulatory approval process.

Furthermore, these CROs and investigators are not our employees, and we will not be able to control, other than by contract, the amount of resources, including time, which they devote to our product candidates and clinical trials. There is no guarantee that any of our CROs, investigators or other third parties will devote adequate time and resources to such trials or studies or perform as contractually required. If any of these third parties fail to meet expected deadlines, adhere to our clinical protocols or meet regulatory requirements, or otherwise perform in a substandard manner, our clinical trials may be extended, delayed or terminated. In addition, many of the third parties with whom we contract may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other development activities that could harm our competitive position.

Our CROs have the right to terminate their agreements with us in the event of an uncured material breach and under other specified circumstances. If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative third parties on commercially reasonable terms, in a timely manner or at all. Switching or adding additional CROs, investigators and other third parties involves additional cost and requires our management’s time and focus. In addition, there is a natural transition period when a new

CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we work to carefully manage our relationships with our CROs, investigators and other third parties, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition, results of operations and prospects.

***We rely on the use of third parties, including Hengrui, to manufacture our product candidates, which may increase the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable time and cost, which could delay, prevent or impair our development or commercialization efforts.***

We do not own or operate manufacturing facilities for the production of clinical or commercial supplies of our product candidates. We have limited personnel with experience in drug manufacturing and lack the resources and the capabilities to manufacture any of our product candidates on a clinical or commercial scale. We currently rely on third parties, including Hengrui, for supply of the active pharmaceutical ingredients, or API, drug substance or drug product, in our product candidates. Hengrui supplies us with drug substance and drug product for our clinical trials, but if the Hengrui License Agreement is terminated, then our supply from Hengrui will also be terminated. Our strategy is to outsource all manufacturing of our product candidates and products to third parties.

We have supply arrangements with Hengrui and with other third-party manufacturers for development, validation and manufacturing of our product candidates to support near-term clinical supply and, if approved, potential commercial supply of our future products. We are in the process of further establishing agreements with third party manufacturers for the long-term clinical and commercial supply of our product candidates. We may be unable to conclude agreements for commercial supply with third-party manufacturers, or may be unable to do so on acceptable terms. For instance, while we are engaged in a number of efforts to reduce the cost of goods sold of our product candidates, particularly for oral ribupatide, such efforts may not be successful, which could limit the commercial profitability of such product candidates, if approved. The third-party manufacturers may not successfully carry out their contractual duties or obligations, the occurrence of which could substantially increase our costs and limit our supply of such product candidates. The demand for third-party manufacturer's services is very high, and such manufacturers could be subject to market transactions including mergers, acquisitions and other market consolidation transactions that limit their ability to provide products and services to us thereby increasing the time and cost it could take us to manufacture our product candidates.

Even if we are able to establish and maintain arrangements with third-party manufacturers, reliance on third-party manufacturers, including Hengrui, entails additional risks, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party;
- the possible diversion of manufacturing capacity to other customers by the third party;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how; and
- the possible termination or non-renewal of the agreement by the third party at a time that is costly or inconvenient for us.

Third-party manufacturers, including Hengrui, may not be able to comply with current good manufacturing practice, or cGMP, regulations or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, including Hengrui, to comply with applicable regulations could result in

sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates. For example, in 2024, Hengrui received a Warning Letter from the FDA that was unrelated to the production of our product candidates. It is possible that Hengrui or other third-party manufacturers may in the future receive similar allegations of noncompliance or regulatory enforcement that may implicate the production of our product candidates, which could significantly and adversely affect supplies of our product candidates.

Our product candidates and any products that we may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us.

In addition, in order to conduct late-stage clinical trials of our product candidates, we will need to have them manufactured in large quantities. Our third-party manufacturers, including Hengrui, 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.

Moreover, if our third-party manufacturers, including Hengrui, are unable to successfully scale up the manufacture of our product candidates in sufficient quality and quantity, the development, testing and clinical trials of those product candidates may be delayed or infeasible, and regulatory approval or commercial launch of such product candidates may be delayed or not obtained, which could significantly harm our business.

In addition, we rely on our licensors and third party manufacturers, including Hengrui, to transfer manufacturing know how, analytical methods, reference standards and any process improvements relating to our product candidates. If we do not receive, retain or are otherwise unable to use such know how, we may incur additional transition costs, need to repeat development or validation activities and experience delays in manufacturing and delivery. Drug substance or drug product supplied by third parties may not comply with regulatory quality requirements or have sufficient stability for commercialization, which could require additional investment, revalidation or process changes and delay our development, approval and commercialization plans. Manufacturing may also depend on raw materials, single source reagents or specialized equipment that may be difficult to secure. Because some supply originates outside the United States, any delay in obtaining or maintaining required import or export licenses or clearances could delay our timelines. Termination, expiration or breach of our supply, manufacturing or technology transfer arrangements could have a material adverse effect on our business.

If the third parties, including Hengrui, that we engage to manufacture product for our nonclinical studies and clinical trials should cease to continue to do so for any reason, including due to outbreaks, geopolitical disruptions, natural disaster, epidemic or pandemic, trade wars, political unrest, economic conditions, changes in legislation or other events beyond their control, we likely would experience delays in advancing these clinical trials while we identify and qualify replacement suppliers, and we may be unable to obtain replacement supplies on terms that are favorable to us. For example, the passage of the People's Republic of China's Biosecurity law, which became effective on April 15, 2021, and subsequent legislation that China or the United States may adopt in the future, or other events in China could disrupt our ability to continue to rely upon manufacturers located in China, including Hengrui. In addition, if we are not able to obtain adequate supplies of our product candidates or the drug substances used to manufacture them, it will be more difficult for us to develop our product candidates and compete effectively.

Large pharmaceutical companies with greater resources, either through acquisitions, market consolidation or otherwise, may be able to obtain privileged access to manufacturing capacity and supply of material needed for the manufacture of our product candidates or other similar competing drugs. If our competitors are able to use

their resources to secure preferential access to the supply capacity of third party manufacturers, or if third party manufacturers elect to terminate their contracts with us in favor of exclusive contracts with other larger pharmaceutical companies, our ability to obtain supply of our product candidates or any other future product candidates may be impacted resulting in significant delays and higher costs for development and commercialization of our product candidates. We may not be able to complete our clinical trials or market our product candidates at scale without stable partnerships with third party manufacturers who produce our product candidates or other drug compounds necessary for our product candidates. Shifting manufacturing relationship to another third-party manufacturer takes significant time and resources, and could delay development and commercialization of our product candidates.

***We may seek to establish collaborations and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans.***

The advancement of our product candidates and development programs and the potential commercialization of our current and future product candidates will require substantial additional cash to fund expenses. For some of our programs, we may decide to collaborate with other pharmaceutical and biotechnology companies with respect to development and potential commercialization. Likely collaborators may include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. In addition, if we are able to obtain regulatory approval for product candidates from foreign regulatory authorities, we may enter into collaborations with international biotechnology or pharmaceutical companies for the commercialization of such product candidates.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the potential differentiation of our product candidate from competing product candidates, design or results of clinical trials, the likelihood of approval by the FDA or comparable foreign regulatory authorities and the regulatory pathway for any such approval, the potential market for the product candidate, the costs and complexities of manufacturing and delivering the product to patients and the potential of competing products. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available for collaboration and whether such a collaboration could be more attractive than the one with us for our product candidate. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

Collaborations are complex and time-consuming to negotiate and document. Further, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. Any collaboration agreements that we enter into in the future may contain restrictions on our ability to enter into potential collaborations or to otherwise develop specified product candidates. We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense.

In addition, if we enter into such collaborations, we will have limited control over the amount and timing of resources that our collaborators will dedicate to the development or commercialization of our product candidates. Our ability to generate revenues from these arrangements will depend on any future collaborators'

abilities to successfully perform the functions assigned to them in these arrangements. Any future collaborators may have the right to abandon research or development projects and terminate applicable agreements, including funding obligations, prior to or upon the expiration of the agreed upon terms.

***Our employees and independent contractors, including collaborators, principal investigators, CROs, consultants and vendors, may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.***

We are exposed to the risk that our employees and independent contractors, including collaborators, principal investigators, CROs, consultants and vendors may engage in misconduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violate: (i) the laws and regulations of the FDA and other comparable foreign regulatory requirements, including those laws that require the reporting of true, complete and accurate information to such authorities; (ii) manufacturing standards, including cGMP requirements, (iii) federal and state data privacy, security, fraud and abuse and other healthcare laws and regulations in the United States and abroad; (iv) laws that require the true, complete and accurate reporting of financial information or data; or (v) laws that prohibit insider trading. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, the creation of fraudulent data in our or our collaborators' nonclinical studies or clinical trials, or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. In addition, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and financial results, including, without limitation, the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, imprisonment, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws and curtailment of our operations, any of which could adversely affect our business, financial condition, results of operations and prospects.

***Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor or other third party will discover them or that our trade secrets will be misappropriated or disclosed.***

Because we currently rely on third parties to manufacture our product candidates and to perform quality testing, we must, at times, share our proprietary technology and confidential information, including trade secrets, with them. We seek to protect our trade secrets, in part, by entering into confidentiality agreements, and, if applicable, material transfer agreements, collaborative research agreements, service agreements, consulting agreements or other similar agreements with our collaborators, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors or other third parties, are intentionally or inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets and despite our efforts to protect our trade secrets, a competitor's or other third party's discovery of our confidential information or other unauthorized use or disclosure of such information would impair our

competitive position and may have a material adverse effect on our business, financial condition, results of operations and prospects.

## Risks Related to Commercialization of Our Product Candidates

***We face significant competition from entities that have made substantial investments into developing novel treatments for patients with obesity, including large pharmaceutical companies with approved therapies in our current indications, and biopharmaceutical, specialty pharmaceutical and biotechnology companies developing novel treatments and technology platforms.***

The development and commercialization of therapies for the treatment of obesity is highly competitive. Our product candidates, if approved, will face significant competition, including from well-established, currently marketed therapies that have been developed by large, well-known pharmaceutical companies, and our failure to demonstrate a meaningful improvement to the existing standard of care may prevent us from achieving significant market penetration. In particular, there is intense competition in the obesity field, especially with the advent of GLP-1 weight management medications, such as Wegovy, marketed by Novo Nordisk, and Zepbound, marketed by Eli Lilly. There are numerous other companies that have commercialized or are developing treatments for obesity that we will compete with, including Amgen, AstraZeneca, Boehringer Ingelheim, Merck, Pfizer, QL Biopharma, Roche, Structure Therapeutics, Viking Therapeutics and Zealand Pharma. We face competition from these companies and other major pharmaceutical and biotechnology companies, including specialty pharmaceutical companies, and academic institutions, governmental agencies and public and private research institutions, among others.

Many of these aforementioned products have been marketed for several years and are well established among physicians, patients, guidelines and third-party payers, creating potential adoption and pricing challenges for new entrants, such as requiring demonstration of incremental value or benefits and/or reduction of healthcare system costs. These challenges will impact current and future products as they look to enter or expand the market.

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 be a longer lasting or a more efficacious treatment, or receive FDA or other applicable regulatory approval more rapidly than any of 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. Furthermore, established competitors have, and may in the future, pursue aggressive pricing strategies or enter into discounted distribution arrangements to defend or expand their market share, which could intensify pricing pressure and create additional barriers to commercial success for our product candidates. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic products. There are generic products currently on the market for certain of the indications that we are pursuing and additional products are expected to become available on a generic basis over the coming years. If our product candidates are approved, we expect that they will be priced at a significant premium over competitive generic products.

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, nonclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do.

Moreover, many of these aforementioned competing products have been marketed for several years and are well established among physicians, patients and guidelines. Mergers and acquisitions in the pharmaceutical 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 commercial success of any of our current or future product candidates will depend upon the degree of market acceptance of such product candidates by physicians, patients, healthcare payors and others in the medical community.***

Even if any of our current or future product candidates receive regulatory approval, they may not gain market acceptance among physicians, patients, healthcare payors or others in the medical community. The commercial success of any of our current or future product candidates will depend significantly on the broad adoption and use of the resulting product by these individuals and organizations for approved indications. The degree of market acceptance of our products will depend on a number of factors, including:

- demonstration of clinical efficacy and safety, including as compared to any more-established products or other alternative products that may later be approved;
- the indications for which any of our current or future product candidates are approved, if any;
- the limitation of our targeted patient population and other limitations or warnings contained in any FDA-approved labeling;
- acceptance of a new drug for the relevant indication by healthcare providers and their patients;
- the pricing and cost-effectiveness of our products, as well as the cost of treatment with our products in relation to alternative treatments and therapies;
- our ability to obtain and maintain sufficient third-party coverage and adequate reimbursement from government healthcare programs, including Medicare and Medicaid, private health insurers and other third-party payors;
- the price concessions required by third-party payors to obtain coverage;
- the willingness of patients to pay all, or a portion of, out-of-pocket costs associated with our products in the absence of sufficient third-party coverage and adequate reimbursement;
- any restrictions on the use of our products, and the prevalence and severity of any adverse effects;
- potential product liability claims;
- the timing of market introduction of our products as well as availability, safety and efficacy of competitive drugs;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the effectiveness of our or any current or future collaborators' sales and marketing strategies; and
- unfavorable publicity relating to the product, or favorable publicity about competitive products.

If any of our current or future product candidates is approved but does not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors or patients, we may not generate sufficient revenue from that product and may not become or remain profitable. Our efforts to educate the medical community and third-party payors regarding the benefits of our products may require significant resources and may never be successful.

***The successful commercialization of any of our current or future product candidates, if approved, will depend in part on the extent to which governmental authorities and health insurers establish coverage, adequate reimbursement levels and favorable pricing policies.***

The availability of coverage and the adequacy of reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third-party payors are essential for most patients to be able to afford prescription medications such as any of our current or future product candidates, if approved. Our ability to achieve coverage and acceptable levels of reimbursement for our products by third-party payors will have an effect on our ability to successfully commercialize those products. Accordingly, we will need to successfully implement a coverage and reimbursement strategy for any approved product candidate. Even if we obtain coverage for a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments or other cost-sharing that patients find unacceptably high.

If we participate in the Medicaid Drug Rebate Program or other governmental pricing programs, in certain circumstances, our products would be subject to ceiling prices, rebates, or other limitations set by such programs, which could reduce the revenue we may generate from any such products. Participation in such programs would also expose us to the risk of significant civil monetary penalties, sanctions and fines should we be found to be in violation of any applicable obligations thereunder.

Third-party payors increasingly are challenging prices charged for biopharmaceutical products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs when an equivalent generic drug or a less expensive therapy is available. It is possible that a third-party payor may consider our products as substitutable and offer to reimburse patients only for a less expensive competitor product. Even if we are successful in demonstrating improved efficacy or improved convenience of administration with our products, pricing of existing drugs may limit the amount we will be able to charge for our products. These payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in product development. Statutory constraints, including those limiting use of drugs for weight loss, or agency interpretations of those statutes may limit coverage for certain drug products by governmental payors. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our products and may not be able to obtain a satisfactory financial return on products that we may develop.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs will be covered. Some third-party payors may require pre-approval of coverage or implement prior authorization or step therapy programs for new or innovative devices or drug therapies before they will reimburse patients who use such therapies, which may be time-consuming or costly for patients and lead to a reduction in revenue. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for any of our current or future product candidates. Our success instead could depend on the ability and willingness of patients to pay out-of-pocket for our product candidates, if approved.

Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from

countries where they may be sold at lower prices than in the United States. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, the level of reimbursement. In addition, if we participate in the Medicaid Drug Rebate Program or other federal programs, we would be required to calculate and report certain price reporting metrics to the government, such as best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, programs we participate in may require us to extend mandatory discounts or pay rebates.

Obtaining and maintaining reimbursement status is time-consuming, costly and uncertain. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs. However, no uniform policy for coverage and reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, and, in some cases, at short notice, and we believe that changes in these rules and regulations are likely. For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used may not be available, which may impact physician utilization.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe and other countries has and will continue to put pressure on the pricing and usage of any of our current or future product candidates, if approved in these jurisdictions. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our products. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our products. We expect to experience pricing pressures in connection with the sale of any of our products due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative and regulatory changes. The downward pressure on healthcare costs in general, and prescription drugs, surgical procedures and other treatments in particular, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. See “Risks Related to Our Business Operations and Industry—Current and future U.S. healthcare reform legislation or regulation may increase the difficulty and cost for us to obtain coverage for and commercialize any of our current or future product candidates and may adversely affect the prices we may set” below for additional related information.

***Economic uncertainty may reduce patient demand for any of our current or future product candidates, if approved, which may adversely affect our business, financial condition and results of operations.***

To the extent that any of our current or future product candidates are approved for indications that are not covered by or reimbursable through governmental authorities and health insurers, patients will bear the entire cost of our products. The decision to undergo therapy using our products for non-covered indications is thus driven by patient demand, which may be influenced by a number of factors, such as:

- the success of our sales and marketing programs, including our consumer marketing initiatives;
- the extent to which physicians recommend our products, if approved, to their patients;
- consumer sentiment about the benefits and risks of obesity drugs generally and our products, if approved, in particular, including satisfaction of patient expectations;
- the cost, safety and effectiveness of our products, if approved, in comparison to other obesity drugs; and
- general consumer confidence, which may be impacted by economic and political conditions.

Economic downturns in the United States and international markets would likely have an adverse effect on demand for our products, if approved. Our business, financial condition and results of operations will be adversely affected if we cannot generate significant patient demand for our products, if approved.

***If we receive regulatory approvals for any of our current or future product candidates, we may face substantial competition from compounding pharmacies.***

Under the Federal Food, Drug, and Cosmetic Act, or the FDCA, the FDA has oversight over the compounding of human drug products without an approved drug application. Compounding is a practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient.

Section 503A of the FDCA establishes conditions under which compounded human drug products are exempt from certain requirements of the FDCA, including prior approval of an NDA, compliance with cGMPs, and labeling requirements, provided that the drug is compounded on the basis of receipt of valid patient-specific prescriptions and meets other requirements. Section 503B of the FDCA established conditions for a new category of compounders known as outsourcing facilities, which may compound a drug without marketing approval, but are subject to cGMP requirements and other obligations. Subject to these conditions, outsourcing facilities may distribute compounded drugs either pursuant to patient-specific prescriptions or in response to an order from a health care provider, such as a hospital, that is not for an identified individual patient (e.g., for office stock).

Section 503A of the FDCA restricts compounding drugs that are essentially copies of commercially available drugs, but certain amounts are permissible under the law as long as the compounding is not done “regularly or in inordinate amounts.” However, all other conditions of Section 503A must be met, including that the compounding is done on the basis of a valid prescription for an individual patient. When a drug is on the FDA’s drug shortage list, meaning that the demand or projected demand for the drug within the United States exceeds the supply of the drug, that drug is not considered to be “commercially available” such that the limitation on compounding “essentially copies” is lifted. The FDA intends to consider a compounded drug product to be essentially a copy of a commercially available drug if it has the same API, has the same, similar, or an easily substitutable dosage strength; and can be used by the same route of administration.

Outsourcing facilities registered under Section 503B are also restricted from making essentially a copy of an FDA-approved drug, but this limitation is lifted for identical or nearly identical copies of an FDA-approved drug if that drug is on the FDA's drug shortage list. When a drug is on the FDA's drug shortages list, an outsourcing facility regulated under Section 503B of the FDCA can use a bulk drug substance, also known as an API, to make that drug. The FDA considers a compounded drug to be essentially a copy of a commercially available drug under Section 503B if the compounded drug product and the FDA-approved drug have the same API, route of administration, dosage form, strength, and excipients.

A number of GLP-1 products have previously been identified on the FDA shortage list, allowing for "essentially copies" of these drugs to be compounded by outsourcing facilities, and where applicable, 503A compounders, and sold to meet demand. For example, tirzepatide and semaglutide, the active ingredients in Zepbound and Wegovy, respectively, have previously been on the FDA's drug shortage list, and compounding facilities have and continue to compound these drugs. These compounded formulations of GLP-1 products are generally less expensive than the branded, approved products, so could be a more attractive option for patients, particularly where not covered and reimbursed by third party payors.

Although the FDA announced that the shortages of tirzepatide and semaglutide have been resolved, the FDA was recently challenged in a lawsuit brought by the compounding industry regarding this decision. The Court denied the plaintiffs' preliminary injunction motions with respect to both the removal of tirzepatide and semaglutide. While the lawsuit is currently on appeal, the FDA has announced that it has ended enforcement discretion against compounders of both tirzepatide and semaglutide. However, the FDA's removal of these products from the shortage list in March and April 2025 has not yet cleared the market of compounded versions of the products, which could present a competitive threat to us if we obtain approval for our product candidates. Moreover, even if we obtain approval and our products are not on the shortage list, we could nevertheless face competition from compounded, less expensive versions of our product candidates akin to the availability of compounded tirzepatide and semaglutide.

The immediate availability of compounded versions of GLP-1 products may impact our pricing strategy and market penetration, and undermine our ability to establish a strong market position. Furthermore, any adverse events or quality issues associated with compounded versions of these products could negatively impact the perception of our product. These competitive pressures could materially and adversely affect our business and financial condition.

***Governments outside the United States tend to impose strict price controls, which may adversely affect our revenues, if any.***

In some countries, particularly the EU member states, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU member states and parallel distribution, or arbitrage between low-priced and high-priced EU member states, can further reduce prices. In some countries, we may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of our product candidate to other available therapies in order to obtain or maintain reimbursement or pricing approval. Publication of discounts by third-party payors or authorities may lead to further pressure on prices or reimbursement levels within the country of publication and other countries. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be adversely affected.

***If we are unable to develop our sales, marketing and distribution capability on our own or through collaborations with marketing partners, we will not be successful in commercializing our product candidates.***

We currently have no marketing, sales or distribution capabilities. We intend to establish a sales and marketing organization, either on our own or in collaboration with third parties, with technical expertise and supporting distribution capabilities to commercialize one or more of our product candidates that may receive regulatory approval in key territories. These efforts will require substantial additional resources, some or all of which may be incurred in advance of any approval of the product candidate. Any failure or delay in the development of our or third parties' internal sales, marketing and distribution capabilities would adversely impact the commercialization of our product candidates.

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

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe any future products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

With respect to our existing and future product candidates, we may choose to collaborate with third parties that have direct sales forces and established distribution systems to serve as an alternative to our own sales force and distribution systems. Our future product revenue may be lower than if we directly marketed or sold our product candidates, if approved. In addition, any revenue we receive will depend in whole or in part upon the efforts of these third parties, which may not be successful and are generally not within our control. If we are not successful in commercializing any approved products, our future product revenue will suffer and we may incur significant additional losses.

If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

***If the market opportunities for any of our current or future product candidates are smaller than we believe they are, our revenue may be adversely affected, and our business may suffer.***

The precise incidence and prevalence for all the conditions we aim to address with our product candidates are unknown. Our projections of both the number of people who have these conditions and their associated diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including sales of our competitors, our own market insights, internal market intelligence and internally generated data and assumptions, scientific literature, surveys of clinics, patient foundations or market research. Market opportunity estimates, whether obtained or derived from third-party sources or developed internally, are subject to significant uncertainty and are based on assumptions and estimates that may not prove to be accurate. Further, new clinical trials may change the estimated incidence or prevalence of these diseases. The total addressable market across all of our product candidates will ultimately depend upon, among other things, the diagnosis criteria included in the final label for each of our product candidates approved for sale for these indications, the ability of our product candidates to improve on the safety, convenience, cost and efficacy of competing therapies or therapies in development, acceptance by the medical community and patients, drug pricing and reimbursement. The number of patients in the United States and other major markets and elsewhere may turn out to be lower than expected, patients may not be otherwise

amenable to treatment with our product candidates or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our business, financial condition, results of operations and prospects. Further, even if we obtain significant market share for our product candidates, because some of our potential target populations are very small, we may never achieve profitability despite obtaining such significant market share.

***Public opinion and scrutiny of treatments for obesity may impact public perception of our company and product candidates, or may adversely affect our ability to conduct our business and our business plans.***

Public perception may be influenced by claims, such as claims that our product candidates are unsafe, unethical or immoral and, consequently, our approach may not gain the acceptance of the public or the medical community. Negative public reaction to treatments for obesity in general could result in greater government regulation and stricter labeling requirements of products to treat these chronic conditions, including our product candidates, if approved, and could cause a decrease in the demand for any product candidates we may develop. For example, there is widespread awareness of gastrointestinal side effects and lean muscle mass loss associated with obesity management medications, and severe adverse events observed with GLP-1-based therapies include, but are not limited to, acute pancreatitis, acute gallbladder disease, acute kidney injury and worsening of diabetic retinopathy. Such side effects associated with GLP-1-based therapies may negatively impact public perception of us or our incretin-based product candidates. Adverse public attitudes may also adversely impact our ability to enroll clinical trials. Moreover, our success will depend upon physicians specializing in the treatment of those diseases that our product candidates target prescribing, and their patients being willing to receive, treatments that involve the use of our product candidates in lieu of, or in addition to, existing treatments they are already familiar with and for which greater clinical data may be available. Adverse events 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, increased governmental regulation, unfavorable public perception, potential regulatory delays in the testing or approval of our product candidates, stricter labeling requirements for those product candidates that are approved and a decrease in demand for any such product candidates. More restrictive government regulations or negative public opinion could have an adverse effect on our business, financial condition, results of operations and prospects, and may delay or impair the development and, if approved, commercialization of our product candidates or demand for any products we may develop.

## Risks Related to Our Business Operations and Industry

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

Our quarterly and annual operating results may fluctuate significantly in the future due to a variety of factors, many of which are outside of our control and may be difficult to predict, including the following:

- the timing and success or failure of clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry;
- our ability to successfully recruit and retain subjects for clinical trials, and any delays caused by difficulties in such efforts;
- our ability to obtain marketing approval for our product candidates and the timing and scope of any such approvals we may receive;
- the timing and cost of, and level of investment in, research and development activities relating to our product candidates, which may change from time to time;

- the cost of manufacturing our product candidates, which may vary depending on the quantity of production and the terms of its agreements with manufacturers;
- our ability to attract, hire and retain qualified personnel;
- expenditures that we will or may incur to develop additional product candidates;
- the level of demand for our product candidates should they receive approval, which may vary significantly;
- the risk/benefit profile, cost and reimbursement policies with respect to our product candidates, if approved, and existing and potential future therapeutics that compete with our product candidates;
- the changing and volatile U.S. and global economic environments;
- the timing of milestone and royalty payments under the Hengrui License Agreement; and
- future accounting pronouncements or changes in its accounting policies.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our operating results or revenue fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated guidance we may provide.

***Our success is dependent on our ability to attract and retain highly qualified management and other clinical and medical personnel.***

Our success depends in part on our continued ability to attract, recruit, retain, manage and motivate highly qualified management, clinical, and scientific personnel, and we face significant competition for experienced personnel. We are highly dependent upon our executive team, as well as our other employees. The loss of services of any of these individuals could delay or prevent the successful development of our product pipeline, initiation or completion of our clinical trials and nonclinical studies, regulatory approvals or the commercialization of any of our current or future product candidates. Although we have executed employment agreements with each of the members of our executive team, these agreements are terminable at will with or without notice and, therefore, we may not be able to retain their services as expected. We do not currently maintain “key person” life insurance on the lives of our executives or any of our employees. This lack of insurance means that we may not have adequate compensation for the loss of the services of these individuals.

In addition, employment 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 will need to expand and effectively manage our managerial, operational, financial and other resources in order to successfully pursue our clinical development and commercialization efforts. We may not be successful in maintaining our unique company culture and continuing to attract or retain qualified management, clinical, and scientific personnel in the future due to the intense competition for qualified personnel among

biopharmaceutical, biotechnology and other businesses. Our industry has experienced a high rate of turnover of management personnel in recent years. If we are not able to attract, integrate, retain and motivate necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

***Due to the significant resources required for the development of our pipeline, and depending on our ability to access capital, we must prioritize the development of certain product candidates over others. Moreover, we may fail to expend our limited resources on product candidates or indications that may have been more profitable or for which there is a greater likelihood of success.***

We are initially focused on the development of ribupatide for obesity, and we have three other product candidates that are at various stages of clinical development. We must seek to maintain a process of prioritization and resource allocation to maintain an optimal balance between aggressively pursuing ribupatide, and ensuring the development of additional potential product candidates in our pipeline.

Due to the significant resources required for the development of our product candidates, we are focusing on obesity-first and must decide which product candidates to pursue and advance and the amount of resources to allocate to each. Our decisions concerning the allocation of research, development, collaboration, management and financial resources toward particular product candidates or therapeutic areas may not lead to the development of any viable commercial products and may divert resources away from better opportunities. If we make incorrect determinations regarding the viability or market potential of any of our product candidates or misread trends in the pharmaceutical industry, in particular for obesity treatments, our business, financial condition and results of operations could be materially adversely affected. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other product candidates or other indications that may later prove to have greater commercial potential than those we choose to pursue, or relinquish valuable rights to such product candidates through collaboration, licensing, or other royalty arrangements in cases in which it would have been advantageous for us to invest additional resources to retain sole development and commercialization rights.

***We are subject to various U.S. federal, state and foreign healthcare laws and regulations, which could increase compliance costs, and our failure to comply with these laws and regulations could harm our reputation, subject us to significant fines and liability or otherwise adversely affect our business.***

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, marketing personnel, third-party payors, patient organizations and customers expose us to broadly applicable foreign, federal and state fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute any products for which we obtain regulatory approval. Such laws include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or providing any remuneration (including any kickback, bribe or certain rebates), directly or indirectly, overtly or covertly, in cash or in kind, in return for, either the referral of an individual or the purchase, lease, or order, or arranging for or recommending the purchase, lease, or order of any good, facility, item or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. In

addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act or federal civil monetary penalties (discussed below);

- the federal false claims laws, including the civil False Claims Act, and civil monetary penalties laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, to the federal government, claims for payment or approval 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 or causing to be made a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. Manufacturers can be held liable under the federal False Claims Act even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The federal False Claims Act also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the federal False Claims Act and to share in any monetary recovery;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, 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;
- the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to payments and other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician practitioners (physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiology assistants and certified nurse-midwives), and teaching hospitals and other healthcare providers, as well as ownership and investment interests held by physicians and their immediate family members; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; some state laws require biopharmaceutical companies to comply with the biopharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; some state laws that require biopharmaceutical companies to report information on the pricing of certain drug products; and some state and local laws that require the registration or pharmaceutical sales representatives.

Efforts to ensure that our current and future business arrangements both internally and with third parties will comply with applicable healthcare laws and regulations will involve ongoing substantial costs. It is possible that governmental authorities will conclude that our business practices, including certain consulting agreements we have entered into with physicians who are paid, in part, in the form of stock or stock options, may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. Due to the breadth of these laws, the narrowness of statutory exceptions and regulatory safe harbors available, and the range of interpretations to which they are subject, it is possible that some of our

current or future practices might be challenged under one or more of these laws. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government-funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations. Defending against any such actions can be costly and time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business are found not to be in compliance with applicable laws or regulations, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs.

***Current and future U.S. healthcare reform legislation or regulation may increase the difficulty and cost for us to obtain coverage for and commercialize any of our current or future product candidates and may adversely affect the prices we may set.***

In the United States and some foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system, including cost-containment measures that may reduce or limit coverage and reimbursement for newly approved drugs and affect our ability to profitably sell any of our current or future product candidates for which we obtain regulatory approval. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare.

For example, in 2010, the Affordable Care Act, or the ACA, was enacted in the United States. Among other provisions, the ACA established an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents; extended manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations; expanded the entities eligible for discounts under the 340B drug pricing program; increased the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program; established a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research; and established a Center for Medicare & Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

Since its enactment, there have been executive, judicial and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, beginning April 1, 2013, Medicare payments to providers were reduced under the sequestration required by the Budget Control Act of 2011, which will remain in effect through the 2032 fiscal year, unless additional Congressional action is taken. Additionally, on January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers. On March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminated the statutory cap on drug manufacturers' Medicaid drug rebate liability, beginning January 1, 2024. The rebate was previously capped at 100% of a drug's average manufacturer price. Further, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs. Such scrutiny has resulted in several recent 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 assistance programs, and reform government program reimbursement methodologies for products.

Most significantly, the Inflation Reduction Act, or the IRA, was enacted in 2022. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare, with prices that can be negotiated subject to a cap (with resulting prices for the initial ten drugs first effective in 2026), imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023), redesigns the Medicare Part D benefit (beginning in 2025), and replaces the Part D coverage gap discount program with a new discounting program (which began on January 1, 2025). Under the IRA, small molecule drugs and biologics that otherwise qualify for selection first become eligible for price negotiation seven and eleven years, respectively, after U.S. FDA approval. The IRA permits the Secretary of Health and Human Services, or HHS, to implement many of these provisions through guidance, as opposed to regulation, for the initial years. CMS published the negotiated prices for the initial ten drugs, which went into effect in January 2026, and for the subsequent 15 drugs, which will first be effective in 2027, as well as the next 15 drugs that will be subject to price negotiation. Each year thereafter, more Part B and Part D products will become subject to the HHS price negotiation program. HHS has issued and will continue to issue guidance implementing the IRA, although the program is currently subject to legal challenges. While the impact of the IRA on us and the pharmaceutical industry cannot yet be fully determined, it is likely to be significant. Additional drug pricing proposals could appear in future legislation.

The One Big Beautiful Bill Act, which was enacted in July 2025, imposes significant reductions in the funding of the Medicaid program. Such reductions are expected to decrease the number of persons enrolled in Medicaid and reduce the services covered by Medicaid, which could adversely affect our sales of any product candidate that we commercialize.

The Trump administration is also pursuing a two-fold strategy to reduce drug costs in the U.S. While it is unclear whether and how the Trump proposals will be implemented, the Trump policies are likely to have a negative impact on the pharmaceutical industry and on our ability to receive adequate revenues for our product candidates, if approved. On the one hand, President Trump has threatened to impose significant tariffs on pharmaceutical manufacturers that do not adopt pricing policies such as most favored nation pricing, which would tie the price for drugs in the U.S. to the lowest price in a group of other countries. In response, multiple manufacturers have reportedly entered into confidential pricing agreements with the federal government. On the other hand, the Trump administration is pursuing traditional regulatory pathways to impose drug pricing policies, although final regulations have not yet been published. Even regulatory proposals or executive actions that are ultimately deemed unlawful could negatively impact the U.S. pharmaceutical sector and our business. In addition, pharmaceutical pricing and marketing has long been the subject of considerable discussion in Congress and among policymakers, and it is possible that Congress could enact additional laws that negatively affect the pharmaceutical industry.

At the state level, state governments have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or reimbursement constraints, discounts, restrictions on certain product access, marketing cost disclosure, drug price reporting and other transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Some states have enacted legislation creating so-called prescription drug affordability boards with the goal of imposing price limits on certain drugs in these states, and at least one state board is imposing an upper payment limit. States are also seeking to implement general, across the board price caps for pharmaceuticals, or are seeking to regulate drug distribution. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, financial condition, results of operations and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in

their prescription drug and other healthcare programs. These measures could reduce the ultimate demand for any of our current and future product candidates, if approved, or put pressure on our product pricing, which could negatively affect our business, financial condition, results of operations and prospects.

We expect that these existing laws and other healthcare reform measures both at the federal and state level that may be adopted in the future may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

Our revenue prospects could be affected by changes in healthcare spending and policy in the United States and abroad. We operate in a highly regulated industry and new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to healthcare availability, the method of delivery or payment for healthcare products and services could negatively impact our business, operations and financial condition. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our current or future product candidates, if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to obtain coverage and reimbursement approval for a product;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

Similar political, economic and regulatory developments are occurring in the EU and may affect the ability of pharmaceutical companies to profitably commercialize their products. In addition to continuing pressure on prices and cost containment measures, legislative developments at the EU or member state level may result in significant additional requirements or obstacles that may increase our operating costs. The delivery of healthcare in the EU, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than EU, law and policy. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most EU member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing EU and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to commercialize our product candidates, if approved. In markets outside of the United States and EU, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies.

On December 13, 2021, Regulation No 2021/2282 on Health Technology Assessment, or HTA, amending Directive 2011/24/EU, was adopted. The Regulation entered into force in January 2022 and has been applicable since January 2025, with phased implementation based on the type of product, i.e. oncology and advanced therapy medicinal products as of 2025, orphan medicinal products as of 2028, and all other medicinal products by 2030. The Regulation intends to boost cooperation among EU member states in assessing health technologies, including new medicinal products, and provide the basis for cooperation at the EU level for joint

clinical assessments in these areas. It will permit EU member states to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the highest potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU member states will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technology, and making decisions on pricing and reimbursement.

***Product liability lawsuits against us or any of our future collaborators could divert our resources and attention, cause us to incur substantial liabilities and limit commercialization of our product candidates.***

We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing and use of pharmaceutical products. Currently, we have no products that have been approved for commercial sale; however, the use of our product candidates by us and any collaborators in clinical trials, and the sale of these product candidates, if approved, in the future, may expose us to liability claims. We face an inherent risk of product liability lawsuits related to the use of our product candidates in patients and will face an even greater risk if product candidates are approved by regulatory authorities and introduced commercially. Product liability claims may be brought against us by participants enrolled in our clinical trials, patients, health care providers, pharmaceutical companies, our collaborators or others using, administering or selling any of our future approved products. If we cannot successfully defend ourselves against any such claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for any of our future approved products;
- injury to our reputation;
- withdrawal of clinical trial participants;
- termination of clinical trial sites or entire trial programs;
- significant litigation costs;
- substantial monetary awards to, or costly settlements with, patients or other claimants;
- product recalls or a change in the indications for which they may be used;
- loss of revenue;
- diversion of management and scientific resources from our business operations; and
- the inability to commercialize our product candidates.

Although the clinical trial process is designed to identify and assess potential side effects, clinical development does not always fully characterize the safety and efficacy profile of a new medicine, and it is always possible that a drug, even after regulatory approval, may exhibit unforeseen side effects. If our product candidates were to cause adverse side effects during clinical trials or after approval, we may be exposed to substantial liabilities. Physicians and patients may not comply with any warnings that identify known potential adverse effects and patients who should not use our product candidates. If any of our product candidates are approved for commercial sale, we will be highly dependent upon consumer perceptions of us and the safety and quality of our products. We could be adversely affected if we are subject to negative publicity associated with illness or other adverse effects resulting from patients' use or misuse of our products or any similar products distributed by other companies.

Although we maintain product liability insurance coverage consistent with industry norms, including clinical trial liability, this insurance may not fully cover potential liabilities that we may incur. The cost of any product liability litigation or other proceeding, even if resolved in its favor, could be substantial. We will need to increase our insurance coverage if we commercialize any product that receives regulatory approval. In addition, insurance coverage is becoming increasingly expensive. If we are unable to maintain sufficient insurance coverage at an acceptable cost or to otherwise protect against potential product liability claims, it could prevent or inhibit the development and commercial production and sale of our product candidates, which could harm our business, financial condition, results of operations and prospects.

***Our insurance policies are expensive and protect us from only some business risks, which will leave us exposed to significant uninsured liabilities.***

We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include property, general liability, employee benefits liability, commercial automobile, workers' compensation, transportation and storage, cyber liability, clinical trials, directors' and officers' and employment practices insurance. We do not know, however, if we will be able to maintain insurance with adequate levels of coverage. No assurance can be given that an insurance carrier will not seek to cancel or deny coverage after a claim has occurred. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our business, financial condition, results of operations and prospects.

***We and our service providers may be subject to a variety of ever-evolving state, federal, and foreign data protection, privacy and security obligations, including laws, regulations, and contractual provisions, which could increase compliance costs, and our actual or perceived failure to comply with such laws and obligations could subject us to potentially significant liability, fines or penalties and otherwise harm our business.***

We and our service providers receive, maintain, use and otherwise process sensitive information, including confidential business, employee and health-related information, and are subject to laws and regulations governing the privacy and security of such information. The global data protection landscape is rapidly evolving, and we and our service providers may be affected by or subject to existing, amended, or new laws and regulations in the future, including due to expanding operations or if we operate in foreign jurisdictions. These laws and regulations may be subject to differing interpretations, thus creating potentially complex compliance issues for us and our service providers, strategic partners and future customers. 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 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.

As our operations and business grow, we may become subject to or affected by new or additional data protection laws and regulations and face increased scrutiny or attention from regulatory authorities. In the United States, numerous federal and state laws and regulations, including health information privacy laws, data breach notification laws and consumer protection laws, that govern the collection, use, storage, transfer, disclosure, protection and other processing of health-related and other personal information could apply to our operations or the operations of our collaborators and third-party service providers. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data and CROs) that are subject to privacy and security requirements under HIPAA. Consequently, depending on the facts and circumstances, we could be subject to significant penalties if we knowingly receive individually identifiable health information from a HIPAA-covered healthcare provider, research institution, or CRO that has not satisfied HIPAA's requirements for disclosure of individually identifiable health information. In addition, certain state laws govern the privacy and security of health-related and other personal information, many of

which may differ from each other and from HIPAA, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. By way of example, the California Consumer Privacy Act, as amended by the California Privacy Rights Act, or collectively, the CCPA, requires covered businesses that process the personal information of California residents to, among other things: (i) provide certain disclosures to California residents regarding the business's collection, use, and disclosure of their personal information; (ii) receive and respond to requests from California residents to access, delete, and correct their personal information, or to opt out of certain disclosures of their personal information; and (iii) enter into specific contractual provisions with service providers that process California resident personal information on the business's behalf. Additional compliance investment and potential business process changes may be required. Similar laws have been passed in other states, and are continuing to be proposed at the state and federal level, reflecting a trend toward more stringent privacy legislation in the United States. In addition to these comprehensive consumer privacy laws and proposals, a number of other states have passed or proposed more limited privacy laws that focus on specific privacy issues such as biometric data and the privacy of health and medical information, such as Washington state's My Health My Data Act, which has a private right of action that further increases the relevant compliance risk. Connecticut and Nevada have also passed similar laws regulating consumer health data. These various privacy and security laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products. State laws are changing rapidly and there is discussion in the U.S. Congress of a new comprehensive federal data privacy law to which we may likely become subject, if enacted. In the event that we are subject to or affected by HIPAA, the CCPA or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition.

In 2024, the National Security Division of the U.S. Department of Justice, or the DOJ, issued a new rule—referred to as the "Data Security Program," or DSP, to implement Executive Order 14117 aimed at preventing access to "bulk U.S. sensitive personal data" and "government-related data" by "countries of concern" (including China, Russia, Iran, North Korea, Cuba, and Venezuela) and "covered persons" (as all such terms are defined in the DSP). Effective as of April 8, 2025, and fully enforceable as of July 9, 2025, the DSP imposes stringent obligations on companies within its scope and prohibits or restricts "covered data transactions" that grant countries of concern or covered persons access to bulk U.S. sensitive personal data or any amount of government-related data. The DSP is new, complex and has yet to be enforced, and as such, there is a risk that our interpretation of its applicability, scope, and requirements is incorrect, incomplete, or misapplied. Compliance with the DSP may require us to invest heavily in data security and compliance measures, such as implementing and complying with the Cybersecurity and Infrastructure Security Agency's guidelines and other burdensome recordkeeping, reporting, and auditing requirements. It may also require us to implement new processes, stop or restrict certain data transfers, alter the geographic scope of our operations, cease doing business with certain third parties or using certain tools or vendors, or change how data flows throughout our business, any of which could materially impact our business operations or hinder our ability to grow our business. Finally, non-compliance with the DSP could result in significant civil or criminal penalties, which could materially adversely affect our business, results of operations, and financial condition.

We may in the future be subject to the European Union General Data Protection Regulation and the United Kingdom General Data Protection Regulation, or, together, the GDPR. The GDPR, together with national legislation, regulations and guidelines of the European Economic Area, or EEA, member states and the UK governing the processing of personal data, impose comprehensive data privacy compliance obligations in relation to our collection, processing, sharing, disclosure, transfer and other use of data relating to an identifiable living individual or "personal data", including a principle of accountability and the obligation to demonstrate compliance through policies, procedures, training and audit, as well as regulating cross-border

transfers of personal data out of the EEA and the UK. Companies that are subject to the GDPR face compliance obligations and risk, including regulatory enforcement and potential fines for noncompliance of up to £17.5 million (€20 million) or 4% of the annual global revenues of the noncompliant company, whichever is greater.

Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States, and the efficacy and longevity of current transfer mechanisms between the EEA, and the United States remains uncertain. Case law from the Court of Justice of the European Union, or the CJEU, states that reliance on the standard contractual clauses—a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism—alone may not necessarily be sufficient in all circumstances and that transfers must be assessed on a case-by-case basis. We expect the existing legal complexity and uncertainty regarding international personal data transfers to continue, and international transfers to the United States, China, and to other jurisdictions more generally to continue to be subject to enhanced scrutiny by regulators. 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, and/or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, we may have to stop using certain tools and vendors and make other operational changes; we may have to implement alternative data transfer mechanisms under the GDPR and/ or take additional compliance and operational measures; and/or it could otherwise affect the manner in which we operate our business, and could adversely affect our business, operations and financial condition.

We may be subject to data privacy and similar laws in China. China's Personal Information Protection Law, or the PIPL, imposes various requirements on the collection, use processing, sharing and transfer of personal information. The PIPL also sets out data localization requirements for critical information infrastructure operators and personal information processors who process personal information above a certain threshold prescribed by the relevant authorities, unless a security assessment is passed. The PIPL also requires data processors to rely on a data export mechanism and comply with certain requirements prior to the transfer of personal information outside of China, such as compliance with a security assessment, or the Security Assessment, or certification by an agency designated by the relevant authorities, or Certification, or entering into standard form model contracts approved by the relevant authorities, or SCCs, with the overseas recipient, unless an exemption under the Provisions for Promoting and Regulating Cross-Border Data Flows , or the Provisions, applies, such as the transfer being necessary for the performance of a contract which the individual is a party to or necessary for cross-border HR management or the number of individuals' whose personal information is transferred is less than 100,000 since January 1st of the current year. According to the Provisions published by the CAC on March 22, 2024, a data processor must apply for the Security Assessment organized by the CAC under any of the following circumstances and receive an approval from the relevant authorities before the information may be transferred outside of the PRC: (i) where a data processor or a critical information infrastructure operator, or CIIO, provides important data overseas, (ii) where a CIIO transfers personal information overseas (unless an exemption applies) or (iii) where a personal information processor either transfers more than 1 million individuals' personal information or more than 10,000 individuals' sensitive personal information overseas since January 1st of the current year, in each case unless an exemption applies. Additionally, a data processor must enter into the SCCs with the overseas recipient and file this with the local CAC within 10 working days of the contract's effective date or obtain a Certification before transferring information overseas if the data processor either transfers more than 100,000 but less than 1 million individuals' personal information or transfers less than 10,000 individuals' sensitive personal information since January 1st of the current year, unless an exemption applies.

Our business involves cross-border data transfers from or into China, such as the access of certain PRC patient-level information from overseas. We have signed the SCCs regarding certain cross-border data flows and this has been filed with the local CAC. We expect that we have complied with such filing requirements. However, it is possible for the competent PRC government authorities to take a contrary position or adopt different interpretations on the SCCs, in which case we may become subject to penalties or other liabilities under the applicable CAC regulations in relation to our handling of the cross-border transfers.

Failure to comply with PIPL can result in fines of up to RMB 50 million or 5% of the prior year's total annual revenue for the personal information processor and/or a suspension of services or data processing activities. Other potential penalties include a fine of up to RMB 1 million on the person in charge or directly responsible personnel and, in serious cases, individuals and entities may be exposed to criminal liabilities under other local Chinese law, such as the Criminal Law of the People's Republic of China, thus going beyond the penalties imposed under the GDPR. The PIPL also prohibits responsible personnel for violations of the PIPL from holding high level management or data protection officer positions in relevant enterprises.

It is also generally unclear how the laws will be interpreted and enforced in practice by the relevant government authorities as the PIPL and its implementing regulations and measures are drafted broadly, thus leaving great discretion to the relevant government authorities to exercise. As such, our compliance approach towards the PIPL may be subject to further change and we may need to expend significant time and resources in re-evaluating our internal compliance framework to comply with the PIPL.

Compliance with U.S. and international data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, store, use, transfer, disclose and otherwise process data, update our data privacy and security policies and procedures, or in some cases, impact our ability to operate in certain jurisdictions. Failure by us or our collaborators and our service providers to comply with U.S. and international data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation and/or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose such information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend, could result in adverse publicity and adversely affect our business, financial condition, results of operations and prospects.

***Our information technology systems, or those of any of our third-party service providers, may fail or suffer security incidents, breaches, or compromises and other disruptions, which could result in a material disruption of our development programs, compromise sensitive information related to our business or prevent us from accessing critical information, potentially exposing us to liability or otherwise adversely affecting our business.***

In the ordinary course of business, we and our third-party service providers collect, store and transmit confidential information (including but not limited to intellectual property, proprietary and confidential business information and personal information). We face numerous and evolving cybersecurity risks that threaten the confidentiality, integrity and availability of our systems and confidential information. Our information technology systems and those of our third-party service providers, strategic partners and other contractors or consultants are vulnerable to attack, damage and interruption from computer viruses and malware (e.g. ransomware), malicious code embedded in open-source software, misconfigurations, "bugs" or other vulnerabilities in commercial software that is integrated into our (or our third-party service providers') systems, products or services, natural disasters, terrorism, war, telecommunication and electrical failures, hacking, cyberattacks, phishing attacks and other social engineering schemes, employee theft or misuse,

human error, fraud, denial or degradation of service attacks, sophisticated nation-state and nation-state-supported actors or unauthorized access or use by persons inside our organization, or persons with access to systems inside our organization. In addition, attacks upon information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. Furthermore, because the techniques (including artificial intelligence) used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. Any integration of artificial intelligence in our or any third party's operations, products or services is also expected to pose new or unknown cybersecurity risks and challenges. We may also experience security incidents that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence. There can also be no assurance that our cybersecurity risk management program and processes, including our policies, controls or procedures, will be fully implemented, complied with or effective in protecting our IT Systems and Confidential Information.

We and certain of our service providers are from time to time subject to cyberattacks and incidents, and we expect such attacks and incidents to continue in varying degrees. While we do not believe that we have experienced any material system failure, accident or security breach to date, we cannot guarantee that material incidents will not occur in the future. For example, the loss of clinical trial data from clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. We also currently rely on a third party to manufacture our product candidates, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any actual or perceived disruption or security incident affects our systems (or those of our third-party service providers) or were to result in a loss of or accidental, unlawful or unauthorized access to, use of, release of, or other processing of personally identifiable information, or damage to, our confidential or proprietary data or applications, or inappropriate disclosure of confidential or proprietary information, it could result in legal claims or proceedings (such as class actions), regulatory investigations and enforcement actions, the further development and commercialization of any of our current or future product candidates could be delayed, negative reputational impacts that cause us to lose existing or future customers, significant incident response, system restoration or remediation and future compliance costs, and we could be subject to significant fines, penalties or liabilities for any noncompliance to certain privacy and security laws. Any or all of the foregoing could materially adversely affect our business, operating results, and financial condition.

We have also outsourced elements of our information technology infrastructure, and as a result a number of third-party vendors may or could have access to our confidential information. If our third-party vendors fail to protect their information technology systems and our confidential and proprietary information, we may be vulnerable to disruptions in service and unauthorized access to our confidential or proprietary information and we could incur liability and reputational damage. If the information technology systems of our third-party vendors and other contractors and consultants become subject to disruptions or security breaches, incidents, or compromises, 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. Some of the federal, state and foreign government requirements include obligations of companies to notify individuals of security breaches involving particular categories of personally identifiable information, which could result from incidents experienced by us or by our vendors, contractors, or organizations with which we have formed strategic relationships. Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data

privacy and security obligations. Although we currently hold cybersecurity insurance, the costs related to significant security breaches or disruptions could be material and cause us to incur significant expenses and we cannot guarantee that any costs and liabilities incurred in relation to an attack or incident will be covered by our existing insurance policies or that such insurance will continue to be available on acceptable terms or in amounts sufficient to cover the potentially significant losses that may result for a security incident or breach.

***Our business could be affected by litigation, government investigations and enforcement actions.***

We currently operate in a number of jurisdictions in a highly regulated industry and we could be subject to litigation, government investigation and enforcement actions on a variety of matters in the United States or foreign jurisdictions, including, without limitation, intellectual property, regulatory, product liability, environmental, whistleblower, false claims, privacy, anti-kickback, anti-bribery, securities, commercial, employment and other claims and legal proceedings that may arise from conducting our business. Any determination that our operations or activities are not in compliance with existing laws or regulations could result in the imposition of fines, civil and criminal penalties, exclusion from participation in government-funded healthcare programs, such as Medicare and Medicaid, equitable remedies, including disgorgement, injunctive relief and/or other sanctions against us, and remediation of any such findings could have an adverse effect on our business operations.

Legal proceedings, government investigations and enforcement actions can be expensive and time-consuming. An adverse outcome resulting from any such proceedings, investigations or enforcement actions could result in significant damages awards, fines, penalties, exclusion from the federal healthcare programs, healthcare debarment, injunctive relief, product recalls, reputational damage and modifications of our business practices, which could have a material adverse effect on our business, financial condition, results of operations and prospects. Even if such a proceeding, investigation or enforcement action is ultimately decided in our favor, the investigation and defense thereof could require substantial financial and management resources.

## Risks Related to Our Intellectual Property

***If we or our current or future licensors are unable to obtain, maintain, defend and enforce patent or other intellectual property protection for any of our current or future product candidates or technology, or if the scope of the patent or other intellectual property protection obtained is not sufficiently broad, our competitors or other third parties could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize any of our current or future product candidates may be adversely affected.***

We rely, and may in the future rely, upon a combination of patent, trade secret and know-how for any of our current and future product candidates, and proprietary technologies to prevent third parties from exploiting our achievements, thus eroding our competitive position in our market. These legal measures afford only limited protection, and competitors or others may gain access to or use our intellectual property and proprietary information. Our success depends in large part on our ability to obtain, maintain, expand, enforce, and defend the scope, ownership or control, validity and enforceability of our intellectual property protection in the United States and other countries with respect to any of our current and future product candidates and other proprietary technologies we may develop. We generally seek, and may in the future seek, to protect our proprietary position, in part, by filing patent applications in the United States and abroad relating to any of our current and future product candidates and technology, manufacturing processes and methods of use. We may also seek to protect our proprietary position by acquiring or further in-licensing relevant issued patents or pending patent applications from third parties. We will endeavor to seek additional patent protection to cover proprietary features of our product candidates and novel discoveries that are important to our business. Many of our in-licensed patent families were initially drafted, filed, and prosecuted by our licensor, Hengrui, and even

where we now control the right to prosecution of such in-licensed patent families, we are and may in the future be required to solicit input and consider comments from Hengrui. Our control of prosecution for such in-licensed patent families is also limited to our territory and Hengrui still controls prosecution outside our territory. Hengrui could potentially make arguments or amendments in their territory that affect the scope or value of our in-licensed patent families in our territory. Additionally, some of our patent families are in an early stage of prosecution and cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, patents are issued from such applications, and then only to the extent the issued claims cover the third parties' activities. If we are unable to obtain, maintain, expand, enforce and defend the scope, ownership or control, validity and enforceability of our intellectual property protection, our business, financial condition, results of operations and prospects could be materially harmed.

Changes in either the patent laws or their interpretation in the United States and other jurisdictions may diminish our ability to protect our intellectual property, obtain, maintain, expand, enforce and defend our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our protection. We cannot predict whether the patent applications we currently or may in the future pursue or may in-license will issue as patents in any particular jurisdiction, whether the claims of any issued patents will provide sufficient protection against competitors or other third parties, or if these patents are challenged by our competitors, whether the patents will be found to be invalid, unenforceable, or not infringed or not owned or controlled by us. The patent prosecution process is expensive, time-consuming, and complex, and we may not be able to file, prosecute, maintain, enforce, defend or license all necessary or desirable patent applications or patents at a reasonable cost or in a timely manner or in all jurisdictions. It is also possible that we or our current or future licensors will fail, or previously failed, to identify patentable aspects of research and development output in time to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, licensees, third-party collaborators, CROs, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. Consequently, we may not be able to prevent any third party from using any of our technology that is in the public domain to compete with any of our current or future product candidates or technologies. In addition, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our inventions and the prior art allow our inventions to be patentable in light of the prior art. Furthermore, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we or our licensors were the first to invent the inventions claimed in any of our owned or licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions. If a third party can establish that we or our licensors were not the first to invent or the first to file for patent protection of such inventions, our patents and patent applications may not issue as patents and even if issued, may be challenged and invalidated or rendered unenforceable.

The patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. In particular, the patent position of obesity treatments is particularly uncertain given a significant amount of competition centered around certain specific chemical scaffolds and mechanisms of action, including certain of those associated with our product candidates. As a result, the issuance, scope, validity, enforceability, and commercial value of our owned and in-licensed patent rights are highly uncertain. Our current and future patent applications may not result in patents being issued.

Further, even if patents are granted, they may not afford sufficient protection of any of our current or future product candidates or their intended uses against competitors, nor can there be any assurance that the issued patents cannot be designed around, invalidated by third parties, or effectively prevent others from commercializing any of our current or future product candidates. Furthermore, even if granted, the resulting patents may be difficult to enforce. Obtaining and maintaining our owned and in-licensed patent protection depends on compliance with various procedural, document submission, information disclosure, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated if we fail to comply with these requirements. If we experience noncompliance events that cannot be corrected and we lose our patent rights, competitors could enter the market, which would have a material adverse effect on our business. Further, any issued patents that we own or license or may own or license in the future covering any of our current or future product candidates could be narrowed or found invalid or unenforceable if challenged in court or before administrative bodies in the United States or other countries, including the U.S. Patent and Trademark Office, or USPTO. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, lack of written description or non-enablement. In addition, patent validity challenges may, under certain circumstances, be based upon non-statutory obviousness-type double patenting, which, if successful, could result in a finding that the claims are invalid for obviousness-type double patenting. In certain circumstances, the finding could be cured by filing a retroactive terminal disclaimer over unexpired reference patent(s), which would result in a reduction of patent term, including a reduction or loss of a patent term adjustment granted by the USPTO. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld information material to patentability from the USPTO, or made a misleading statement, during prosecution. Also, patent terms, including any extensions or adjustments that may or may not be available to us, may not protect our competitive position on any of our current or future product candidates for an adequate amount of time, and we may be subject to claims challenging the inventorship, ownership, validity, enforceability of our owned or in-licensed patents and/or other intellectual property. Changes in U.S. patent law, or laws in other countries, could diminish the value of patents in general, thereby impairing our ability to protect any of our current or future product candidates. Further, if we encounter delays in our development and testing, clinical trials or regulatory review and approval of any of our current or future product candidates, the period of time during which we could market such product candidates under patent protection may be reduced (i.e., patents protecting such product candidates might expire before or shortly after such product candidates are commercialized). Thus, our owned and in-licensed patents may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours or afford us any meaningful competitive advantage.

Moreover, the claim coverage in a patent application can be significantly reduced before the corresponding patent is granted. Even if patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us or otherwise provide us with any competitive advantage. Any patents issuing from our owned and in-licensed patent applications may be challenged, narrowed, circumvented or invalidated by third parties. Consequently, we do not know whether any of our current or future product candidates and other proprietary technology will be protectable or remain protected by valid and enforceable patents. Even if a patent is granted, our competitors or other third parties may be able to circumvent the patent by developing similar or alternative technologies or products in a non-infringing manner which could materially adversely affect our business, financial condition, results of operations and prospects. Furthermore, our competitors or other third parties may avail themselves of safe harbors under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Amendments, to conduct research and clinical trials.

The issuance of a patent is not conclusive as to its inventorship, ownership, scope, validity, or enforceability, and our patent rights may be challenged in the courts or patent offices in the United States and abroad. We may

be subject to post-grant proceedings at the USPTO challenging the validity of one or more claims of our owned and in-licensed patents. Third-party submissions may also be made prior to a patent's issuance, precluding the granting of a patent based on our pending patent application. A third party may also claim that our owned and in-licensed patent rights are invalid or unenforceable in a litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. In addition, we may become involved in opposition, derivation, revocation, reexamination, reissue, interference, inter partes review, post-grant review proceedings or other similar proceedings in the United States and/or foreign jurisdictions challenging our patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, our patent rights, and may allow third parties, including generic drug companies, to commercialize any of our current or future product candidates and use any other proprietary technologies we may develop to compete directly with us.

Moreover, some of our owned and in-licensed patent rights may in the future be co-owned with third parties. In the United States, each co-owner has the freedom to license and exploit the technology. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patent rights, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of such patent rights in order to enforce such patent rights against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

***If we or our licensors fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our current or future licensors, or if any of our material license agreements are terminated, we could lose our rights to key intellectual property and components enabling our technologies.***

Our rights to our product candidates are subject to the licenses and other terms and conditions of the Hengrui License Agreement, and thus our commercial success will heavily depend on the maintenance of the Hengrui License Agreement. If, for any reason, the Hengrui License Agreement is terminated or we otherwise lose our rights under such agreement, it would adversely affect our business. The Hengrui License Agreement imposes, and future agreements may impose, various development, diligence, commercialization, milestone payment, royalty and other obligations on us, such as the requirement to meet development timelines or to exercise commercially reasonable efforts to develop and commercialize licensed products, in order to maintain the licenses. If we materially breach any of our obligations under the Hengrui License Agreement, Hengrui may terminate the Hengrui License Agreement, which would have a material adverse effect on us.

The Hengrui License Agreement is complex, and certain provisions may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology or increase what we believe to be our financial or other obligations under the Hengrui License Agreement, which could have a material adverse effect on our business, financial condition, results of operations, and prospects. For example, disputes may arise regarding the payment of the royalties or other payments due to Hengrui in connection with the rights we license from them. Hengrui may contest the basis of such payments, including the royalties we retained and claim that we are obligated to make payments under a broader basis. In addition, disputes may arise between us and our current or future licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe, misappropriate or otherwise violate intellectual property of the licensor that is not subject to the licensing agreement;

- our right to sublicense patents and other rights to third parties;
- our right to transfer or assign the license;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- our financial or other obligations under the license agreement;
- the priority of invention of patented technology; and
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our current or future licensors and us and our partners.

Such disputes may be costly to resolve and may divert management's attention away from day-to-day activities. In addition to the costs of any litigation we may face, any legal action against us could increase our payment obligations under the respective agreement and require us to pay interest and potentially damages to such licensors. If disputes over intellectual property that we have licensed, or license in the future, prevent or impair our ability to maintain our licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Despite our best efforts, our current or future licensors might conclude that we materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to develop and commercialize products, if approved, and technology covered by the license agreements. Such termination would result in the ability of the prior licensor to assert the prior licensed patents against us, or the prior licensor could license the patents to a competitor who could assert the prior licensed patents against us. As a result, we may be required to cease our development, manufacture and commercialization of our product candidates and use of our proprietary technologies covered by the patent rights owned by the licensors, which could have a material adverse effect on us. Alternatively, the prior licensor could abandon the patent rights, which would reduce the barrier to entry into the market. If these in-licenses are terminated, or if the licensed patents fail to provide the intended exclusivity, and if competitors circumvent any regulatory exclusivity, competitors would have the freedom to market products identical to ours. These events could have a material adverse effect on our competitive position, business, financial condition, results of operations, and prospects.

Termination of the agreements or reduction or elimination of our rights under the agreements may result in our having to negotiate new or reinstated agreements with less favorable terms or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology. For example, we may agree to terms that could enable third parties (potentially including our competitors) to receive licenses to a portion of the intellectual property that is subject to our existing licenses. Any of these events could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects, and we may be required to identify and license replacement technology from third parties, which may not be available on reasonable terms, if at all.

Further development of our proprietary technology and product candidates may require us to enter into additional license or collaboration agreements. Our future licenses may not provide us with exclusive rights to use the licensed intellectual property and technology, or may not provide us with exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our product candidates and proprietary technology in the future.

For a more complete description of these agreements, see "Business—Hengrui License and Collaboration Agreement."

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

Filing, prosecuting, maintaining, enforcing and defending patents on any of our current or future product candidates in all countries throughout the world is expensive, and the laws of foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States. Prosecution of foreign patent applications is often a longer process, and patents may grant at a later date, and with a shorter term, than in the United States. The requirements for patentability differ in certain jurisdictions and countries. Additionally, the patent laws of some countries do not afford intellectual property protection to the same extent as the laws of the United States. For example, other countries may impose substantial restrictions on the scope of claims, including limiting patent protection to specifically disclosed embodiments. 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 intellectual property in and into the United States or other jurisdictions. Competitors may use our intellectual property in jurisdictions where we have not pursued and obtained patent protection to develop their own products and, further, may export infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products, and our owned and in-licensed patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biopharmaceutical products, which could make it difficult for us to stop the infringement of our owned and in-licensed patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. In addition, some jurisdictions, such as Europe, Japan, and Korea, may have a heightened standard for patentability than in the United States, including, for example, the requirement of claims having literal support in the original patent filing and the limitation on using supporting data that is not in the original patent filing. Under those heightened patentability requirements, we may not be able to obtain sufficient patent protection in certain jurisdictions even though the same or similar patent protection can be secured in the United States and other jurisdictions.

Proceedings to enforce our owned and in-licensed intellectual property and proprietary rights in the United States or other jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents and any patents we may own or license in the future at risk of being invalidated or interpreted narrowly, could put our owned and in-licensed patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our owned and in-licensed intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop.

Many countries have compulsory licensing laws under which a patent owner or exclusive licensee may be compelled to grant licenses to third parties, including governmental agencies. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner or exclusive licensee 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. In addition, geo-political actions in the United States and in foreign countries (such as the Russia and Ukraine conflict) 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 which could impair our competitive intellectual property position.

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

The USPTO and various non-U.S. government agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. In some circumstances, we may be dependent on our current or future licensors to take the necessary action to comply with these requirements with respect to any licensed intellectual property. For example, periodic maintenance fees, renewal fees, annuity fees, and various other government fees on patents and applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our owned and in-licensed patents and applications. In certain circumstances, we may rely on licensing partners to pay these fees due to the U.S. and non-U.S. patent agencies. In some cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can cause abandonment or lapse of the patent or patent application, resulting in a partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market with similar or identical products or technology, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

The USPTO and various non-U.S. government agencies require compliance with certain foreign filing requirements during the patent application process. For example, in some countries, including the United States, China, India and some European countries, a foreign filing license is required before certain patent applications are filed. The foreign filing license requirements vary by country and depend on various factors, including where the inventive activity occurred, citizenship status of the inventors, the residency of the inventors and the invention owner, the place of business for the invention owner and the nature of the subject matter to be disclosed (e.g., items related to national security or national defense). In some, but not all cases, for example in China and India, a foreign filing license cannot be obtained retroactively in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment of a pending patent application or can be grounds for revoking or invalidating an issued patent, resulting in the loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, potential competitors might be able to enter the relevant markets with similar or identical products or technology, which could have a material adverse effect on our business, financial condition, results of operations and prospects. We may also be dependent on our current or future licensors to take the necessary actions to comply with these requirements with respect to intellectual property that we license.

Public health pandemics (such as the COVID-19 pandemic), geopolitical instability (war and terrorism), natural disasters, or similar events may impair our and our current or future licensors' ability to comply with these procedural, document submission, fee payment, and other requirements imposed by government patent agencies, which may materially and adversely affect our ability to obtain or maintain patent protection for any of our current and future product candidates.

***Changes in patent laws or their interpretations could diminish the value of patents in general, thereby impairing our ability to protect our products.***

Changes in either the patent laws or interpretation of the patent laws in the United States or in other countries could increase the uncertainties and costs surrounding the prosecution of patent applications and the

enforcement or defense of issued patents. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to 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 America Invents Act, or the America Invents Act, enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013, but before us or our current or future licensors could therefore be awarded a patent covering an invention of ours or our licensors even if we or our licensors had made the invention before it was made by such third party. This requires us to be cognizant of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our current or future licensors are the first to either (i) file any patent application related to any of our current or future product candidates and other proprietary technologies we may develop or (ii) invent any of the inventions claimed in our patents or patent applications.

The America Invents Act also included a number of significant changes that affect the way patent applications are prosecuted and also affect patent litigation. These include allowing third party protests and submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO-administered post-grant proceedings, including post-grant review, inter partes review and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims or any patent claims we may license in the future that would not have been invalidated if first challenged by the third party as a defendant in a district court action.

In addition, the patent positions of companies in the development and commercialization of pharmaceuticals are particularly uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. We cannot predict how decisions by the courts, the U.S. Congress or the USPTO may impact the value of our owned and in-licensed patent rights. For example, the U.S. Supreme Court held in Amgen v. Sanofi (2023) that a functionally claimed genus was invalid for failing to comply with the enablement requirement of the Patent Act. As such, our owned and in-licensed patent rights with functional claims may be vulnerable to third party challenges seeking to invalidate these claims for lacking enablement or adequate support in the specification. Depending on future actions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future. In addition to heightened patentability requirements, the Supreme Court and Federal Circuit’s interpretation of biosimilar product approval under the BPCIA, has evolved in recent years, affecting the “patent dance” provisions of the statute, which are intended to resolve any patent infringement issues before the approval of a biosimilar. Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have or may obtain or license in the future.

In 2012, the European Union Patent Package, or EU Patent Package, regulations were passed with the goal of providing a single pan-European Unitary Patent and a new European Unified Patent Court, or UPC, for litigation

involving European patents. The EU Patent Package was implemented on June 1, 2023. As a result, all European patents, including those issued prior to ratification of the EU Patent Package, now by default automatically fall under the jurisdiction of the UPC, unless otherwise opted out. It is uncertain how the UPC will impact granted European patents in the biotechnology and pharmaceutical industries. Our European patents and patent applications, if issued, could be challenged in the UPC. During the first seven years of the UPC's existence, the UPC legislation allows a patent owner to opt its European patents out of the jurisdiction of the UPC. We may decide to opt out our future European patents from the UPC, but doing so may preclude us from realizing the benefits of the UPC. Moreover, if we do not meet all of the formalities and requirements for opt-out under the UPC, our future European patents could remain under the jurisdiction of the UPC. The UPC will provide our competitors with a new forum to centrally revoke our European patents and allow for the possibility of a competitor to obtain a pan-European injunction. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize our technology and any of our current and future product candidates due to increased competition and, resultantly, on our business, financial condition, results of operations and prospects. The UPC and Unitary Patent are significant changes in European patent practice. As the UPC is a new court system, there is limited precedent for the court, increasing the uncertainty of any litigation in the UPC.

***Issued patents covering any of our current or future product candidates could be found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad.***

Our owned and licensed patent rights may be subject to priority, validity, inventorship, ownership and enforceability disputes. Legal proceedings relating to intellectual property claims, with or without merit, are unpredictable and generally expensive and time-consuming and likely to divert significant resources from our core business, including distracting our management and scientific personnel from their normal responsibilities and generally harm our business. If we or any of our current or future licensors are unsuccessful in any of these proceedings, such patents and patent applications may be narrowed, invalidated or held unenforceable. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

If we initiate legal proceedings against a third party to enforce a patent covering any of our current or future product candidates, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could include an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement, lack of sufficient written description, failure to claim patent-eligible subject matter or obviousness-type double patenting. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading or inconsistent statement, during prosecution. Third parties may raise claims challenging the validity or enforceability of a patent before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, inter partes review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in the revocation of, cancellation of, shortening the term of or amendment to our owned or in-licensed patent rights or any patent rights we may obtain or license in the future in such a way that they no longer cover any of our current or future product candidates or prevent third parties from competing with our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection for any of our current or future product candidates. There is also a risk that, even if

the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our owned and in-licensed patent claims do not cover the invention, or decide that the other party's use of our patented technology falls under the safe harbor to patent infringement under 35 U.S.C. § 271(e). Such a loss of patent protection would have a material adverse impact on our business, financial condition, results of operations and prospects.

***Patent terms may be inadequate to protect the competitive position of any of our current or 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 or international patent application filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering any of our current or future product candidates are obtained, once the patent has expired, we may be vulnerable to competition from competitive products, including generics. Given the amount of time required for the development, testing and regulatory review of any of our current or future product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to our product candidates. If we do not have sufficient patent life to protect our products, our business, financial condition, results of operations and prospects will be adversely affected.

***If we do not obtain additional protection under the Hatch-Waxman Amendments and similar foreign legislation extending the terms of our licensed patents and any future patents we may own, our business, financial condition and results of operations may be materially and adversely affected.***

Depending upon the timing, duration and specifics of FDA regulatory approval for our drug candidates, one or more of our licensed U.S. patents or future U.S. patents that we may license or own may be eligible for limited patent term restoration under the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during drug development and the FDA regulatory review process. This period is generally one-half the time between the effective date of an investigational new drug application (falling after issuance of the patent), and the submission date of an NDA, plus the time between the submission date of an NDA and the approval of that application. Patent term restorations, however, cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval by the FDA, only one patent may be extended, and only claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. The application for patent term extension is subject to approval by the USPTO, in conjunction with the FDA. We may not be granted an extension because of, for example, 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, including due to 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 failing to satisfy other applicable requirements. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our product will be shortened and our competitors may obtain earlier approval of competing products, and our ability to generate revenues could be materially adversely affected.

***We or our current or future licensors may be subject to claims challenging the inventorship or ownership of our owned and in-licensed patents and other intellectual property.***

We or our current or future licensors may be subject to claims that former employees, consultants, licensees, collaborators or other third parties have an interest in our owned or in-licensed patent rights, trade secrets, or other intellectual property as an inventor, co-inventor or owner of trade secrets. For example, we or our current or future licensors may have inventorship or ownership disputes arise from conflicting obligations of consultants or others who are involved in developing any of our current or future product candidates and other proprietary technologies we may develop. We or our current or future licensors may have relied on third-party consultants or collaborators or on funds from third parties, such as from a government entity, such that we or our current or future licensors are not the sole and exclusive owners of the patents we in-licensed. The failure to name the proper inventors on a patent application can result in the patents issuing therefrom being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our product candidates or as a result of questions regarding co-ownership of potential joint inventions. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership of our owned or in-licensed patent rights, trade secrets or other intellectual property. If we or our current or future licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as ownership of, or the right to use intellectual property that is important to any of our current or future 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.

***If we are unable to protect the confidentiality of our and current or future licensors' trade secrets, our business and competitive position would be harmed.***

In addition to seeking patent protection for any of our current or future product candidates and proprietary technologies, we may rely on trade secret protection and confidentiality agreements to protect our unpatented know-how, technology, and other proprietary information and to maintain our competitive position. We seek to protect these trade secrets and other proprietary technology, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, licensees, third-party collaborators, CROs, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Trade secrets and know-how can be difficult to protect. We cannot guarantee that we have entered into applicable agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. Despite these efforts, 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. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. We cannot guarantee that any potential trade secrets and other proprietary and confidential information will not be disclosed or that competitors will not otherwise gain access to trade secrets. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret (such as through a cybersecurity breach) 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. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. Furthermore, others may independently discover similar trade secrets and proprietary information. If any of our trade secrets were to be disclosed or misappropriated or if

any such information were to be independently developed by a competitor or other third party, our competitive position would be materially and adversely harmed. Additionally, we may need to share our proprietary information, including trade secrets, with future business partners, collaborators, contractors and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or foreign actors, and those affiliated with or controlled by state actors.

We may be subject to claims that third parties have an ownership interest in our trade secrets. For example, we may have disputes arise from conflicting obligations of our employees, consultants or others who are involved in developing any of our current or future product candidates. Litigation may be necessary to defend against these and other claims challenging ownership of our trade secrets. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable trade secret rights, such as exclusive ownership of, or right to use, trade secrets that are important to any of our current or future product candidates and other proprietary technologies we may develop. Such an outcome could have a material adverse effect on our business. 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.

***We may be subject to claims that our employees, consultants, or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property.***

Some of our employees, consultants and advisors are currently or were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and advisors 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 these individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer, or that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our management. In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations and prospects.

***We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might adversely affect our ability to develop and market any of our current or future product candidates.***

We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are or will be complete or thorough, nor can we be certain that we have identified or will identify each and every third-party patent and pending patent application in the United States and abroad that is relevant to or necessary for the commercialization of any of our current or future product candidates in any jurisdiction. Patent applications in the United States and elsewhere are not published until approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications

covering any of our current or future product candidates could have been filed by others without our knowledge. The scope of a patent claim is determined by the interpretation of the law, the words of a patent claim, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending patent application may be incorrect, which may negatively impact our ability to market our products. We may incorrectly determine that any of our current or future product candidates are not covered by a third-party patent or may incorrectly predict whether a third party's pending patent application will issue with claims of relevant scope. Alternatively, we may incorrectly determine that the Hatch-Waxman Amendments are a defense for a safe harbor to infringement of a patent we consider relevant to the research or clinical development of any of our current or future product candidates. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, and we may incorrectly conclude that a third-party patent is invalid and unenforceable or not infringed. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market any of our current or future product candidates. If we fail to identify and correctly interpret relevant patents, we may be subject to infringement claims. Also, because the claims of published patent applications can change between publication and patent grant, there may be published patent applications that may ultimately issue with claims that we infringe. As the number of competitors in the market grows and the number of patents issued in this area increases, the possibility of patent infringement claims escalates. Moreover, in recent years, individuals and groups that are non-practicing entities, commonly referred to as "patent trolls," have purchased patents and other intellectual property assets for the purpose of making claims of infringement in order to extract settlements. From time to time, we may receive threatening letters, notices or "invitations to license," or may be the subject of claims that our products and business operations infringe or violate the intellectual property rights of others. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we fail in any such dispute, in addition to being forced to pay damages, we may be temporarily or permanently prohibited from commercializing any of our current or future product candidates that are held to be infringing. We might, if possible, also be forced to redesign any of our current or future product candidates or services so that we no longer infringe the third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

***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 any of our current or future product candidates.***

Our commercial success depends in part on our and our collaborators' 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, inter partes review, post-grant review, and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions.

Numerous U.S. and foreign-issued patents and pending patent applications owned by third parties exist in the fields in which we plan to commercialize our programs (including obesity, weight loss and maintenance programs) and in which we are developing other proprietary technologies. 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 our programs and commercializing activities may give rise to claims of infringement of the patent rights of others. We cannot guarantee that our programs and other proprietary technologies we develop 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 our programs, might assert as infringed by us. 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. For example, we are aware of certain patent applications and patents in the United States and abroad owned by third parties with patent claims that may be relevant to KAI-7535 in the future. 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 any of our current or future product candidates. 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. For example, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover any of our current or future product candidates or the use of any of our current or future product candidates.

If 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 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, results of operations and prospects.

We may in the future pursue invalidity proceedings with respect to third-party patents. The outcome following legal assertions of invalidity is unpredictable. Even if resolved in our favor, these legal proceedings may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. 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. 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 these third parties may be able to sustain the costs of such proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent proceedings could compromise our ability to compete in the marketplace. If we do not prevail in the patent proceedings the third parties may assert a claim of patent infringement directed at any of our current or future product candidates.

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

Third parties, such as competitors, may infringe our owned or in-licensed patent rights. In an infringement proceeding, a court may decide that a patent we own or license is invalid or unenforceable or may refuse to stop the other party from using the invention at issue. In addition, our owned or in-licensed patent rights may become involved in inventorship, ownership, priority, enforceability, or validity disputes. To counter or defend against such claims can be expensive and time-consuming. An adverse result in any litigation proceeding could put our patent rights at risk of being invalidated, held unenforceable or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation and proceedings, there is a risk that some of our confidential information could be compromised by disclosure during such litigation and proceedings.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our personnel from their normal responsibilities. 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. Such litigation or 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 litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

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

Our registered or unregistered trademarks or trade names may be challenged, infringed, diluted, circumvented or declared generic or determined to be infringing, misappropriating or violating other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in the markets of interest. During trademark registration proceedings, we may receive rejections of our applications by the USPTO or in other foreign jurisdictions. Although we are given an opportunity to respond to such rejections, we may be unable to overcome them. If our trademarks are successfully challenged or determined to be infringing, misappropriating or violating other marks, we could be forced to rebrand our products, which could result in loss of brand recognition, and could require us to devote resources to advertising and marketing new brands. In addition, at the USPTO and 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, which may not survive such proceedings. Moreover, any name we may propose to use with any of

our current or future product candidates 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, we may be required to expend significant additional resources to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe, misappropriate or otherwise violate 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.

We may not be able to obtain, protect or enforce our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. 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, misappropriation, dilution or other claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected. Our efforts to obtain, enforce or protect our proprietary rights related to trademarks, trade names, domain name, or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our business, financial condition, results of operations and prospects.

***Intellectual property rights do not necessarily address all potential threats.***

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 make products that are similar to any of our current or future product candidates or utilize similar technology but that are not covered by the claims of the patents that we own or license or may own or license in the future;
- we or our current or future licensors or collaborators might not have been the first to make the inventions covered by our current or future patent applications;
- we or our current or future licensors or collaborators might not have been the first to file patent applications covering our or their 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 our pending and future patent applications that we own or license will not lead to issued patents;
- any issued patent that we currently own or license or may own or license in the future may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties;
- others may have access to the same intellectual property rights licensed to us in the future on a non-exclusive basis;
- our competitors or other third parties might conduct research and development activities in countries where we or our current or future licensors 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;
- we may fail to identify potential patentable subject matter and/or may fail to file on it;
- the patents or other intellectual property rights of others may harm our business; and
- we may choose not to file for patent protection to maintain certain trade secrets or know-how, and a third party may subsequently file a patent application covering such intellectual property or disclose information resulting in a loss of protection for such trade secret.

Should any of the foregoing occur, it could adversely affect our business, financial condition, results of operations and prospects.

***We may not be successful in obtaining or maintaining necessary rights to product components and processes for our development pipeline through future acquisitions and in-licenses.***

The growth of our business may depend in part on our ability to acquire, in-license or use third-party intellectual property and proprietary rights. For example, any of our current or future product candidates may require specific formulations, delivery devices, or dosing regimens to work effectively and efficiently, we may need to use specific synthetic methods, intermediates or other reagents to efficiently manufacture our current or future product candidates, we may develop product candidates containing our compounds and pre-existing pharmaceutical compounds, we may develop combination therapies with our compounds and third-party compounds, any of which could require us to obtain rights to use intellectual property held by third parties. In addition, with respect to any patent or other intellectual property rights we may co-own with third parties, we may require licenses to such co-owners' interest to such patents. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary or important to our business operations. In addition, we may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. Were that to happen, we may need to cease use of the compositions or methods covered by those third-party intellectual property rights and may need to seek to develop alternative approaches that do not infringe, misappropriate or otherwise violate those intellectual property rights, which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we can obtain a license, it may be non-exclusive, which means that our competitors may also receive access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology.

Additionally, we may collaborate with academic institutions to accelerate our research and development under written agreements with these institutions. In certain cases, these institutions provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Even if we hold such an option, we may be unable to negotiate a license from the institution within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to others, potentially blocking our ability to pursue our program. Even if we can obtain a license, it may be non-exclusive, and our competitors may also receive access to the same technologies licensed to us.

The licensing and acquisition of third-party intellectual property rights is a competitive area, and companies that may be more established or have greater resources than we do may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive to commercialize any of our current or future product candidates. More established companies may have a competitive advantage over us due to their size, cash resources or greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. There can be no assurance that we will be able to successfully complete these

types of negotiations and ultimately acquire the rights to the intellectual property surrounding any of our current or future product candidates that we may seek to develop or market. If we are unable to successfully obtain rights to required third-party intellectual property or to maintain the existing intellectual property rights we have, we may have to abandon development of certain programs and our business, financial condition, results of operations, and prospects could suffer."

## Risks Related to This Offering and Ownership of Our Common Stock

***There has been no public market for our common stock. An active, liquid and orderly market for our common stock may not develop, or we may in the future fail to satisfy the continued listing requirements of Nasdaq, and you may not be able to resell your common stock at or above the initial public offering price or at all.***

Prior to this offering, there has been no public market for our common stock. We and the representatives of the underwriters determined the initial public offering price of our common stock through negotiation. This price does not necessarily reflect the price at which investors in the market will be willing to buy and sell our shares following this offering. In addition, an active trading market may not develop following the completion of this offering or, if it is developed, may not be sustained. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. An inactive market may also impair our ability to raise capital by selling shares and may impair our ability to acquire other businesses or technologies using our shares as consideration, which, in turn, could materially adversely affect our business.

If, after listing, we fail to satisfy the continued listing requirements of Nasdaq, such as the corporate governance requirements or the minimum closing bid price requirement, Nasdaq may take steps to delist our common stock. Such a delisting would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. In the event of a delisting, we can provide no assurance that any action taken by us to restore compliance with listing requirements would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the Nasdaq minimum bid price requirement or prevent future non-compliance with the listing requirements of Nasdaq.

***The trading price of the shares of our common stock could be highly volatile, and purchasers of our common stock could incur substantial losses.***

Our stock price is likely to be volatile. The stock market in general and the market for stock of biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. 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 those factors discussed in this "Risk factors" section and many others, including:

- results of our clinical trials and nonclinical studies, and the results of trials of our competitors or those of other companies in our market sector;
- our ability to enroll patients in our future clinical trials;
- our ability to obtain and maintain regulatory approval of any of our current or future product candidates or additional indications thereof, or limitations to specific label indications or patient populations for their use, or changes or delays in the regulatory review process;
- regulatory or legal developments in the United States and foreign countries;
- changes in the structure of healthcare payment systems;

- the success or failure of our efforts to develop, acquire, or license any of our current or future product candidates;
- innovations, clinical trial results, product approvals and other developments regarding our competitors;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, or capital commitments;
- manufacturing, supply, or distribution delays or shortages;
- any changes to our relationship with any manufacturers, suppliers, collaborators or other strategic partners;
- achievement of expected product sales and profitability;
- variations in our financial results or development timelines or those of companies that are perceived to be similar to us, including variations from expectations of securities analysts or investors;
- market conditions in the biopharmaceutical sector and issuance of securities analysts' reports or recommendations;
- trading volume of our common stock;
- an inability to obtain additional funding;
- 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;
- general economic, industry, geopolitical and market conditions, such as military conflict or war, inflation and financial institution instability, or pandemic or epidemic disease outbreaks, many of which are beyond our control;
- additions or departures of senior management, directors or key personnel;
- intellectual property, product liability or other litigation against us or our inability to enforce our intellectual property;
- changes in our capital structure, such as future issuances of securities and the incurrence of additional debt; and
- changes in accounting standards, policies, guidelines, interpretations or principles.

In addition, in the past, stockholders have initiated class action lawsuits against biopharmaceutical companies following periods of volatility in the market prices of these companies' stock. Such litigation, if instituted against us, could cause us to incur substantial costs, divert our management's attention and resources and damage our reputation, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

***Investors will suffer immediate and substantial dilution in the net tangible book value of the common stock they purchase in this offering.***

The initial public offering price of our common stock is substantially higher than the pro forma as adjusted net tangible book value per share of our outstanding common stock immediately after the completion of this offering. Purchasers of common stock in this offering will experience immediate dilution of approximately $6.21 per share (or $6.00 per share if the underwriters' over-allotment option is exercised in full), based on the initial public offering price of $16.00 per share. In the past, we issued options to acquire common stock at prices significantly below the initial public offering price. To the extent these outstanding options are ultimately exercised, investors

purchasing common stock in this offering will sustain further dilution. For a further description of the dilution that you will experience immediately after this offering, see the section titled “Dilution.”

***After this offering, our executive officers, directors, and principal stockholders, if they choose to act together, will continue to have the ability to significantly influence all matters submitted to stockholders for approval.***

Following the completion of this offering, our executive officers, directors and greater than 5% stockholders, in the aggregate, will beneficially own approximately 50.1% of our outstanding common stock (assuming no exercise of the underwriters’ over-allotment option and no exercise of outstanding options and without giving effect to any potential purchases by such persons in this offering). As a result, such persons, acting together, will have the ability to significantly influence all matters submitted to our board of directors or stockholders for approval, including the appointment of our management, the election and removal of directors and approval of any significant transaction, as well as our management and business affairs. This concentration of ownership may have the effect of delaying, deferring or preventing a change in control, impeding a merger, consolidation, takeover or other business combination involving us, or discouraging a potential acquiror from making a tender offer or otherwise attempting to obtain control of our business, even if such a transaction would benefit other stockholders.

***We do not currently intend to pay dividends on our common stock, so any returns on your investment will be limited to the value of our common stock.***

We have never declared or paid any cash dividend on our common stock. We currently anticipate that we will retain future earnings for the development, operation, and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, any future debt agreements may preclude us from paying dividends. Any return to stockholders will therefore be limited to the appreciation of their stock. 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.

***Sales of a substantial number of shares of our common stock by our existing stockholders in the public market could cause our stock price to fall.***

Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur could significantly reduce the market price of our common stock and impair our ability to raise adequate capital through the sale of additional equity or equity-linked securities.

Based on 84,615,439 shares outstanding as of December 31, 2025, upon the completion of this offering, we will have a total of 123,677,939 shares of common stock outstanding (after giving effect to the conversion of all outstanding shares of our convertible preferred stock into 84,596,391 shares of our common stock upon the closing of this offering), assuming no exercise of the underwriters’ over-allotment option or exercise of outstanding options subsequent to December 31, 2025. Of these shares, only the 39,062,500 shares of common stock sold in this offering by us, plus any shares sold upon exercise of the underwriters’ over-allotment option, will be freely tradable, without restriction, in the public market immediately following this offering, unless they are purchased by one of our affiliates.

Our directors and executive officers and substantially all of our securityholders have entered into lock-up agreements with the representatives pursuant to which they may not, with limited exceptions, for a period of 180 days from the date of this prospectus, offer, sell or otherwise transfer or dispose of any of our securities, without the prior written consent of two of the representatives of the underwriters, one of whom must be J.P. Morgan Securities LLC and the other of whom shall be selected by us in our sole discretion. The underwriters may permit our officers, directors and other securityholders who are subject to the lock-up agreements to sell shares prior to the expiration of the lock-up agreements at any time in their sole discretion. See the section titled “Underwriting.” Sales of these shares, or perceptions that they will be sold, could cause the trading price

of our common stock to decline. After the lock-up agreements expire, substantially all of our outstanding shares of common stock will be eligible for sale in the public market, unless held by one of our directors, executive officers or other affiliates, in which case the resale of those shares will be subject to volume limitations under Rule 144 under the Securities Act.

In addition, we intend to register all shares of common stock that we may issue under our equity compensation plans. Following the effectiveness of such registration, 13,470,409 shares of common stock that are subject to outstanding options under our equity compensation plans as of December 31, 2025 and 1,572,649 shares of common stock that are subject to outstanding options under our equity compensation plans granted subsequent to December 31, 2025 became eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules and the lock-up agreements described in the "Underwriting" section of this prospectus. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

After giving effect to this offering, the holders of 84,596,391 shares of our outstanding common stock, or approximately 68.4% of our total outstanding common stock based on shares outstanding as of December 31, 2025, will be entitled to rights with respect to the registration of their shares under the Securities Act, subject to vesting and the 180-day lock-up agreements described above. See the section titled "Description of capital stock—Registration rights." Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by affiliates, as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

***Participation in this offering by our existing stockholders and/or their affiliated entities will reduce the public float for our common stock.***

To the extent our existing stockholders who are our affiliates or their affiliated entities participate in this offering, such purchases would reduce the non-affiliate public float of our common stock after this offering, which is the number of shares of common stock that are not held by our officers, directors and affiliated stockholders. As a result, the number of freely tradeable shares of our common stock following this offering will be reduced relative to what it would have been had these shares been sold to investors that were not existing stockholders or affiliates. This could adversely impact the liquidity of our common stock and depress the price at which you may be able to sell shares of common stock purchased in this offering.

***We are an emerging growth company and a smaller reporting company, and the reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies may make our common stock less attractive to investors.***

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act, or JOBS Act, and may remain an emerging growth company until the last day of the fiscal year following the fifth anniversary of the date of the first sale of our common stock under this offering. However, if certain events occur prior to the end of such five-year period, including if we become a "large accelerated filer", as defined under the Exchange Act, our annual gross revenue exceeds $1.235 billion or we issue more than $1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's discussion and analysis of financial condition and results of operations" disclosure;

- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act of 2002, or Sarbanes-Oxley;
- an exemption from compliance with the requirements of the Public Company Accounting Oversight Board regarding the communication of critical audit matters in the auditor's report on the consolidated financial statements;
- reduced disclosure obligations regarding executive compensation; 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 have taken advantage of reduced reporting burdens in this prospectus. In particular, in this prospectus, we have provided only two years of audited financial statements and have not included all of the executive compensation-related information that would be required if we were not an emerging growth company. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be reduced or more volatile. In addition, 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. This allows an emerging growth company to delay the adoption of these accounting standards until they would otherwise apply to private companies. We have irrevocably elected to avail ourselves of this exemption and, therefore, we may not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. We intend to rely on other exemptions provided by the JOBS Act, including without limitation, not being required to comply with the auditor attestation requirements of Section 404(b) of Sarbanes-Oxley.

We are also a smaller reporting company as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as our voting and non-voting common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100.0 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

***Provisions in our charter documents and under Delaware law could discourage a takeover that stockholders may consider favorable and may lead to entrenchment of management.***

Our amended and restated certificate of incorporation that will be in effect immediately after the closing of this offering and our amended and restated bylaws that will be in effect upon the closing of this offering will contain provisions that could significantly reduce the value of our shares to a potential acquiror or delay or prevent changes in control or changes in our management without the consent of our board of directors. The provisions in our charter documents will include the following:

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the exclusive right of our board of directors, unless the board of directors grants such right to the stockholders, to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;

- the required approval of at least 66-2/3% of the shares entitled to vote to remove a director for cause, and the prohibition on removal of directors without cause;
- the ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquiror;
- the ability of our board of directors to alter our amended and restated bylaws without obtaining stockholder approval;
- the required approval of at least 66-2/3% of the shares entitled to vote to adopt, amend or repeal our amended and restated bylaws or repeal the provisions of our amended and restated certificate of incorporation regarding the election and removal of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- an exclusive forum provision providing that the Court of Chancery of the State of Delaware will be the exclusive forum for certain actions and proceedings;
- the requirement that a special meeting of stockholders may be called only by the board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and
- advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror's own slate of directors or otherwise attempting to obtain control of us.

We are also subject to the anti-takeover provisions contained in Section 203 of the Delaware General Corporation Law. Under Section 203, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other exceptions, the board of directors has approved the transaction.

***Our current amended and restated certificate of incorporation provides, and our amended and restated certificate of incorporation will provide, that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders and that the federal district courts shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees or the underwriters or any offering giving rise to such claim.***

Our current amended and restated certificate of incorporation provides, and our amended and restated certificate of incorporation that will be in effect immediately after the closing of this offering 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 Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws, or any action asserting a claim against us that is governed by the internal affairs doctrine; provided, that, this provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. Furthermore, our amended and restated certificate of incorporation will also provide that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the

Securities Act. These choice of forum provisions may result in increased costs to stockholders to bring a claim, limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, and may generally have the effect of discouraging lawsuits against us and our directors, officers and other employees. By agreeing to this provision, however, stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder. Furthermore, the enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. If a court were to find the choice of forum provisions in our amended and 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 adversely affect our business and financial condition.

***We may allocate the net proceeds from this offering in ways that you and other stockholders may not approve.***

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." Because of the number and variability of factors that will determine our use of the net proceeds from this offering, their ultimate use may vary substantially from their currently intended use. Our management might not apply our net proceeds in ways that ultimately increase the value of your investment, and the failure by our management to apply these funds effectively could harm our business. Pending their use, we may invest the net proceeds from this offering in short-and intermediate-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government. These investments may not yield a favorable return to our stockholders. 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 results, which could cause our stock price to decline.

## General Risk Factors

***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.***

As a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. We will be subject to the reporting requirements of the Exchange Act, which will require, among other things, that we file with the SEC annual, quarterly and current reports with respect to our business and financial condition. In addition, Sarbanes-Oxley and rules subsequently adopted by the SEC and Nasdaq to implement provisions of Sarbanes-Oxley impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and certain corporate governance practices. Further, pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, the SEC has adopted additional rules and regulations in these areas, such as mandatory "say-on-pay" voting requirements that will apply to us when we cease to be an emerging growth company. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

We expect the rules and regulations applicable to public companies to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. The increased costs will decrease our net income or increase our net loss, and may require us to reduce expenditures in other areas of our business. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain directors and officers liability insurance, and we may be required to incur substantial costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of

additional costs we may incur to comply with 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. 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, results of operations and prospects.

***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. We could face criminal liability and other serious consequences for violations, which could harm our business.***

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, and various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls and anti-corruption and anti-money laundering laws and regulations, including the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, CROs, contractors and other collaborators and partners from authorizing, promising, offering, providing, soliciting or receiving, directly or indirectly, improper payments or anything else of value to or from recipients in the public or private sector. We may engage third parties for clinical trials outside of the United States, to sell our products abroad if and when we enter a commercialization phase, and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, CROs, contractors and other collaborators and partners, even if we do not explicitly authorize or have actual knowledge of such activities, and any training or compliance programs or other initiatives we undertake to prevent such activities may not be effective.

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.

Furthermore, U.S. export control laws and economic sanctions prohibit the provision of certain products and services to countries, governments, and persons targeted by U.S. sanctions. U.S. sanctions that have been or may be imposed may impact our ability to continue activities at future clinical trial sites within regions covered by such sanctions. If we fail to comply with export and import regulations and such economic sanctions, penalties could be imposed, including fines and/or denial of certain export privileges. These export and import controls and economic sanctions could also adversely affect our supply chain.

***We and any of our third-party manufacturers or suppliers may use potent chemical agents and hazardous materials, and any claims relating to improper handling, storage, or disposal of these materials could be time-consuming or costly.***

We and any of our third-party manufacturers or suppliers and our current or any future collaborators may use biological materials, potent chemical agents and hazardous materials, including chemicals and biological agents and compounds that could be dangerous to human health and safety of the environment. Our operations and the operations of our third-party manufacturers and suppliers also produce hazardous waste products. Federal, state and local laws and regulations govern the use, generation, manufacture, storage, handling and disposal of these materials and wastes. Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our product development efforts. In addition, neither we or our third-party manufacturers and suppliers can eliminate the risk of accidental injury

or contamination from these materials or wastes. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. In the event of contamination or injury at our, our manufacturers' or our suppliers' sites, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended. Although we maintain workers' compensation insurance for certain costs and expenses we may incur due to injuries to our employees resulting from work-related injuries, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for toxic tort claims that may be asserted against us in connection with the storage or disposal of biologic, 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, which have tended to become more stringent over time. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions or liabilities, which could materially adversely affect our business, financial condition, results of operations and prospects.

***Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.***

Our operations and the operations of our manufacturers, suppliers, collaborators, CROs and clinical sites could be subject to earthquakes, power shortages, telecommunications or infrastructure failures, cybersecurity incidents, physical security breaches, water shortages, floods, hurricanes, typhoons, blizzards and other extreme weather conditions, fires, public health pandemics or epidemics and other natural or manmade disasters, geopolitical actions or business interruptions, for which we are predominantly self-insured. We rely on third-party manufacturers or suppliers in various countries to produce our current or future product candidates and its components and on CROs and clinical sites to conduct our clinical trials, and do not have a redundant source of supply for all components of any of our current or future product candidates. Our ability to obtain clinical or, if approved, commercial, supplies of any of our current or future product candidates could be disrupted if the operations of these suppliers were affected by a man-made or natural disaster, geopolitical action or other business interruption, and our ability to commence, conduct or complete our clinical trials in a timely manner could be similarly adversely affected by any of the foregoing. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

***Unstable market and economic conditions and adverse developments with respect to financial institutions and associated liquidity risk may have serious adverse consequences on our business, financial condition and stock price.***

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, including the conflicts between Russia and Ukraine and in the Middle East, 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. In addition, in 2023 the closures of financial institutions and their placement into receivership with the FDIC created bank-specific and broader financial institution liquidity risk and concerns. Future adverse developments with respect to specific financial institutions or the broader financial services industry may lead

to market-wide liquidity shortages, impair the ability of companies to access near-term working capital needs, and create additional market and economic uncertainty. There can be no assurance that future credit and financial market instability and a deterioration in confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, liquidity shortages, volatile business environment or continued unpredictable and unstable market conditions. If the equity and credit markets deteriorate, or if adverse developments are experienced by financial institutions, it may cause short-term liquidity risk and also make any necessary debt or equity financing more difficult, more costly, more onerous with respect to financial and operating covenants and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay, limit, reduce or abandon product development or future commercialization efforts or grant rights to develop and market our product candidates even if we would otherwise prefer to develop and market such product candidates ourselves. In addition, there is a risk that one or more of our current service providers, financial institutions, manufacturers and other partners may be adversely affected by the foregoing risks, which could directly affect our ability to attain our operating goals on schedule and on budget.

***If securities or industry analysts do not publish research or reports or publish unfavorable research or reports about our business, our stock price and trading volume could decline.***

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us, our business, our market or our competitors. We do not currently have and may never obtain research coverage by securities and industry analysts. If no securities or industry analysts commence coverage of our company, the trading price for our stock would be negatively impacted. In the event we obtain securities or industry analyst coverage, if one or more of the analysts who covers us downgrades our stock, or if we fail to meet the expectations of one or more of these analysts, our stock price would likely decline. If one or more of these analysts ceases to cover us or fails to regularly publish reports on us, interest in our stock could decrease, which could cause our stock price or trading volume to decline.

***If we fail to maintain proper and effective internal control over financial reporting, our ability to produce accurate and timely financial statements could be impaired, investors may lose confidence in our financial reporting and the trading price of our common stock may decline.***

Pursuant to Section 404 of Sarbanes-Oxley, our management will be required to report upon the effectiveness of our internal control over financial reporting beginning with the second annual report following the completion of this offering. When we are no longer an “emerging growth company” and do not otherwise qualify as a “smaller reporting company” under the SEC rules, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for our management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. To comply with the requirements of being a reporting company under the Exchange Act, we may need to upgrade our information technology systems; implement additional financial and management controls, reporting systems and procedures; and hire additional accounting and finance staff. If we or, if required, our auditors are unable to conclude that our internal control over financial reporting is effective, investors may lose confidence in our financial reporting and the trading price of our common stock may decline.

We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our

internal control over financial reporting once that firm begins its Section 404 reviews, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

***We could be subject to securities class action litigation.***

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and biopharmaceutical companies have experienced significant stock price volatility in recent years. If we face such litigation, even if ultimately decided in our favor, it could result in substantial costs and a diversion of our management's attention and resources, which could harm our business.

# Special note regarding forward-looking statements

This prospectus contains forward-looking statements that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this prospectus, including statements regarding our future results of operations and financial position, business strategy, product candidate development, prospective products, product candidate approvals, research and development activities and costs, future revenue, timing and likelihood of success of our business plans, plans and objectives of management, future results and timing of clinical trials, treatment potential of our product candidates, and the market potential of our product candidates are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as “anticipate,” “believe,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “target,” “should,” “will,” or “would” or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words.

These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. We have based these forward-looking statements largely on our current expectations and projections about our business, the industry in which we operate and financial trends that we believe may affect our business, financial condition, results of operations and prospects. However, there can be no assurance that management’s expectations, beliefs, and projections will result or be achieved. Actual results may differ materially from these expectations due to changes in global, regional, or local economic, business, competitive, market, regulatory, and other factors, many of which are beyond our control. We believe that these factors include but are not limited to those described under “Risk factors” and the following:

- the success, cost, timing, progress and results of nonclinical studies and clinical trials for our current and future product candidates and the reporting and interpretation of data from those studies and trials;
- our ability to develop our current product candidates and additional potential product candidates in our pipeline;
- our ability to identify and enroll a specified and sufficient number of eligible patients to participate and remain in our clinical trials;
- the timing or likelihood of regulatory filing and approvals or of alternative regulatory pathways for our product candidates and any related restrictions, limitations or warnings in the label of an approved product candidate;
- our ability to combine our team’s drug development track record with Hengrui’s clinical data to inform and accelerate our development strategy;
- our ability to establish scaled third-party manufacturing prior to commercial launch of our product candidates;
- the likelihood of our clinical trials demonstrating safety and efficacy of our product candidates and other positive results;
- the timing of announcement of interim, topline and preliminary results from clinical trials;
- our ability to commercialize our product candidates and to establish, manage, or expand our marketing, distribution, and manufacturing capabilities;

- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates;
- developments related to our competitors and our industry and market acceptance of our current and future product candidates;
- our ability to maintain the Hengrui License Agreement underlying our product candidates;
- our ability to identify and enter into future license agreements and collaborations and the terms of such future agreements;
- our reliance on third parties having accurately generated, collected, interpreted and reported data from certain nonclinical studies and clinical trials that were previously conducted for our product candidates;
- the pricing and cost-effectiveness of our products, if approved, in relation to alternative treatments and therapies;
- our ability to attract and retain highly qualified management, clinical and scientific personnel;
- regulatory developments in the United States and foreign countries;
- our expectations regarding the period during which we will qualify as an emerging growth company under the JOBS Act or a smaller reporting company; and
- our use of proceeds from this offering, our financial performance, estimates of our expenses, capital requirements and needs for additional financing.

These forward-looking statements speak only as of the date of this prospectus and are subject to a number of risks, uncertainties and assumptions described in the section titled “Risk factors” and elsewhere in this prospectus. See also the section titled “Industry and other market data.” The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein until after we distribute this prospectus, whether as a result of any new information, future events or otherwise.

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.

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

# Use of proceeds

We estimate that we will receive net proceeds of approximately $575.0 million from the sale of shares of our common stock in this offering (or approximately $662.1 million if the underwriters' option to purchase additional shares of our common stock is exercised in full), based on the initial public offering price of $16.00 per share, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

We anticipate that we will use the net proceeds of this offering, together with our existing cash, cash equivalents and marketable securities, as follows:

- approximately $625 million to fund the development of ribupatide, our once-weekly injectable GLP-1/GIP receptor dual agonist peptide, including to fund our three ongoing global Phase 3 KaiNETIC clinical trials into the second quarter of 2028;
- approximately $150 million to fund the development of oral ribupatide, our once-daily oral tablet formulation of ribupatide, including to fund our planned Phase 3 trials into the second quarter of 2028;
- approximately $50 million to fund the development of KAI-7535, our once-daily oral small molecule GLP-1 receptor agonist, including through the completion of our planned Phase 2 clinical trial of KAI-7535; and
- the remainder to fund other research and development activities, including development of KAI-4729, our once-weekly injectable GLP-1/GIP/glucagon receptor tri-agonist, and for working capital and other general corporate purposes.

This expected use of 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. We may also use a portion of the net proceeds to in-license, acquire, or invest in additional businesses, technologies, products or assets, although currently we have no specific agreements, commitments or understandings in this regard. We cannot predict with certainty all of the particular uses for the net proceeds to be received upon the closing of this offering or the amounts that we will actually spend on the uses set forth above. Predicting the cost necessary to develop product candidates can be difficult and we anticipate that we will need additional funds to complete the development of our product candidates. The amounts and timing of our actual expenditures and the extent of clinical development may vary significantly depending on numerous factors, including the progress of our development efforts, the status of and results from pre-clinical studies and clinical trials, as well as any unforeseen cash needs. As a result, our management will retain broad discretion over the allocation of the net proceeds from this offering, and investors will be relying on the judgment of our management regarding the application of those net proceeds.

We do not expect that our existing cash, cash equivalents and marketable securities and the anticipated net proceeds from this offering alone will be sufficient to enable us to fund the completion of the development of any of our product candidates. Based on our planned use of the net proceeds of this offering and our existing cash, cash equivalents and marketable securities, we estimate that such funds will be sufficient to enable us to fund our operating expenses and capital expenditure requirements into the second quarter of 2028. We have based this estimate on assumptions that may prove to be incorrect, and we could use our available capital resources sooner than we currently expect. We may satisfy our future cash needs through the sale of equity securities, debt financings, working capital lines of credit, corporate collaborations or license agreements, grant funding, interest income earned on invested cash balances or a combination of one or more of these sources.

Pending our use of the net proceeds from this offering, we intend to invest the net proceeds in a variety of capital preservation investments, including short-term and intermediate-term, investment-grade, interest-bearing instruments and U.S. government securities.

# Dividend policy

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain all available funds and future earnings, if any, for the operation and expansion of our business and do not anticipate declaring or paying any dividends in the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our board of directors after considering our financial condition, results of operations, capital requirements, contractual requirements, business prospects and other factors the board of directors deems relevant, and subject to the restrictions contained in any future financing instruments. Investors should not purchase our common stock with expectation of receiving cash dividends.

# Capitalization

The following table sets forth our cash and cash equivalents and capitalization as of December 31, 2025, as follows:

- on an actual basis;
- on a pro forma basis to give effect to (i) the conversion of all outstanding shares of our preferred stock into 84,596,391 shares of our common stock upon the closing of this offering and (ii) the filing and effectiveness of our amended and restated certificate of incorporation, which will be effective immediately after the completion of this offering; and
- on a pro forma as adjusted basis to give further effect to our issuance and sale of 39,062,500 shares of our common stock in this offering at the initial public offering price of $16.00 per share, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

You should read this information in conjunction with our consolidated financial statements and the related notes included elsewhere in this prospectus and the section titled “Management’s discussion and analysis of financial condition and results of operations” and other financial information contained in this prospectus.

| | As of December 31, 2025 | | |
|---|---|---|---|
| **(in thousands, except share data)** | **Actual** | **Pro forma** | **Pro forma as adjusted** |
| Cash, cash equivalents and marketable securities | $ 652,728 | $ 652,728 | $ 1,227,678 |
| Convertible preferred stock: | | | |
| Series A convertible preferred stock: $0.00001 par value; 35,677,603 shares authorized, 35,677,603 shares issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted | 390,306 | — | — |
| Series B convertible preferred stock: $0.00001 par value; 43,084,539 shares authorized, 43,084,539 shares issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted | 602,058 | — | — |
| Stockholders’ (deficit) equity: | | | |
| Preferred stock, $0.00001 par value; no shares authorized, no shares issued and outstanding; actual; 10,000,000 shares authorized, no shares issued and outstanding, pro forma and pro forma as adjusted | — | — | — |
| Common stock, $0.00001 par value: 105,384,000 shares authorized, 19,048 shares issued and outstanding, actual; 800,000,000 shares authorized, pro forma and pro forma as adjusted; 84,615,439 shares issued and outstanding, pro forma; 123,677,939 shares issued and outstanding, pro forma as adjusted | — | — | — |
| Additional paid in capital | 11,981 | 1,004,345 | 1,579,295 |
| Accumulated other comprehensive income | 229 | 229 | 229 |
| Accumulated deficit | (368,668) | (368,668) | (368,668) |
| Total stockholders’ (deficit) equity | (356,458) | 635,906 | 1,210,856 |
| Total capitalization | $ 635,906 | $ 635,906 | $ 1,210,856 |

The number of shares in the table above excludes:

- 13,470,409 shares of our common stock issuable upon the exercise of stock options outstanding under the 2024 Plan, as of December 31, 2025, at a weighted-average exercise price of $6.20 per share;
- 1,572,649 shares of our common stock issuable upon the exercise of outstanding options granted under the 2024 Plan subsequent to December 31, 2025, at a weighted average exercise price of $10.65 per share;
- 4,142,000 shares of our common stock issuable upon the exercise of the IPO Grants granted in connection with this offering under the 2026 Plan, which became effective in connection with this offering, to certain of our executive officers, directors and employees, at an exercise price per share equal to the initial public offering price in this offering;
- 14,011,037 shares of our common stock reserved for future issuance under the 2026 Plan (which number includes the IPO Grants), plus any automatic increases in the number of shares reserved for future issuance pursuant to the terms of the 2026 Plan; and
- 1,295,482 shares of our common stock reserved for future issuance under our ESPP, plus any automatic increases in the number of shares reserved for future issuance pursuant to the terms of the ESPP.

# 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 and the pro forma as adjusted net tangible book value per share of our common stock after this offering.

As of December 31, 2025, we had a historical net tangible book value (deficit) of $(359.0) million, or $(18,849) per share of common stock. Our historical net tangible book value (deficit) per share represents total tangible assets less total liabilities and convertible preferred stock, divided by the number of shares of our common stock outstanding as of December 31, 2025.

Our pro forma net tangible book value as of December 31, 2025 was $633.3 million, or $7.48 per share. Pro forma net tangible book value represents the amount of our total tangible assets less total liabilities, after giving effect to the automatic conversion of all shares of our preferred stock outstanding as of December 31, 2025 into an aggregate of 84,596,391 shares of our common stock in connection with this offering. Pro forma net tangible book value per share represents our pro forma net tangible book value divided by the total number of shares outstanding as of December 31, 2025, after giving effect to the pro forma adjustment described above.

After giving further effect to receipt of the net proceeds from our issuance and the sale of 39,062,500 shares of our common stock in this offering at the initial public offering price of $16.00 per share, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of December 31, 2025 would have been $1.2 billion, or $9.79 per share. This amount represents an immediate increase in pro forma net tangible book value of $2.31 per share to our existing stockholders and an immediate dilution of approximately $6.21 per share to investors participating in this offering. We determine dilution by subtracting the pro forma as adjusted net tangible book value per share after this offering from the amount of cash that a new investor paid for a share of common stock. The following table illustrates this dilution:

| | | |
|---|---|---|
| Initial public offering price per share | | $16.00 |
| Historical net tangible book value (deficit) per share as of December 31, 2025 | $(18,849) | |
| Increase (decrease) per share attributable to the pro forma adjustments described above | 18,856 | |
| Pro forma net tangible book value (deficit) per share as of December 31, 2025 | 7.48 | |
| Increase in pro forma net tangible book value per share attributable to new investors in this offering | 2.31 | |
| Pro forma as adjusted net tangible book value per share after this offering | | 9.79 |
| Dilution per share to investors in this offering | | $ 6.21 |

If the underwriters exercise their option to purchase additional shares of our common stock in full, the pro forma as adjusted net tangible book value after this offering would be $10.00 per share, the increase in pro forma net tangible book value per share would be $2.52 and the dilution to investors participating in this offering would be $6.00 per share, at the public offering price of $16.00 per share, and after deducting the underwriting discounts and commissions and the estimated offering expenses payable by us.

The following table summarizes on the pro forma as adjusted basis described above, as of December 31, 2025, the differences between the number of shares purchased from us, the total consideration paid to us in cash and the average price per share that existing stockholders and investors participating in this offering paid. The

calculation below is based on the initial public offering price of $16.00 per share, before deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

| | Shares purchased | | Total consideration | | Average price per share |
|---|---|---|---|---|---|
| | Number | Percent | Amount | Percent | |
| Existing stockholders | 84,615,439 | 68.4% | $ 996,363,867 | 61.5% | $ 11.78 |
| Investors participating in this offering | 39,062,500 | 31.6 | 625,000,000 | 38.5 | $ 16.00 |
| **Total** | 123,677,939 | **100.0%** | $1,621,363,867 | **100.0%** | |

The table above assumes no exercise by the underwriters of their option to purchase additional shares of our common stock in this offering. If the underwriters were to exercise in full their option to purchase 5,859,375 additional shares from us, the number of shares of common stock held by existing stockholders would be reduced to 65.3% of the total number of shares of common stock to be outstanding upon completion of this offering, and the number of shares of common stock held by new investors participating in this offering will be increased to 34.7% of the total number of shares of our common stock to be outstanding upon completion of the offering.

Except as otherwise indicated, the discussion and the tables above assume no exercise of the underwriters' option to purchase additional shares of our common stock and excludes:

- 13,470,409 shares of our common stock issuable upon the exercise of stock options outstanding, pursuant to the 2024 Plan, as of December 31, 2025 at a weighted-average exercise price of $6.20 per share;
- 1,572,649 shares of our common stock issuable upon the exercise of outstanding options granted under the 2024 Plan subsequent to December 31, 2025, at a weighted average exercise price of $10.65 per share;
- 4,142,000 shares of our common stock issuable upon the exercise of the IPO Grants to be granted in connection with this offering under the 2026 Plan, which became effective in connection with this offering, to certain of our executive officers, directors and employees, at an exercise price per share equal to the initial public offering price in this offering;
- 14,011,037 shares of our common stock reserved for future issuance under the 2026 Plan (which number includes the IPO Grants), plus any automatic increases in the number of shares reserved for future issuance pursuant to the terms of the 2026 Plan; and
- 1,295,482 shares of our common stock reserved for future issuance under our ESPP, plus any automatic increases in the number of shares reserved for future issuance pursuant to the terms of the ESPP.

To the extent that any outstanding options are exercised or new options are issued under our incentive award plans, or we issue additional shares of common stock or other securities convertible into or exercisable or exchangeable for shares of our capital stock in the future, there will be further dilution to investors participating in this offering. 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 together with our consolidated financial statements and the related notes and other financial information appearing elsewhere in this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks, uncertainties and assumptions. Our historical results are not necessarily indicative of the results that may be expected for any period in the future. Our actual results and the timing of selected events could differ materially from those discussed in these forward-looking statements. You should read the "Special note regarding forward-looking statements" and "Risk factors" sections of this prospectus for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.*

## Overview

We are an advanced clinical-stage biotechnology company focused on elevating the next era of obesity care by advancing a diversified pipeline to provide options for people living with obesity no matter where they are in their treatment journey. Obesity is a chronic, progressive and debilitating disease that impacts over 1 billion people globally and requires long-term comprehensive treatment. Since obesity is the driving factor for more than 200 comorbidities and represents a significant contributor to increased morbidity and mortality, our vision is to deliver category-leading obesity management medications that give people the power to restore their health and transform their lives. With our obesity-first focus, we have built a diversified pipeline of product candidates specifically designed to address critical needs in the current therapeutic landscape with a lead product candidate that we believe offers the potential for the greatest weight loss.

Our lead product candidate, ribupatide (also known as KAI-9531), is currently being evaluated in global Phase 3 trials as a once-weekly injectable GLP-1/glucose-dependent insulinotropic polypeptide receptor dual agonist peptide that we believe offers the potential for the greatest weight loss compared to all obesity management medications currently available or in development. However, we have not conducted head-to-head clinical trials of ribupatide or any of our other product candidates against currently approved products or those in development; all of our product candidates are still in clinical development in the United States, and it will take several years to develop and, if approved, commercialize them; and even if we are successful in obtaining regulatory approval, there can be no guarantee as to our product candidates' ability to outperform other therapies in terms of efficacy or tolerability. We have in-licensed ribupatide and our other product candidates through a strategic collaboration with Jiangsu Hengrui Pharmaceuticals Co., Ltd., or Hengrui, a global pharmaceutical company with extensive experience in drug discovery and development. In May 2024, we entered into a license and collaboration agreement with Hengrui, or the Hengrui License Agreement, which provides us with exclusive rights to the development and commercialization of our product candidates outside of China, Hong Kong, Macau and Taiwan, or Greater China, with Hengrui responsible for development and commercialization within Greater China.

Since our inception in May 2024, we have devoted substantially all of our resources to organizing and staffing our company, business planning, raising capital, acquiring intellectual property rights, and conducting research and development activities for our product candidates. We do not have any products approved for sale and have not generated any revenue from any sources, including product sales. Through December 31, 2025, we have funded our operations primarily with proceeds from the sale and issuance of shares of our convertible preferred stock and the issuance of convertible promissory notes, which converted into shares of convertible preferred stock.

Since our inception, we have incurred significant operating losses. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our current or future product candidates. Our net loss was $219.7 million for the period from May 8, 2024 (inception) to December 31, 2024, including $214.1 million related to the acquisition of in-process research and development, and $149.0 million for the year ended December 31, 2025. As of December 31, 2024 and 2025, we had an accumulated deficit of $219.7 million and $368.7 million, respectively. We expect to continue to incur significant expenses and recognize operating losses for at least the next several years as we advance our product candidates through later stage clinical development and seek regulatory approval of our product candidates. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. We may also incur expenses in connection with the in-licensing or acquisition of additional product candidates. Furthermore, upon the closing of this offering, we expect to incur additional costs associated with operating as a public company, including significant legal, accounting, investor relations and other expenses that we did not incur as a private company.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations with proceeds from outside sources, with a majority of such proceeds to be derived from sales of equity securities, including the anticipated net proceeds from this offering. As we continue to pursue our business plan, we expect to finance our operations through a combination of equity offerings, debt financings, or other capital sources, including current or potential future collaborations, licenses, and other similar arrangements. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements as, and when, needed, we may have to significantly delay, scale back or discontinue the development and commercialization of one or more of our product candidates or delay our pursuit of potential in-licenses or acquisitions.

Because of the numerous risks and uncertainties associated with product development, 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, we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

As of December 31, 2025, we had cash, cash equivalents and marketable securities of $652.7 million. We believe that the cash, cash equivalents and marketable securities on hand as of December 31, 2025, and the anticipated net proceeds from this offering, will be sufficient to fund our operating expenses and capital expenditure requirements into the second quarter of 2028. 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. See “—Liquidity and capital resources.”

## Components of our consolidated results of operations

***Revenue***

Through December 31, 2025, we have not generated revenue from any sources, including product sales, and do not expect to generate any revenue from the sale of products in the near future. If development efforts for our product candidates are successful and result in regulatory approval, we may generate revenue in the future from product sales.

***Operating expenses***

*Research and development expenses*

Research and development expenses consist primarily of costs incurred in connection with the development of our product candidates. These expenses include:

- employee-related expenses, including salaries, related benefits, and stock-based compensation expense for employees engaged in research and development;
- costs incurred related to the Hengrui License Agreement;
- expenses incurred in connection with the nonclinical and clinical development of our product candidates, including under agreements with third parties, such as consultants and contract research organizations, or CROs;
- the cost of manufacturing drug products for use in our nonclinical studies and clinical trials, including under agreements with third parties, such as consultants and contract manufacturing organizations, or CMOs;
- costs related to compliance with regulatory requirements;
- allocated facilities costs, depreciation and other expenses, which include rent and utilities; and
- other expenses incurred as a result of research and development activities.

We expense research and development costs as incurred. Non-refundable advance payments that we make for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. The prepaid amounts are expensed as the related goods are delivered or the services are performed, or when it is no longer expected that the goods will be delivered or the services rendered.

Our direct research and development expenses are tracked on a program-by-program basis for our product candidates and consist primarily of external costs, such as fees paid to consultants, contractors, CROs, and CMOs in connection with our nonclinical, clinical and manufacturing development activities. We do not allocate employee costs and costs associated with facilities, including rent and depreciation, or other indirect costs, to specific product candidates because these costs are deployed across multiple product candidates and, as such, are not separately classified. We use internal resources primarily to conduct our research and discovery activities, as well as to manage our nonclinical, clinical and manufacturing development activities. These employees work across multiple product candidates and, therefore, we do not track these costs by product candidate.

Research and development activities are central to our business model. Product candidates in later stages of clinical development, particularly in obesity, 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. As a result, we expect that our research and development expenses will increase substantially over the next several years for increased costs related to the development of our product candidates, which were acquired in May 2024, as we conduct our global Phase 3 trials for ribupatide which were initiated in December 2025 and January 2026, as well as continue to advance the development of our other product candidates. We also expect to incur additional expenses related to milestone payments payable related to the acquired intellectual property rights to these product candidates.

The successful development and commercialization of our product candidates is highly uncertain. At this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the development of any of our product candidates or when, if ever, material net cash inflows may

commence from any of our product candidates. This uncertainty is due to the numerous risks and uncertainties associated with product development and commercialization, including the uncertainty of:

- the scope, progress, outcome and costs of our research and development activities;
- successful patient enrollment in, and the initiation and completion of, clinical trials;
- the timing, receipt and terms of any marketing approvals from applicable regulatory authorities;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- development and timely delivery of drug formulations that can be used in our clinical trials and for commercial launch;
- obtaining, maintaining, defending and enforcing patent claims and other intellectual property rights;
- significant and changing government regulation;
- launching commercial sales of our product candidates, if and when approved, whether alone or in collaboration with others; and
- maintaining a continued acceptable safety profile of the product candidates following approval.

A change in the outcome of any of these variables with respect to the development of any of our product candidates could significantly change the costs and timing associated with the development of that product candidate. We may elect to discontinue, delay or modify clinical trials of some product candidates or focus on others. In addition, we may never succeed in obtaining regulatory approval for any of our product candidates. Even if approved, our product candidates may not achieve commercial success.

*Acquired in-process research and development as part of the acquisition of the Hengrui license*

Acquired in-process research and development, or IPR&D, as part of the acquisition of the Hengrui License consists primarily of costs to acquire intellectual property in May 2024. These costs, which included cash and the fair value of shares of our Series A-2 convertible preferred stock issued to Hengrui, related to the initial acquisition of intellectual property rights and are not expected to recur. We expensed the cost of the acquired intellectual property rights because they had no alternative future use as of the acquisition date.

*General and administrative expenses*

General and administrative expenses consist primarily of salaries, related benefits, and stock-based compensation expense for personnel in executive, finance, legal, and other administrative functions. General and administrative expenses also include professional fees for legal, patent, consulting, accounting, audit and tax services, information technology costs, and general and administrative allocated rent expense and depreciation.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support our continued research activities and development of our product candidates. We also anticipate that we will incur increased accounting, audit, legal, regulatory, compliance, and director and officer insurance costs, as well as investor and public relations expenses associated with being a public company.

***Interest income***

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

***Other income (expense), net***

Other income (expense), net primarily consists of the change in fair value of the preferred stock tranche right liability, a derivative instrument embedded in the Hengrui License Agreement, and convertible promissory notes for which we elected the fair value measurement option.

## Consolidated Results of Operations

The following table summarizes our results of operations for the period from May 8, 2024 (inception) to December 31, 2024 and for the year ended December 31, 2025 (in thousands):

| | Period from May 8, 2024 (inception) to December 31, 2024 | Year Ended December 31, 2025 | $ Change |
|---|---|---|---|
| Operating expenses: | | | |
| Research and development | $ 6,975 | $ 109,113 | $ 102,138 |
| Acquired in-process research and development as part of the acquisition of the Hengrui License | 214,070 | — | (214,070) |
| General and administrative | 9,371 | 49,227 | 39,856 |
| Total operating expenses | 230,416 | 158,340 | (72,076) |
| Loss from operations | (230,416) | (158,340) | 72,076 |
| Other income (expense) | | | |
| Interest income | 2,508 | 11,048 | 8,540 |
| Other income (expense), net | 8,195 | (1,663) | (9,858) |
| Total other income | 10,703 | 9,385 | (1,318) |
| Net loss | $ (219,713) | $ (148,955) | $ 70,758 |

*Research and development expenses*

The following table summarizes our research and development expenses by program for the period from May 8, 2024 (inception) to December 31, 2024 and for the year ended December 31, 2025 (in thousands):

| | Period from May 8, 2024 (inception) to December 31, 2024 | Year Ended December 31, 2025 | $ Change |
|---|---|---|---|
| Ribupatide | $ 4,443 | $ 62,607 | $ 58,164 |
| KAI-7535 | 346 | 8,524 | 8,178 |
| KAI-4729 | 43 | 740 | 697 |
| Oral ribupatide | — | 47 | 47 |
| Personnel related (including stock-based compensation) | 1,661 | 28,603 | 26,942 |
| Unallocated research and development expenses and other | 482 | 8,592 | 8,110 |
| Total research and development expenses | $ 6,975 | $ 109,113 | $ 102,138 |

Research and development expenses increased by $102.1 million from $7.0 million for the period from May 8, 2024 (inception) to December 31, 2024 to $109.1 million for the year ended December 31, 2025. The increase was primarily driven by the ramp up in product candidate development and the related nonclinical, clinical and

contract manufacturing costs associated with our portfolio of injectable and oral development programs as well as an increase in headcount, resulting in an increase in personnel-related expenses, including stock-based compensation, to support our ongoing research and development activities.

Personnel-related expenses primarily includes salaries, related benefits, and stock-based compensation expense for employees engaged in research and development.

Unallocated research and development expenses and other primarily includes external costs that were not program specific, primarily related to consultant and contractor costs, in addition to research and development allocated rent expense and depreciation.

*Acquired in-process research and development as part of the acquisition of the Hengrui license*

In May 2024, we entered into the Hengrui License Agreement. Upon execution of the agreement, we paid $100.0 million in a non-refundable upfront payment and incurred a $10.0 million technology transfer fee, which was paid in December 2024. The Hengrui License Agreement also would have required us to pay Hengrui specified percentages of revenue from partnership agreements with third parties entered into prior to November 15, 2025. This feature was determined to represent an embedded derivative instrument. We did not enter into any such partnership agreements prior to November 15, 2025. In addition, we issued Hengrui 5,677,603 shares of our Series A-2 convertible preferred stock as partial consideration for the rights granted to us under the Hengrui License Agreement. The fair value of the derivative instrument of $4.8 million and the fair value of these issued shares of $96.4 million were accounted for as additional consideration for the arrangement for the period from May 8, 2024 (inception) to December 31, 2024.

*General and administrative expenses*

General and administrative expenses increased $39.9 million from $9.4 million for the period from May 8, 2024 (inception) to December 31, 2024 to $49.2 million for the year ended December 31, 2025. The increase was driven primarily by an increase in headcount, resulting in increases in personnel-related expenses of $19.8 million, stock-based compensation expenses of $8.6 million, and increases in professional service costs as we continue to expand our operations.

*Interest income*

Interest income for the period from May 8, 2024 (inception) to December 31, 2024 and for the year ended December 31, 2025 was $2.5 million and $11.0 million, respectively, which related to interest earned from our cash equivalents and marketable securities balances. The increase in interest income was primarily driven by higher cash equivalents and marketable securities balances, as well as interest income earned for only a partial year in 2024 compared to a full year in 2025.

*Other income (expense), (net)*

Other income (expense), net for the period from May 8, 2024 (inception) to December 31, 2024 and for the year ended December 31, 2025 was income of $8.2 million and expense of $(1.7) million, respectively. Other income (expense), net for the period from May 8, 2024 (inception) to December 31, 2024 consisted primarily of income due to the change in fair value of the preferred stock tranche right liability and a derivative instrument embedded in the Hengrui License Agreement. Other income (expense), net for the year ended December 31, 2025 consisted primarily of expense due to the change in fair value of our convertible promissory notes issued in May 2025, partially offset by income due to the change in fair value of the preferred stock tranche right liability.

## Liquidity and capital resources

Since our inception, we have not generated revenue from any sources, including from product sales, and have incurred significant operating losses and negative cash flows from our operations. As of December 31, 2025, we had cash, cash equivalents and marketable securities of $652.7 million and an accumulated deficit of $368.7 million. To date, we have funded our operations primarily with proceeds from the sale and issuance of shares of our convertible preferred stock and the issuance of convertible promissory notes, which converted into shares of convertible preferred stock.

### *Cash flows*

The following table summarizes our cash flows for the period from May 8, 2024 (inception) to December 31, 2024 and for the year ended December 31, 2025 (in thousands):

| | Period from May 8, 2024 (inception) to December 31, 2024 | Year Ended December 31, 2025 |
|---|---|---|
| Net cash used in operating activities | $ (123,302) | $ (120,210) |
| Net cash used in investing activities | (262) | (492,599) |
| Net cash provided by financing activities | 298,742 | 598,659 |
| Net increase (decrease) in cash and cash equivalents | $ 175,178 | (14,150) |

*Operating activities*

During the period from May 8, 2024 (inception) to December 31, 2024, operating activities used $123.3 million of cash, cash equivalents and restricted cash, primarily due to our net loss of $219.7 million, which included $214.0 million related to the acquisition of the Hengrui License intellectual property rights. The net loss included $101.2 million related to non-cash expense for the acquisition of the Hengrui License intellectual property rights from the issuance of preferred stock, as well as a contractual payment obligation for potential partnership payments which was determined to be a derivative instrument. The net loss was partially offset by $8.2 million related to the non-cash changes in fair values of the outstanding preferred stock tranche right liability and embedded derivative instrument liability. The net cash provided by changes in our operating assets and liabilities was $2.4 million. The changes in operating assets and liabilities primarily related to an increase in accounts payable and accrued expenses and other liabilities of $5.0 million, partially offset by an increase in prepaid expense of $2.4 million.

During the year ended December 31, 2025, operating activities used $120.2 million of cash, cash equivalents and restricted cash, primarily due to our net loss of $149.0 million, offset by a $16.8 million net decrease in our operating assets and liabilities and non-cash charges of $12.0 million. The changes in operating assets and liabilities primarily related to a net increase in accounts payable and accrued expenses and other liabilities of $37.9 million, partially offset by an increase in other non-current assets of $12.3 million and an increase in prepaid expenses of $8.8 million. Non-cash changes consisted primarily of $10.9 million in stock-based compensation expense and $3.2 million in non-cash interest on our convertible promissory notes, partially offset by $1.4 million in changes in the fair value of the preferred stock tranche right liability along with $1.7 million in accretion of discounts on our investment portfolio.

*Investing activities*

During the period from May 8, 2024 (inception) to December 31, 2024, investing activities used $0.3 million in cash, cash equivalents and restricted cash consisting of purchases of property and equipment.

During the year ended December 31, 2025, investing activities used $492.6 million in cash, cash equivalents and restricted cash consisting of purchases of investments of $632.2 million and purchases of property and equipment of $2.1 million, partially offset by maturities of investments of $141.6 million.

*Financing activities*

During the period from May 8, 2024 (inception) to December 31, 2024, financing activities provided $298.7 million in cash, cash equivalents and restricted cash consisting of net cash proceeds from our issuances of Series A convertible preferred stock.

During the year ended December 31, 2025, financing activities provided $598.6 million in cash, cash equivalents and restricted cash consisting of $498.9 million in net cash proceeds from our issuance of Series B convertible preferred stock, $100.0 million in cash proceeds from our issuance of convertible promissory notes, and $0.1 million in proceeds from the exercise of stock options, partially offset by $0.3 million in offering costs.

***Funding requirements***

We expect our expenses, excluding costs related to the acquisition of in-process intellectual property rights, to increase substantially in connection with our ongoing activities, particularly as we advance our product candidates into later stages of development. In addition, upon the closing of this offering, we expect to incur additional costs associated with operating as a public company. Our expenses will also increase as we:

- advance global clinical trials for ribupatide and oral ribupatide;
- continue the development of our other product candidates, including an ongoing Phase 2 clinical trial for KAI-7535 and initiating a Phase 1 trial for KAI-4729;
- advance our manufacturing strategy to support global scale and long-term continuity;
- seek to in-license or acquire additional product candidates and technologies;
- seek regulatory and marketing approvals for any product candidates that successfully complete clinical trials, if any;
- hire and retain additional personnel, such as clinical, quality control, commercial and scientific personnel;
- establish a sales, marketing and distribution infrastructure to commercialize any product candidates for which we may obtain marketing approval;
- expand our infrastructure and facilities to accommodate our growing employee base;
- maintain, expand and protect our intellectual property portfolio;
- make milestone, royalty or other payments due under the Hengrui License Agreement and any future license or collaboration agreements;
- make milestone, royalty, interest or other payments due under any future financing or other arrangements with third parties; and
- add operational, legal, compliance, financial and management information systems and personnel to support our operations as a public company.

We believe that the cash, cash equivalents and marketable securities on hand as of December 31, 2025, and the anticipated net proceeds from this offering, will be sufficient to fund our operating expenses and capital expenditure requirements into the second quarter of 2028. We have based these estimates on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect.

Until such time, if ever, that we can generate product revenue sufficient to achieve profitability, we expect to finance our cash needs through a combination of equity offerings, debt financings, royalty financings or other capital sources, including potential future collaborations, licenses, or other similar arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and 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. If we raise additional funds through government and other third-party funding, royalty financings, collaboration agreements, strategic alliances, licensing arrangements or marketing and distribution arrangements, we may have to relinquish valuable rights to our future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. We do not currently have any committed external source of funds. 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 products or product candidates that we would otherwise prefer to develop and market ourselves.

## Contractual obligations and commitments

The following table summarizes our contractual obligations as of December 31, 2025, and the effects that such obligations are expected to have on our liquidity and cash flows in future periods:

| | Payments due by period | | | | |
|---|---|---|---|---|---|
| | Total | Less than 1 Year | 1 to 3 Years | 4 to 5 Years | More than 5 Years |
| | | | | | (in thousands) |
| Operating lease commitments | $15,753 | $2,251 | $6,778 | $4,716 | $2,008 |
| Total | $15,753 | $2,251 | $6,778 | $4,716 | $2,008 |

From May 8, 2024 (inception) to December 31, 2024, we entered into lease agreements for office space located in Waltham, Massachusetts and San Diego, California, both of which were scheduled to expire in 2025 and were classified as operating leases. Each lease contained both fixed and variable lease payments. The lease for the premises in Waltham, Massachusetts included an option to extend the lease term for one six-month period. In accordance with the lease agreements, we provided security deposits which are refundable at the end of the lease term. The security deposits, for a total of less than $0.1 million, were recorded within prepaids and other current assets as of December 31, 2024. The security deposit, for a total of less than $0.1 million, related to the San Diego, California lease was recorded within prepaids and other current assets as of December 31, 2025.

On March 21, 2025, we executed a new, seven-year, non-cancellable operating lease agreement for approximately 39,500 square feet of office space in Waltham, Massachusetts for our corporate headquarters. The lease commenced on October 15, 2025 following completion of construction to prepare the premises for our intended use. The lease provides for base rent of $2.2 million for the first year, which will increase by approximately 2% each year. Our lease payments also include real estate taxes and other operating expenses allocable to the leased premises, which exceed base year amounts. Upon commencement of the lease, future minimum lease payments for the corporate headquarters were $15.9 million. We have the option to extend the lease for one additional five-year term with base rent calculated on the then-market rate. In accordance with the lease agreement, we maintained a letter of credit of $0.8 million, which is refundable at the end of the lease term. Subsequent to December 31, 2024, the underlying cash balance collateralizing this letter of credit was

classified as restricted cash (non-current) on our consolidated balance sheets based on the release date of the restrictions of this cash. In connection with the new lease agreement, we amended our existing lease in Waltham, Massachusetts to extend the lease term to end shortly after the lease commencement date of our new lease agreement, which occurred in the fourth quarter of 2025.

We enter into contracts in the normal course of business with CROs, CMOs and other third parties for nonclinical, clinical and manufacturing, and other development services. Payments due upon cancellation consist only of payments for services provided or expenses incurred, including noncancelable obligations of our service providers, up to the date of cancellation. These payments are not included in the preceding table as the amount and timing of such payments are not known.

In addition, pursuant to the Hengrui License Agreement, we are required to make certain milestone, royalty and other payments, which are contingent on the achievement or non-achievement of certain specified events. These payments are not included in the preceding table as the amount and timing of such payments are not known. For a more detailed description of the Hengrui License Agreement, see the section titled “Business—Hengrui license and collaboration agreement.”

## Critical accounting estimates

Our consolidated financial statements are prepared in accordance with generally accepted accounting principles in the United States. The preparation of our consolidated financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue, costs and expenses, and the disclosure of contingent assets and liabilities in our consolidated financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions and any such difference may be material.

While our significant accounting policies are described in more detail in Note 2 to our consolidated financial statements appearing elsewhere in this prospectus, we believe certain aspects of the following accounting policies require those most significant judgments and estimates in the preparation of our consolidated financial statements.

***Research and Development Expenses***

In preparing the consolidated financial statements, we are required to estimate our accrued research and development expenses as of each balance sheet date. 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. This process involves reviewing open contracts, open purchase orders, communicating with internal 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. We periodically confirm the accuracy of our estimates with our service providers and make adjustments, if necessary. The majority of our service providers invoice in arrears for services performed or when contractual milestones are met. The financial terms of agreements with these service providers are subject to negotiation, vary from contract-to-contract and may result in uneven payment flows. In circumstances where amounts have been paid in excess of costs incurred, we record a prepaid expense.

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.

***Preferred stock tranche right liability, derivative instrument and convertible promissory notes***

In order to determine the fair value of the derivative instrument embedded in the Hengrui License Agreement, we utilized available facts and circumstances to make estimates utilized in the valuation model. The valuation models utilized a Monte Carlo simulation model to estimate the enterprise value of the business to estimate the partnership payments that would be subject to the derivative instrument. The most significant estimates utilized in the valuation models are the total value of the equity, the expected volatility of future equity, risk-free rate based on the U.S. Treasury yield terms commensurate with the simulation term, and the potential change of control event timeline. The potential change of control event scenario timelines considered as of May 15, 2024 are less than six months, between six and twelve months, and between twelve and eighteen months from execution of the Hengrui License Agreement. The potential change of control event scenario timelines considered as of December 31, 2024 are between six and twelve months and between twelve and eighteen months from the initial closing date of the Series A-1 convertible preferred stock financing. The instrument expired on November 15, 2025.

In order to determine the fair value of the preferred stock tranche obligation, we utilized a hybrid method. We prepared valuations with two scenarios, an initial public offering, or IPO, scenario and a trade sale scenario to allocate the equity value to the respective share classes and a forward contract model to estimate the value associated with the remaining preferred stock tranche. The two scenarios are weighted based on management's assessment of the probability of each event occurring. The most significant estimate utilized in the valuation models is the estimated time to the closing of the Series A-1 convertible preferred stock second tranche in the potential change of control event timeline. The potential change of control event scenario timelines considered as of May 15, 2024 were less than six months, between six and twelve months, and at twelve months from the initial closing date of the Series A-1 convertible preferred stock financing. The potential change of control event scenario timelines considered as of December 31, 2024 were between six and twelve months and at twelve months from the initial closing date of the Series A-1 convertible preferred stock financing. On May 8, 2025, the preferred stock tranche obligation was settled through the issuance of convertible promissory notes. As the convertible promissory notes were issued at fair value, the preferred stock tranche obligation did not have any value upon settlement.

The convertible promissory notes are accounted for utilizing the fair value option. The convertible promissory notes were converted into preferred stock on October 31, 2025. The fair value of the convertible promissory notes upon conversion was equal to the fair value of the underlying stock.

***Stock-based compensation***

Given the absence of an active market for our common stock, our board of directors, the members of which we believe have extensive business, finance, and venture capital experience, were required to estimate the fair value of our common stock at the time of each grant of a stock-based award. We and our board of directors determined the estimated fair value of our equity instruments based on a number of factors, including external market conditions affecting the biopharmaceutical industry. We and our board of directors utilized various valuation methodologies in accordance with the framework of the American Institute of Certified Public Accountants' Technical Practice Aid, Valuation of Privately-Held Company Equity Securities Issued as Compensation, to estimate the fair value of our common stock. Each valuation methodology includes estimates and assumptions that require our judgment. These estimates and assumptions include a number of objective and subjective factors in determining the value of our common stock at each grant date, including: (1) prices paid for our convertible preferred stock, which we had sold to outside investors in arm's-length transactions,

and the rights, preferences, and privileges of our convertible preferred stock and common stock; (2) our stage of development; (3) the fact that the grants of stock-based awards involved illiquid securities in a private company; and (4) the likelihood of achieving a liquidity event for our common stock underlying the stock-based awards, such as an IPO or sale, given prevailing market conditions.

*Determination of the fair value of common stock*

For financial reporting purposes, we performed ordinary share valuations, with the assistance of a third-party specialist, at various dates, which resulted in valuations of our common stock of $5.40 per share as of December 31, 2024, $7.24 per share as of October 7, 2025, and $10.09 per share as of December 19, 2025. In conducting the valuations, our board of directors, with input from management, considered various objective and subjective factors to determine the fair value of our common stock as of each grant date, including:

- the prices at which we sold preferred stock and the superior rights and preferences of the preferred stock relative to our common stock at the time of each grant;
- the progress of our research and development programs, including the status of nonclinical studies and planned clinical trials for our product candidates;
- our stage of development and commercialization and our business strategy;
- external market conditions affecting the biopharmaceutical industry, and trends within the biopharmaceutical industry;
- our financial position, including cash on hand, and our historical and forecasted performance and operating results;
- the lack of an active public market for our common stock and our preferred stock;
- the likelihood of achieving a liquidity event, such as an IPO or a sale of our company in light of prevailing market conditions; and
- the analysis of IPOs and the market performance of similar companies in the biopharmaceutical industry.

The assumptions underlying these valuations represent management's best estimates, which involve inherent uncertainties and the application of management's judgment. As a result, if factors or expected outcomes change and we use significantly different assumptions or estimates, our stock-based compensation expense could be materially different.

The dates of our valuations have not always coincided with the dates of our stock option grants. In determining the fair value of the shares underlying options, we considered, among other things, the most recent contemporaneous valuations of our convertible preferred stock and our assessment of additional objective and subjective factors we believed were relevant as of the grant date. The additional factors considered when determining any changes in fair value between the most recent contemporaneous valuation and the grant dates included our stage of development and commercialization, our business strategy, our operating and financial performance, and current business conditions.

Following the closing of this offering, the fair value of our common stock will be determined based on the quoted market price of our common stock.

Our common stock valuations were prepared using the option-pricing method, which treats common stock and preferred stock as call options on the total equity value of a company, with exercise prices based on the value thresholds at which the allocation among the various holders of a company's securities changes. Under this

method, the common stock has value only if the funds available for distribution to stockholders exceeded the value of the preferred stock liquidation preferences at the time of the liquidity event, such as a strategic sale or a merger. The future value of the common stock 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.

## Emerging growth company status and smaller reporting company status

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies. We may take advantage of these exemptions until we are no longer an emerging growth company. Section 107 of the JOBS Act provides that an emerging growth company can take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards. We have elected to use the extended transition period for complying with new or revised accounting standards and, as a result of this election, our financial statements may not be comparable to companies that comply with public company effective dates. We intend to rely on other exemptions provided by the JOBS Act, including without limitation, not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act of 2002. We may take advantage of these exemptions up until the last day of the fiscal year following the fifth anniversary of this offering or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company if we have more than $1.235 billion in annual revenue, we have more than $700.0 million in market value of our stock held by non-affiliates (and we have been a public company for at least 12 months and have filed one annual report on Form 10-K) or we issue more than $1.0 billion of non-convertible debt securities over a three-year period.

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 million and our annual revenue was less than $100 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 million or (ii) our annual revenue is less than $100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700 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.

## Off-balance sheet arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the Securities and Exchange Commission.

## Recently issued accounting pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations, and cash flows is disclosed in Note 2 to our consolidated financial statements appearing elsewhere in this prospectus.

# Business

## Overview

We are an advanced clinical-stage biotechnology company focused on elevating the next era of obesity care by advancing a diversified pipeline to provide options for people living with obesity no matter where they are in their treatment journey. Obesity is a chronic, progressive and debilitating disease that impacts over 1 billion people globally and requires long-term comprehensive treatment. Since obesity is the driving factor for more than 200 comorbidities and represents a significant contributor to increased morbidity and mortality, our vision is to deliver category-leading obesity management medications that give people the power to restore their health and transform their lives. With our obesity-first focus, we have built a diversified pipeline of product candidates specifically designed to address critical needs in the current therapeutic landscape with a lead product candidate that we believe offers the potential for the greatest weight loss.

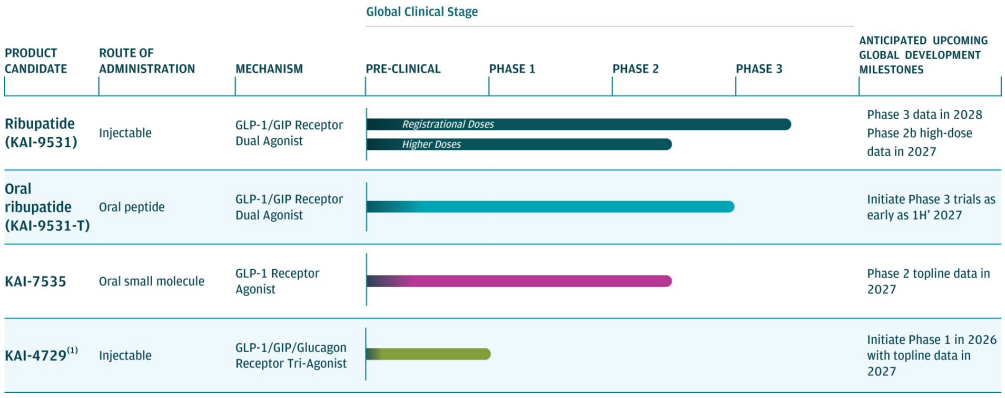
We are rapidly progressing four clinical-stage product candidates, leveraging multiple glucagon-like peptide-1, or GLP-1, based mechanisms of action and routes of administration. Our lead product candidate, ribupatide, is currently being evaluated in global Phase 3 trials as a once-weekly injectable GLP-1/glucose-dependent insulinotropic polypeptide, or GIP, receptor dual agonist peptide that we believe offers the potential for the greatest weight loss compared to all obesity management medications currently marketed or in development with a tolerability profile that is class-like or better. We are expanding our ribupatide franchise by developing a once-daily oral tablet formulation, oral ribupatide, based on the same peptide as injectable ribupatide, to provide a convenient oral option with the potential for highly differentiated tolerability with compelling weight loss among oral treatments. Additionally, we are advancing a second oral product candidate, KAI-7535, a once-daily small molecule GLP-1 receptor agonist with the potential to improve on the clinical profile of existing oral treatments. Finally, we are developing KAI-4729, a once-weekly injectable GLP-1/GIP/glucagon receptor tri-agonist, that leverages an incremental mechanism to potentially deliver compelling weight loss, improved liver fat reduction and a differentiated tolerability profile. KAI-4729 is based on a different peptide than injectable ribupatide and oral ribupatide.

Obesity is a chronic, complex disease characterized by the accumulation of excessive body fat, resulting in significant negative impacts on health and quality of life. The most severely impacted patient population, people with a body mass index, or BMI, of 35 $kg/m^2$ or greater, which we refer to as a BMI of 35+, represents the fastest growing and largest segment of this population, with half of U.S. adults with obesity expected to have a BMI of 35+ by 2030. While the approvals of GLP-1-based obesity management medications have changed the landscape of obesity management, there remains a critical need for medications offering greater weight loss, especially for those living with a higher BMI. For example, in the SURMOUNT-1 Phase 3 clinical trial, the majority of patients who had a baseline BMI of 35+ and were treated with tirzepatide, the most prescribed weight loss medicine today, were still living with obesity at the end of treatment. Both physicians and patients have identified expected weight loss as a primary treatment goal, with the magnitude of weight reduction serving as a crucial driver in therapy selection. We believe that injectable treatments will remain foundational for patients needing significant weight reduction. Meanwhile, for patients with a lower BMI, lower incidences of gastrointestinal side effects may be needed to achieve optimal weight loss and treatment persistence, and we believe oral treatments can unlock adoption for those with more modest weight loss needs, while also supporting the chronic treatment journey of those living with higher BMIs.

## Our diversified GLP-1-based pipeline

We are advancing a diversified GLP-1-based pipeline of clinical-stage therapeutic candidates for the treatment of obesity. Our pipeline is informed by decades of experience with GLP-1-based therapies and substantial research efforts and clinical data. Our obesity-first approach seeks to capitalize on and improve upon proven science to

advance product candidates which have the potential to maximize weight loss and address other critical needs in the current therapeutic landscape and to provide options, including oral options and alternative mechanisms, for people living with obesity no matter where they are in their treatment journey. We hold exclusive worldwide development and commercialization rights to all our product candidates outside of Greater China.




(1) Hengrui is conducting an ongoing Phase 1 clinical trial of HRS-4729 in China.

***Ribupatide: Potential for the greatest weight loss***

Our lead product candidate, ribupatide (also known as KAI-9531 and being developed by Jiangsu Hengrui Pharmaceuticals Co., Ltd., or Hengrui, our collaboration partner discussed in greater detail below, in Greater China as HRS9531), is a once-weekly injectable GLP-1/GIP receptor dual agonist peptide that we believe offers the potential for a category-leading profile with the greatest weight loss compared to all obesity management medications currently marketed or in development and a tolerability profile that is class-like or better. We are currently evaluating ribupatide in a global Phase 3 clinical program, named the KaiNETIC program, comprised of three Phase 3 trials.

Based on the current clinical data and commercial success of tirzepatide, we believe GLP-1/GIP dual agonism will continue to be the foundational therapy for the treatment of obesity and overweight, with a proven mechanism of action that provides substantial weight loss and a favorable tolerability profile. However, there remains a critical unmet medical need for therapies that provide greater weight loss, especially for the growing population of people living with a BMI of 35+. For example, in the SURMOUNT-1 Phase 3 clinical trial, 68% of participants who had a baseline BMI of 35+ and were treated with tirzepatide, the most prescribed weight loss medicine today, were still living with obesity at the end of 72 weeks of treatment.

Ribupatide was designed to have a clinical profile superior to tirzepatide, with modified potency on the GLP-1 and GIP receptors and *in vitro* studies demonstrating 3x GLP-1 receptor binding affinity and 0.5x GIP receptor binding affinity compared to tirzepatide, and a half-life of approximately seven days, roughly two days longer than tirzepatide, resulting in improved exposure through the full weekly dosing period. We believe this profile could result in the greatest weight loss compared to all obesity management medications currently marketed or in development with a tolerability profile that is class-like or better. However, we have not conducted head-to-head clinical trials of ribupatide or any of our other product candidates against currently approved products or those in development; all of our product candidates are still in clinical development in the United States, and it will take several years to develop and, if approved, commercialize them; and even if we are successful in obtaining regulatory approval, there can be no guarantee as to our product candidates' ability to outperform other therapies in terms of efficacy or tolerability.

Over 2,500 clinical trial participants have been dosed with ribupatide with treatment out to 52 weeks, including in multiple late-stage clinical trials conducted by Hengrui in China. Based on compelling clinical data evaluating doses up to 6 mg, Hengrui rapidly initiated a Phase 3 trial with 6 mg as the top dose. Concurrently, Hengrui evaluated an 8 mg dose in a Phase 2 trial to explore the potential for greater weight loss. These data have informed the doses being evaluated in our global Phase 3 clinical program discussed below.

With only 12 weeks of treatment at the 8 mg dose, ribupatide reduced weight by a mean of 23.6% from baseline, compared to a 1.8% reduction with placebo, when analyzed using the efficacy estimand, which reflects treatment effect assuming participants adhered to protocol treatment and excludes data collected after premature treatment discontinuations or use of other weight-loss therapies from the analysis. Using the treatment policy estimand, the primary estimand of the trial, which reflects treatment effect including the impact of premature discontinuations or use of other weight-loss therapies, the mean weight reduction was 22.8%, compared to a 1.7% reduction with placebo.

In the 48-week Phase 3 trial evaluating doses up to 6 mg, dose-dependent weight loss was observed at three different dose levels, including up to a mean reduction of 19.2% based on the efficacy estimand and a mean reduction of 17.7% based on the treatment policy estimand at the highest dose level of 6 mg, compared to a mean 1.4% reduction with placebo. Importantly, weight loss did not plateau in either trial, suggesting the potential for greater weight loss with longer treatment duration and higher doses. In both trials, ribupatide was found to be generally well-tolerated with most adverse events, or AEs, being mild or moderate, gastrointestinal, or GI-, related and consistent with the GLP-1-based class. Importantly, both trials showed that treatment-emergent AEs stabilized at doses of 3 mg and above, indicating the potential to continue dosing higher without a corresponding increase in GI-related AEs.

Based on the compelling results of the clinical program to date, we initiated our KaiNETIC global Phase 3 clinical program consisting of three Phase 3 trials to evaluate doses of 4 mg, 6 mg, 8 mg and 10 mg of ribupatide for the treatment of adults living with obesity or overweight. We believe that the range of doses being evaluated will enable personalized treatment to meet patients where they are in their treatment journey.

The first Phase 3 clinical trial, KaiNETIC-1, was initiated in December 2025 and we plan to enroll approximately 2,340 participants with a BMI of 30+ or a BMI of 27+ with a co-morbidity, excluding type 2 diabetes, or T2D. We anticipate reporting topline results from the KaiNETIC-1 trial in 2028. In the second trial, KaiNETIC-2, we plan to enroll 1,156 participants with a BMI of 27+ with T2D. In the third trial, KaiNETIC-3, we plan to enroll 1,200 adults with a BMI of 35+ and no T2D. Participants in these global, double-blind, randomized, placebo-controlled trials will receive either placebo or ribupatide up to 10 mg administered over a period of 76 weeks. In addition, KaiNETIC-3 will include an arm that will be randomized to open-label 2.4 mg semaglutide. We initiated the global Phase 3 clinical trials of KaiNETIC-2 and -3 in January 2026 and December 2025, respectively, and expect to report topline results in 2028.

To evaluate the potential to achieve greater weight loss with higher doses of ribupatide, we have also initiated a Phase 2b clinical trial to evaluate higher doses of ribupatide in adults living with obesity. The randomized, double-blind, placebo-controlled Phase 2b trial is expected to enroll approximately 250 participants with a BMI of 35+ and no T2D. Participants will receive either placebo or doses up to 20 mg of ribupatide administered over a period of 48 weeks. We initiated the Phase 2b high-dose trial in March 2026 and expect to report topline results from this trial in 2027.

***Oral ribupatide: Potential for franchise expansion with an oral option providing highly differentiated tolerability and compelling weight loss***

We are expanding our ribupatide franchise to include a once-daily oral tablet formulation, oral ribupatide (also known as KAI-9531-T and being developed by Hengrui in Greater China as HRS9531-T). Based on initial Hengrui

clinical data, we believe oral ribupatide has the potential for highly differentiated tolerability among oral treatments with compelling weight loss, representing an attractive clinical profile. Because it is an oral version of our extensively studied injectable ribupatide product candidate, we believe oral ribupatide may also have certain regulatory, development and commercial advantages, including increased speed to market and cost efficiencies.

In a Phase 2 clinical trial conducted by Hengrui in China evaluating doses up to 50 mg of oral ribupatide in 166 adults with obesity over 26 weeks, participants receiving oral ribupatide demonstrated a mean weight reduction from baseline of up to 12.1% at 26 weeks based on the efficacy estimand and up to 11.9% based on the treatment policy estimand, in each case with no observed plateau in weight loss, compared to 2.3% with placebo. Rates of vomiting (2.4% at 10 mg, 11.4% at 25 mg and 7.5% at 50 mg) and nausea (11.9% at 10 mg, 22.7% at 25 mg and 20.0% at 50 mg) were low, which we believe illustrates the potential of oral ribupatide to deliver highly differentiated tolerability with compelling weight loss among oral obesity treatments. Subject to discussions with the FDA and other regulatory agencies, we plan to initiate global Phase 3 trials of oral ribupatide as early as the first half of 2027, while Hengrui plans to advance oral ribupatide to a Phase 3 trial in China.

A next-generation formulation of oral ribupatide with enhanced bioavailability is also being evaluated in a Phase 1 clinical trial conducted by Hengrui in China.

***KAI-7535: Potential for competitive clinical profile in an oral small molecule***

We are advancing KAI-7535 (also being developed by Hengrui in Greater China as HRS-7535) as a once-daily oral small molecule GLP-1 receptor agonist with the potential to improve on the clinical profile of existing oral treatments. We believe that oral small molecule treatments will play an important role in the treatment of obesity worldwide driven by their convenience and improved scalability. As part of our approach to develop a pipeline that can benefit patients throughout their weight loss journey, we believe that KAI-7535 has the potential to offer a competitive weight loss and tolerability profile compared to other oral GLP-1 therapies.

In a Phase 2 clinical trial conducted by Hengrui in China evaluating doses ranging from 30 mg to 180 mg, treatment with 180 mg of HRS-7535 demonstrated a 9.5% (8.1% placebo-adjusted) mean weight reduction from baseline at Week 36 based on the efficacy estimand. Based on a *post-hoc*, exploratory analysis of patients with detectable drug concentrations at all post-baseline visits, treatment with 180 mg resulted in a 15.0% mean weight reduction from baseline at Week 36. Treatment-emergent AEs reported in this trial were primarily mild or moderate in severity, and mainly GI-related, which is consistent with the oral GLP-1 class.

A Phase 3 clinical trial conducted by Hengrui is ongoing evaluating doses of 180 mg of HRS-7535, with two different titration schedules, in 556 adults with obesity or overweight in China over 50 weeks. Topline results are anticipated in 2026.

We initiated a double-blind, randomized, placebo-controlled Phase 2 trial of KAI-7535 in April 2026. This trial is expected to enroll approximately 320 participants with a BMI of 30+ or a BMI of 27+ with at least one co-morbidity (which may include T2D). Participants will receive either placebo or doses up to 360 mg of KAI-7535 administered over a period of 44 weeks. We expect to report topline results from this trial in 2027.

***KAI-4729: Potential for compelling weight loss, improved liver fat reduction and a differentiated tolerability profile***

We are advancing KAI-4729 (also being developed by Hengrui in Greater China as HRS-4729), a once-weekly injectable GLP-1/GIP/glucagon receptor tri-agonist, which was designed to improve upon existing tri-agonist profiles. We believe KAI-4729's combination of the proven GLP-1/GIP mechanism with the addition of glucagon

agonism has the potential to result in greater weight reduction than currently marketed treatments with improved liver fat reduction and a differentiated efficacy and tolerability profile.

KAI-4729 was designed to have augmented potency on the GLP-1 receptor compared to reference drug retatrutide, a GLP-1/GIP/glucagon receptor tri-agonist in development by Eli Lilly. *In vitro* cell-based receptor potency data demonstrated 1.6x higher GLP-1 receptor binding affinity of KAI-4729 compared to reference drug retatrutide and similar potency on the GIP and glucagon receptors. This evaluation was conducted in an *in vitro* human cell-based receptor potency study and KAI-4729 may perform differently in *in vivo* studies. Additionally, results from testing of KAI-4729 compared to reference drug retatrutide in a nonclinical animal model of obesity showed the potential for greater weight loss.

A Phase 1 single ascending dose, or SAD, and multiple ascending dose, or MAD, trial of HRS-4729 conducted by Hengrui is ongoing in China.

We intend to initiate a Phase 1 clinical trial of KAI-4729 in 2026 and expect to report topline results from this trial in 2027.

## Our collaboration with Hengrui

Our pipeline was in-licensed through a strategic collaboration with Hengrui, a leading global innovative pharmaceutical company with robust research and development capabilities. We entered into a license and collaboration agreement with Hengrui which provides us with exclusive rights to the development and commercialization of our product candidates outside of Greater China, with Hengrui responsible for development and commercialization within Greater China. This collaboration provides us with access to broad and deep clinical data sets that inform and accelerate our global development plans based on data relating to dosing, titration, and patient populations enabling us to advance these global programs in a capital efficient manner. Moreover, Hengrui continues to generate additional data in obesity-related conditions that allow us to strategically evaluate value-creating opportunities for our product candidates. In addition to the four clinical candidates in our portfolio, we also have the right of first refusal on certain additional metabolic assets in development by Hengrui.

## Our team

Our leadership team and board of directors have significant experience discovering, developing and commercializing therapies, particularly for metabolic diseases. We believe the team we assembled has the experience needed to efficiently and effectively advance our pipeline, as well as to identify and capitalize upon the future opportunities which will arise in this large, growing market.

- **Ron Renaud**, **President and Chief Executive Officer** is a biotech leader with over 25 years of experience and a proven track record of leading companies through strategic growth, innovation and industry-defining milestones. Previous roles include:
    - President and Chief Executive Officer of Cerevel Therapeutics, prior to its acquisition by AbbVie
    - Chairman and Chief Executive Officer of Translate Bio, prior to its acquisition by Sanofi
    - Chief Financial Officer, Chief Business Officer and ultimately President and Chief Executive Officer of Idenix, prior to its acquisition by Merck
- **Scott Wasserman, M.D.**, **Chief Medical Officer** is a drug developer and cardiologist with more than two decades of experience driving global therapeutic innovation, regulatory strategy and successful drug approvals. Previous roles include:
    - Venture Partner at Frazier Life Sciences

  - Chief Executive Officer and co-founder of Latigo Biotherapeutics
  - Vice President, Global Development Therapeutic Area Head for Bone, Cardiovascular, Metabolic and Neuroscience at Amgen
- **Jamie Coleman**, **Chief Commercial Officer** is a commercial leader with nearly 25 years of experience driving global brand strategy, market leadership and revenue growth. Previous roles include:
  - Vice President, U.S. Brand Leader for Zepbound at Eli Lilly
  - Vice President, U.S. Brand Leader for Trulicity at Eli Lilly
- **Paul Burgess**, **Chief Operating Officer and Chief Business Officer** is a life sciences executive with over two decades of experience driving strategic growth, operations and cross-functional leadership. Previous roles include:
  - Chief Business Development and Strategic Operations Officer at Cerevel Therapeutics
  - Chief Operating Officer and Chief Legal Officer at Translate Bio
- **Douglas Pagán, Chief Financial Officer** is a financial executive with over two decades of experience driving organizational growth, operational excellence and long-term value creation. Previous roles include:
  - Chief Financial Officer and Chief Operating Officer at Atalanta Therapeutics
  - Chief Financial Officer and Chief Operating Officer at Jnana Therapeutics, prior to its acquisition by Otsuka Pharmaceutical
  - Chief Financial Officer at Dicerna Pharmaceuticals, prior to its acquisition by Novo Nordisk
- **Scott Akamine**, **Chief Legal Officer** is a legal executive with deep expertise in navigating complex regulatory and competitive environments to support strategic growth and corporate leadership. Previous roles include:
  - Chief Legal Officer and Corporate Secretary at Cerevel Therapeutics
  - General Counsel and Corporate Secretary of AEON Biopharma
- **Paula Cloghessy**, **Chief People Officer** is a human resources leader with over 20 years of experience building people-first cultures and guiding companies through transformative growth. Previous roles include:
  - Executive Vice President, Chief People Officer at Seres Therapeutics
  - Chief People Officer at Translate Bio

Since our inception, we have raised $900 million in proceeds from leading life science investors, including Bain Capital Life Sciences, Bain Capital Private Equity, RTW Investments, Atlas Venture and Canada Pension Plan Investment Board (CPP Investments). Prospective investors should not rely on the investment decisions of our existing investors, as these investors may have different risk tolerances and purchased their shares in financings that were conducted at a significant discount to the price offered to the public in this offering. See “Certain relationships and related party transactions” for more information.

## Our strategy

- **Advance our lead product candidate, ribupatide, through currently ongoing global Phase 3 clinical development with the goal of demonstrating the greatest weight loss for people living with obesity:** We are focused on progressing our lead GLP-1/GIP receptor dual agonist ribupatide through global Phase 3

development. In December 2025, we initiated a Phase 3 clinical program, KaiNETIC, comprised of three clinical trials designed to demonstrate our belief in ribupatide's potential to deliver the greatest weight loss of any marketed or in development treatment with a tolerability profile that is class-like or better. This program includes a dedicated Phase 3 trial in BMI of 35+, the most severely impacted patient population. We believe this clinical strategy will support global regulatory approval of ribupatide with a differentiated clinical profile. Additionally, we believe evaluating a range of doses in our Phase 3 program will enable personalized dosing to meet patients where they are in their treatment journey. We expect to report topline data from our Phase 3 trials in 2028.

- **Accelerate clinical development of our oral therapies, oral ribupatide and KAI-7535, and our injectable tri-agonist, KAI-4729, to address critical needs in the current obesity landscape:** In parallel to our Phase 3 program of ribupatide, we are advancing a diversified portfolio of product candidates to address the range of preferences and needs of people living with obesity. We believe our oral product candidates, oral ribupatide, a once-daily oral formulation of ribupatide, and KAI-7535, an oral GLP-1 receptor agonist small molecule, have the potential to serve the unmet need of a broad spectrum of patients. We are planning to initiate Phase 3 trials of oral ribupatide as early as the first half of 2027 and initiated a Phase 2 trial of KAI-7535 in 2026. Through the development of KAI-4729, an injectable GLP-1/GIP/glucagon receptor tri-agonist, we are exploring the potential for incremental benefits of glucagon agonism. We believe KAI-4729 has the potential to provide a new option for patients that would benefit from an alternative mechanism of action and may result in greater weight reduction than currently marketed treatments with improved liver fat reduction and a differentiated efficacy and tolerability profile. We anticipate initiating a Phase 1 trial of KAI-4729 in 2026.
- **Combine our team's extensive drug development track record with Hengrui's broad and deep clinical data to inform and accelerate our development strategy:** We will utilize our team's deep experience in drug development, including in the cardiometabolic space, to maximize the value of our strategic partnership with Hengrui. This partnership provides us with access to clinical data funded and generated by Hengrui in China to inform the dosing, titration, and patient populations for our global clinical programs, as well as identify new value-creating indication expansion opportunities and expansion into new mechanisms and routes of administration.
- **Establish broad commercial reach and manufacturing scale to bring differentiated obesity treatments to market:** We are building our team to establish expertise and capabilities needed to achieve global commercial success upon the potential approval of ribupatide and our other product candidates. We have established a robust, diversified, and scalable supply chain based in the United States, which can be supported by Hengrui's established manufacturing capacity. For certain programs, indications or geographies, we may selectively evaluate opportunities to partner in order to accelerate and fund development and commercialization.

## Obesity: One of the most prevalent diseases globally with broad health consequences

Obesity, which is defined by the World Health Organization as having a BMI of 30+, is a chronic, complex disease characterized by the accumulation of excessive body fat, resulting in significant negative impact on overall health, quality of life and lifespan.

Obesity is one of the most prevalent diseases in the world, affecting over 1 billion people worldwide, representing approximately one-eighth of the global population. In the United States, the rates are even higher with 40.3% of the population living with obesity and 19.4% living with a BMI of 35+. Even with the increased uptake of GLP-1-based obesity management medications, the rate of obesity continues to rise. By 2030, 50% of adults with obesity in the United States are expected to have a BMI of 35+. The global prevalence of obesity is expected to rise from 13% of the world's population in 2022 to 25%, or 1.9 billion, by 2035.

The broad ranging health consequences of obesity are well understood, with studies having shown that obesity is associated with more than 200 comorbidities. Chronic conditions with a significant risk of morbidity and mortality, such as kidney disease, osteoarthritis, cancer, diabetes, sleep apnea, metabolic dysfunction-associated steatotic liver disease, hypertension, and cardiovascular disease, are directly related to obesity. In 2019, an estimated 5 million noncommunicable disease deaths were caused, in part, by BMI above the healthy range. In assessing measures of quality of life, men and women with obesity experienced lower health-related quality of life compared to people at a normal weight.

Despite the known health complications of obesity, the obesity health crisis continues to worsen. The causes of obesity are multifactorial, including obesogenic environments (e.g., environments that promote weight gain), psycho-social factors and genetic variants. Once an individual has obesity, it is often very difficult to lower weight with exercise and diet alone due to the compensatory mechanisms of the body to counter-regulate body weight. Calorie restriction as a weight loss strategy can result in both an increased drive to eat and a reduction in energy expenditure, stymying efforts at weight loss and instead favoring weight gain. Because of the complex nature of weight gain and the physiological challenges with weight loss, there is no single approach for effective weight loss and long-term management in this diverse patient population.

Beyond the health burden, obesity presents a tremendous financial cost to individuals and health systems around the world. People living with obesity incur significantly higher medical costs. The economic impact of overweight and obesity in the United States was estimated to be over $705 billion in 2019 and predicted to increase to $2.6 trillion by 2060.

***Obesity treatment landscape***

The first line treatment for obesity is lifestyle modification, which incorporates a combination of diet, exercise, and behavior therapy. Lifestyle modifications can produce weight loss; however, the magnitude needed to have a disease modifying effect on obesity-related health conditions (approximately 15%) is difficult to achieve and sustain over time. Additionally, for the growing population of people with a BMI of 35+, a 15% loss in weight may not be sufficient to achieve a healthy weight. For example, if a person who is 5 feet 5 inches tall and weighs 250 pounds loses 15% of their weight, they would still be classified as having obesity with a BMI of 35+.

A third-party retrospective observational study of over 10,000 participants with obesity enrolled in a “real-world” medically supervised weight management program demonstrated an average weight loss of 5.8% over a 5-year period, which is still significantly less than what would be considered disease-modifying for many people. Until the recent approval of GLP-1 based obesity management medications, there have been very few pharmacological treatments available that have safely produced a disease modifying magnitude of weight loss.

In the last decade, there have been major advancements in obesity treatments with multiple approved GLP-1 obesity management medications that have been shown to result in significant weight loss. In 2014, liraglutide 3 mg, marketed as Saxenda, became the first long-acting GLP-1 receptor agonist approved by the FDA for weight management in people with a BMI of 30+ or at least 27+ with one or more weight-related comorbidity, as an adjunct to diet and exercise. Today, several long-acting injectable GLP-1 receptor agonists have been approved by the FDA for a weight loss indication, including the current market leaders, semaglutide 2.4 mg, marketed as Wegovy, and the dual GLP-1/GIP receptor agonist tirzepatide, marketed as Zepbound. It is estimated that there are more than 80 obesity therapeutics currently in clinical-stage development. For once-weekly injectable obesity management medications, the current marketed and in-development therapies demonstrate average weight loss of approximately 15% to 20% of weight, as summarized below.

**Summary of weight loss observed in clinical trials of select marketed and in-development injectable GLP-1-based obesity management medications (treatment policy estimand, placebo adjusted)**

| Asset | Mechanism of Action | Study | Dose | Weight Loss | Trial Duration | Time at Top Dose |
|---|---|---|---|---|---|---|
| Wegovy (Marketed). | GLP-1 | Ph 3 | 2.4 mg QW | 12.4% | 68 weeks | 52 weeks |
| Zepbound (Marketed) | GLP-1/GIP | Ph 3 | 15 mg QW | 17.8% | 72 weeks | 52 weeks |
| CagriSema | GLP-1/Amylin | Ph 3 | 2.4 mg/2.4 mg QW | 17.3% | 68 weeks | Flexible |
| Retatrutide* | GLP-1/GIP/GCG | Ph 3 | 12 mg QW | 19.1% | 68 weeks | 52 weeks |
| Retatrutide | GLP-1/GIP/GCG | Ph 2b | 12 mg QW | 18.3% | 48 weeks | 36 weeks |
| CT-388 | GLP-1/GIP | Ph 2 | 24 mg QW | 18.3% | 48 weeks | N/A |

* *TRIUMPH-4, a Phase 3 trial in adults with obesity or overweight and knee osteoarthritis*

Clinical data with GLP-1-based therapeutics have demonstrated substantial and sustained reductions in weight, as well as the ability to lower blood glucose and improve Hemoglobin A1c, or HbA1c, a blood test measuring glucose levels that is utilized to diagnose and monitor diabetes. The current market leaders, semaglutide (marketed by Novo Nordisk) and tirzepatide (marketed by Eli Lilly) have achieved commercial success in both obesity and T2D based on the strength of their clinical results.

In a 68-week Phase 3 clinical trial, STEP 1, adults with obesity or overweight and at least one weight-related comorbidity, lost a mean of 14.9% of their weight from baseline to Week 68 with 2.4 mg once-weekly semaglutide injections along with diet and exercise, compared to a 2.4% loss with placebo, based on the treatment policy estimand.

A 72-week randomized controlled trial of tirzepatide (SURMOUNT-1) demonstrated an average weight loss of approximately 15.0%, 19.5% and 20.9% in over 2,500 adults with obesity or overweight and at least one weight-related complication, excluding T2D, who were treated once-weekly with 5 mg, 10 mg and 15 mg of tirzepatide, respectively, compared to a 3.1% weight loss with placebo, based on the treatment policy estimand. As part of the SURMOUNT development program, tirzepatide was studied in 210 participants with a BMI of 28+ (the criteria to be considered to have obesity in China) with at least one weight-related comorbidity in a 52-week randomized placebo-controlled clinical trial in China (SURMOUNT-CN). Participants had a placebo-adjusted mean weight loss of 11.3% with 10 mg of tirzepatide and 15.1% with 15 mg of tirzepatide at Week 52 based on the treatment policy estimand.

In a Phase 3b open-label clinical trial (SURMOUNT-5) adult participants with obesity, but without T2D, were randomized to receive either tirzepatide or semaglutide once-weekly for 72 weeks. The mean weight loss at Week 72 for those taking tirzepatide was 20.2% compared to 13.7% for those taking semaglutide based on the treatment policy estimand. Participants in the tirzepatide group were also more likely to have weight reductions of at least 10%, 15%, 20% and 25%, compared to the semaglutide group.

In addition to the approved and in-development injectable obesity management medications for obesity, there has been significant interest in the development of a once-daily oral therapy for weight management. Clinical data from a representative group of oral GLP-1-based obesity management medications currently in development has been summarized below.

**Summary of weight loss for select oral GLP-1-based obesity management medications in development (treatment policy estimand, placebo adjusted)**

| Asset | Modality | Study | Dose | Weight Loss | Nausea | Vomiting | Trial Duration |
|---|---|---|---|---|---|---|---|
| Semaglutide | Oral Peptide | Ph 3 | 25 mg | 11.4% | 46.6% | 30.9% | 64 weeks |
| Orforglipron | Small molecule | Ph 3 | 17.2 mg | 9.1% | 33.7% | 24% | 72 weeks |
| Aleniglipron* | Small molecule | Ph 2b | 180 mg | 16.3% | >69%** | >44%** | 36 weeks |
| VK2735 | Oral Peptide | Ph 2 | 90 mg | 9.8% | 73% | 35% | 13 weeks |
| Zenagamtide (amycretin)* | Oral Peptide | Ph 1 | 50 mg twice daily | 11.8% | 75% | 56% | 12 weeks |

* *Results are efficacy estimand (treatment policy estimand not available).*
** *Events reported for Part 1 of the study only, though some additional events occurred in the second half.*

In a 72-week randomized controlled Phase 3 trial of orforglipron (ATTAIN-1) in adults with obesity or overweight and at least one weight-related complication, excluding T2D, orforglipron demonstrated a mean weight reduction of 11.2% in participants who were treated once daily with 36 mg of orforglipron, compared to a 2.1% weight loss with placebo, based on the treatment policy estimand.

Additionally, a 64-week randomized controlled Phase 3 trial of oral semaglutide (OASIS 4) demonstrated a mean weight reduction of 13.6% in adults with obesity or overweight and at least one weight-related complication, excluding T2D, who were treated once-daily with 25 mg oral semaglutide, compared to a placebo group that lost 2.2% of weight, based on the treatment policy estimand.

## Our diversified GLP-1-based pipeline

***Ribupatide: Potential for the greatest weight loss***

Ribupatide (also known as KAI-9531 and being developed by Hengrui in Greater China as HRS9531), a once-weekly injectable GLP-1/GIP receptor dual agonist, is in clinical development for the treatment of obesity. Based on clinical data generated to date, we believe ribupatide has the potential for the greatest weight loss compared to all obesity management medications currently marketed or in development with a tolerability profile that is class-like or better. However, we have not conducted head-to-head clinical trials of ribupatide or any of our other product candidates against currently approved products or those in development; our product candidates are still in clinical development in the United States, and it will take several years to develop and, if approved, commercialize them; and even if we are successful in obtaining regulatory approval, there can be no guarantee as to our product candidates' ability to outperform other therapies in terms of efficacy or tolerability.

Ribupatide's potential in obesity is supported by multiple completed and ongoing clinical trials run by Hengrui in China, with over 2,500 clinical trial participants dosed with ribupatide to date. Based on compelling clinical data evaluating doses up to 6 mg Hengrui rapidly initiated a Phase 3 trial with 6 mg as the top dose. Concurrently Hengrui evaluated an 8 mg dose in a Phase 2 trial to explore the potential for greater weight loss. In this 36-week Phase 2 trial in China in adults living with obesity or overweight, despite only 12 weeks of treatment at the 8 mg dose, ribupatide 8 mg reduced weight by a mean of 23.6% from baseline at Week 36 based on the efficacy estimand, compared to a 1.8% reduction with placebo, and by 22.8% based on the treatment policy estimand, compared to a 1.7% reduction with placebo. In a 48-week Phase 3 trial in China in adults living with obesity or overweight evaluating doses up to 6 mg, dose-dependent weight loss was observed at the three dose levels tested, including up to a mean of 19.2% based on the efficacy estimand and by 17.7% based on the treatment policy estimand at the highest dose level of 6 mg, compared to a 1.4% reduction with

placebo. Importantly, weight loss did not plateau in either trial, suggesting the potential for greater weight loss with higher doses and longer duration of treatment. In both trials, ribupatide was found to be generally well-tolerated with most AEs being mild or moderate, GI-related, and consistent with the GLP-1-based class. Importantly, both trials showed that treatment-emergent AEs stabilized at doses of 3 mg and above, indicating the potential to continue dosing higher without a corresponding increase in AEs.

We designed a global Phase 3 clinical program, KaiNETIC, that consists of three Phase 3 clinical trials. We initiated our first global Phase 3 clinical trial, KaiNETIC-1, in December 2025 and we expect to report topline data in 2028. Our second global Phase 3 clinical trial, KaiNETIC-2, was initiated in January 2026 and we expect to report topline data in 2028. Our third global Phase 3 clinical trial, KaiNETIC-3, was initiated in December 2025 and we expect to report topline data in 2028. To evaluate the potential to achieve greater weight loss with higher doses of ribupatide, in March 2026, we initiated a Phase 2b clinical trial to evaluate doses up to 20 mg of ribupatide in adults living with obesity, with topline results expected in 2027.

*Unmet need: Greater weight loss*

Based on the clinical data and commercial success of tirzepatide, we believe GLP-1/GIP dual agonism will continue to be the foundational mechanism in obesity treatment, with a proven mechanism of action that provides substantial weight loss balanced with a favorable tolerability profile. However, there remains a critical need to further increase weight loss, especially for the growing population of people living with a BMI of 35+. For example, in the SURMOUNT-1 Phase 3 clinical trial, 68% of patients who had a baseline BMI of 35+ and were treated with tirzepatide, the most prescribed weight loss medicine today, were still living with obesity at the end of treatment after 72 weeks. Both physicians and patients have identified expected weight loss as a primary treatment goal, with the magnitude of weight reduction serving as a crucial driver in treatment selection.

*Our solution: Ribupatide*

Ribupatide was designed to have modified potency on the GLP-1 and GIP receptors, with *in vitro* studies demonstrating 3x GLP-1 binding affinity and 0.5x GIP binding affinity compared to tirzepatide, and a half-life of seven days, approximately two days longer than tirzepatide, resulting in improved exposure through the full week-long dosing period. We believe this profile could result in the greatest weight loss compared to all obesity management medications currently marketed or in development with a tolerability profile that is class-like or better.

*Phase 1 Clinical trials in healthy volunteers*

Two Phase 1 clinical trials of ribupatide were conducted by Hengrui in China. The first, a randomized, double-blind, placebo-controlled SAD and MAD trial was designed to investigate the safety, tolerability, pharmacokinetics, or PK, and pharmacodynamics, or PD, of ribupatide in healthy volunteers. The SAD portion of the clinical trial enrolled 60 healthy volunteers who were assigned to receive one subcutaneous injection of ribupatide at 0.1 mg, 0.3 mg, 0.9 mg, 2.7 mg. 5.4 mg, or 8.1 mg or placebo. The MAD portion of the clinical trial enrolled 30 healthy volunteers who received once-weekly injections of ribupatide for four weeks at 0.9 mg, 2.7 mg, or 5.4 mg or placebo. The MAD cohort receiving the highest dose of ribupatide titrated each week to a higher dose and received the 5.4 mg dose during the final week (2.7 mg, 2.7 mg, 4 mg and 5.4 mg titration).

Ribupatide was generally well-tolerated in healthy volunteers, with AEs being primarily mild in nature and no severe AEs reported. The most common AEs were abdominal distension and nausea in the SAD phase, and urine ketone bodies present and nausea in the MAD phase.

Ribupatide exhibited a dose proportional PK profile in healthy volunteers. In the SAD portion of the trial, the median time to peak plasma concentration, or Tmax, which measures the time it takes for drug to reach

maximum plasma concentration, was 48 to 72 hours. The mean half-life of ribupatide was 156 to 182 hours. In the MAD portion of the trial, the Tmax was also 72 to 120 hours and the mean half-life was 169 to 192 hours after the fourth dose.

The second Phase 1 clinical trial investigated the safety, PK and PD of ribupatide in participants with T2D. The randomized, double-blind, placebo- and open-label positive controlled Phase 1b clinical trial enrolled 63 participants aged 18 to 65 years with a six month or longer history of T2D and prior lifestyle intervention or stable metformin treatment of 8 weeks or greater. Participants received weekly subcutaneous injections of ribupatide at 0.3 mg, 1.5 mg, or 4.5 mg, dulaglutide at 1.5 mg, or placebo for four weeks. The cohort receiving the highest dose of ribupatide were titrated to a higher dose each week and received the 4.5 mg dose during the final week (2 mg, 2 mg, 3 mg and 4.5 mg titration). Ribupatide was well-tolerated in participants with T2D with AEs being primarily mild and GI-related.

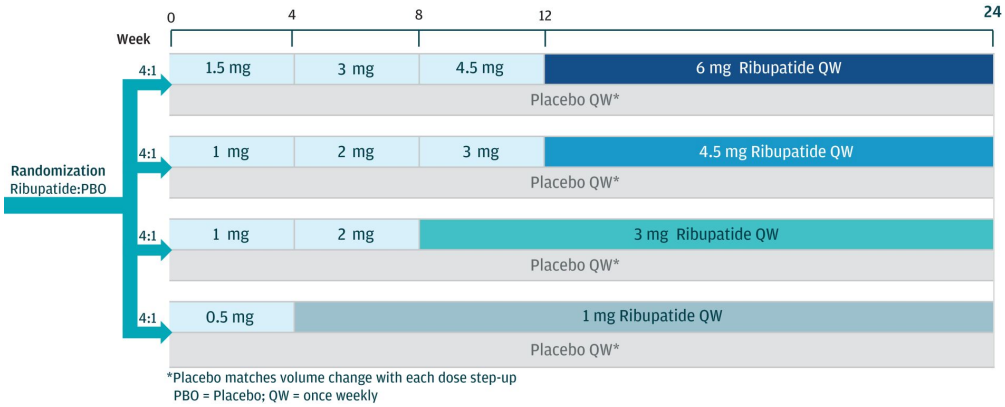
Ribupatide exhibited a dose proportional PK profile in participants with T2D. The median Tmax was 71.9 to 94.8 hours after a single dose of ribupatide and 48.1 to 71.8 hours after the fourth dose of ribupatide. The mean half-life was measured to be approximately one week (168 hours).

*Phase 2 clinical trial of participants with obesity and without T2D (up to 6 mg)*

*Trial design*

Ribupatide was evaluated in a multi-center, randomized, double-blind, placebo-controlled, Phase 2 clinical trial in participants with obesity (defined as BMI of 28+ China) and without T2D. Four once-weekly dose levels of ribupatide at 1 mg, 3 mg, 4.5 mg and 6 mg were evaluated, with participants being randomized 4:1 within each of these dose cohorts to receive either ribupatide or placebo. The 24-week double-blind core treatment period titration schedule for each dose level is outlined in the figure below with all participants reaching and maintaining their highest dose by Week 12.

**Design of Phase 2 clinical trial investigating up to 6 mg dose of ribupatide (core treatment period)**




The primary endpoint of the trial was percent change from baseline in body weight at Week 24. Secondary endpoints included percentage of subjects with ≥5%, ≥10%, and ≥15% reduction in body weight, changes in systolic blood pressure, diastolic blood pressure, waist circumference, HbA1c, homeostatic model assessment of insulin resistance, or HOMA-IR, and triglycerides as well as measures of safety and tolerability.

At the completion of 24 weeks, the trial continued for two voluntary extensions – Extension 1 was 8 weeks and Extension 2 was 20 weeks – for a total of 52 weeks of exposure to ribupatide. In Extension 1, participants who opted to continue in the trial remained at their dose level and continued to receive weekly doses. In Extension 2, participants in the 3 mg, 4.5 mg and 6 mg active arms remained at their dose level and either continued to take once-weekly doses or switched to every other week dosing. All participants in the 1 mg arm or on placebo were titrated to receive 3 mg of ribupatide once weekly.

*Demographics and baseline measures*

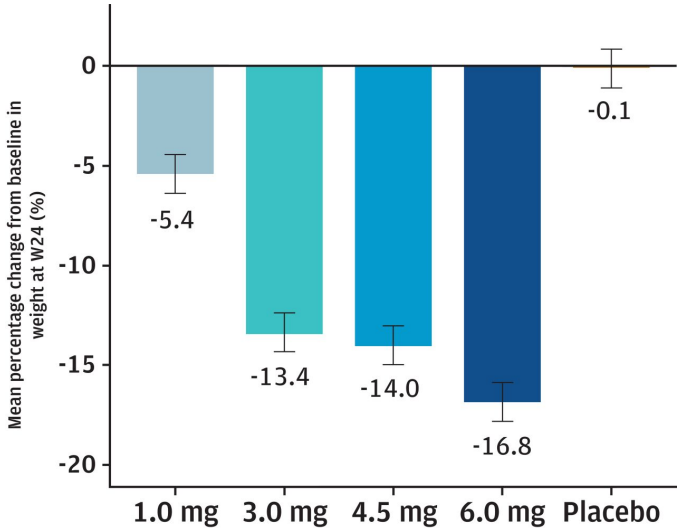
The trial enrolled 249 participants of which 240 participants completed the 24 week double-blind treatment period. The average age of participants was 34.2 years and 51.8% were female. The average weight and BMI of the participants was 91.5 kg and 32.3, respectively. The inclusion criteria included a BMI measure of 28 to 40.

The average baseline levels of HbA1c for each cohort (5.3%-5.4%) were within the normal range which is less than 5.7%, consistent with a non-diabetic population.

*Efficacy data*

The Phase 2 clinical trial met the primary endpoint of percent change from baseline in body weight at Week 24. The mean reduction of body weight from baseline to Week 24 for the 1 mg, 3 mg, 4.5 mg and 6 mg cohorts was 5.4%, 13.4%, 14.0% and 16.8%, respectively, based on the treatment policy estimand. The placebo group lost 0.1% from baseline to Week 24.

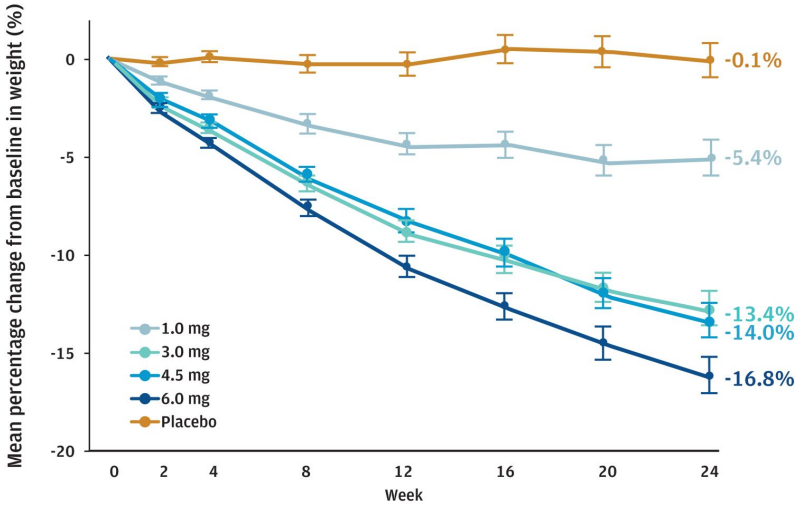
**Mean percentage change in body weight from baseline at Week 24 in Phase 2 clinical trial of ribupatide**




*Primary estimand: treatment policy estimand*

For the 3 mg, 4.5 mg and 6 mg cohorts, weight loss continued throughout the 24 weeks of the trial, with no observed plateau, indicating the potential for further weight loss with longer treatment duration.

**Mean percentage change in weight loss from baseline to Week 24**



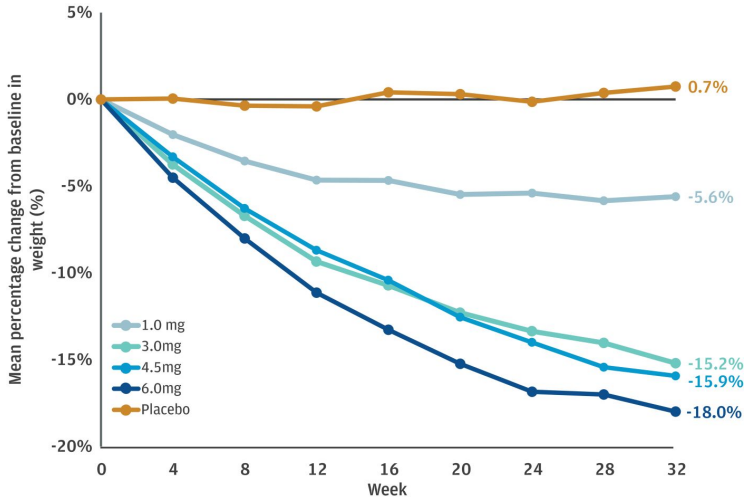

*Primary estimand: treatment policy estimand*

The proportion of participants who achieved prespecified weight reduction targets at Week 24 was also assessed. In the highest dose cohort, 91.8% of participants achieved a 5% or greater reduction in baseline weight, 77.6% achieved 10% or greater and 53.1% achieved a 15% or reduction in baseline loss.

The clinical trial also assessed several key measures of health and comorbidities associated with obesity, including changes in systolic blood pressure, diastolic blood pressure, waist circumference, HbA1c, HOMA-IR, and triglycerides. Improvements in all measures were observed across all four dosing cohorts of ribupatide.

At the completion of 24 weeks, 168 participants opted to continue treatment in the 28-week extension period, of whom 166 completed Extension 1. At the completion of Extension 1, participants had a mean percent decrease in weight from baseline to Week 32 of 5.6%, 15.2%, 15.9% and 18% for 1 mg, 3 mg, 4.5 mg and 6 mg cohorts, respectively, based on the treatment policy estimand, compared to an increase in body weight of 0.7% for those on placebo during the extension period.

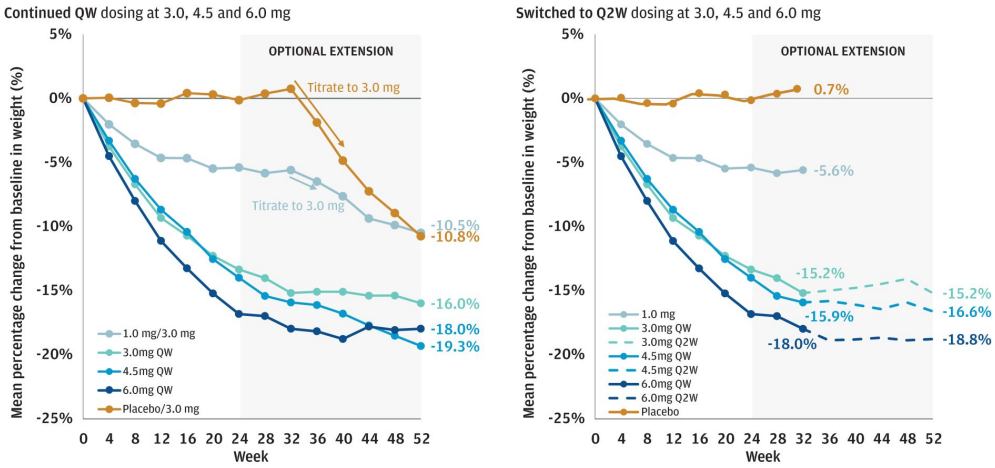
**Extension 1: Mean percentage change in weight from baseline to Week 32 in Phase 2 clinical trial of ribupatide**




*Primary estimand: treatment policy estimand*

Thereafter, 163 participants were re-randomized to receive ribupatide for Extension 2, and 154 completed this treatment. At the completion of Extension 2, participants who continued once weekly dosing of ribupatide showed a mean percent weight loss of 16.0%, 18.0% and 19.3% for those being treated with 3 mg, 4.5 mg and 6 mg of ribupatide, respectively, from baseline to Week 52 based on the treatment policy estimand. Participants who transitioned from placebo or 1 mg of ribupatide to receive 3 mg of ribupatide lost a mean percentage of 10.5% and 10.8% of weight from baseline to Week 52, respectively, based on the treatment policy estimand. Participants that switched to once every other week dosing at Week 32 showed a mean weight loss from baseline of 15.2%, 16.6% and 18.8% with 3 mg, 4.5 mg and 6 mg cohorts, respectively, suggesting that switching from weekly to every other week dosing may be an effective maintenance dosing strategy.

**Extension 2: Mean percentage change in weight from baseline to Week 52 with once weekly (left) and once every other week (right) dosing schedules in Phase 2 clinical trial of ribupatide**




*Non-randomized sample of those who opted to continue in 28-week extension: 2/3 of core period participants (168 of 249)*
*Primary estimand: treatment policy estimand*

*Safety and tolerability data*

Ribupatide was found to be generally well-tolerated with most reported AEs being mild or moderate. A total of six serious AEs were observed, two in the 3 mg cohort, one in the 4.5 mg cohort and three in the placebo cohort. AEs leading to discontinuation occurred in the 1 mg, 3 mg and placebo cohorts (one participant in each cohort). No treatment-related serious AEs were observed and no participants discontinued treatment due to a treatment-related AE.

The most common AEs were GI-related, which is consistent with the GLP-1-based class. GI-related AEs reported with a 5% or greater frequency in any arm include nausea, diarrhea and vomiting. There were no treatment-related adverse events, or TRAEs, leading to discontinuation.

**Summary of adverse events in Phase 2 (up to 6 mg) clinical trial of ribupatide**

| | 1 mg (N=49) | 3 mg (N=51) | 4.5 mg (N=50) | 6 mg (N=49) | Placebo (N=49) |
|---|---|---|---|---|---|
| Any AE | 34 (69.4) | 42 (82.4) | 39 (78.0) | 44 (89.8) | 38 (77.6) |
| Serious Adverse Event (SAE)[1] | 0 | 2 (3.9) | 1 (2.0) | 0 | 3 (6.1) |
| AEs leading to treatment discontinuation | 1 (2.0) | 1 (2.0) | 0 | 0 | 1 (2.0) |
| Treatment-related SAE | 0 | 0 | 0 | 0 | 0 |
| TRAEs leading to treatment discontinuation | 0 | 0 | 0 | 0 | 0 |
| **Gastrointestinal disorders with ≥ 5% frequency in any arm** | | | | | |
| Nausea | 8 (16.3) | 14 (27.5) | 16 (32.0) | 16 (32.7) | 4 (8.2) |
| Diarrhea | 5 (10.2) | 17 (33.3) | 15 (30.0) | 16 (32.7) | 4 (8.2) |
| Vomiting | 3 (6.1) | 10 (19.6) | 11 (22.0) | 14 (28.6) | 1 (2.0) |

[1]Treatment-emergent SAEs observed in this trial in the ribupatide arms were intervertebral disc protrusion, facet joint syndrome and ventricular fibrillation (in a participant with pre-existing congenital heart disease), none of which were assessed by the investigator to be related or potentially related to ribupatide treatment.

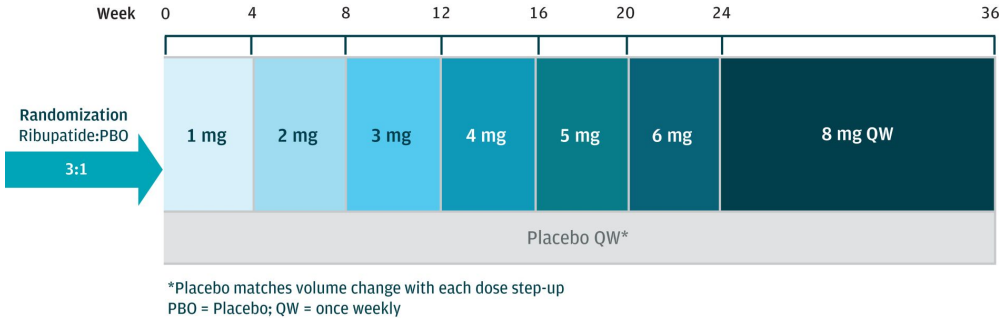
*Phase 2 Clinical Trial of Participants with Obesity or Overweight and Without T2D (up to 8 mg)*

*Trial design*

Based on the results of the Phase 2 dose-ranging clinical trial of participants with obesity and without T2D, ribupatide was evaluated in an additional Phase 2 clinical trial in China by Hengrui to explore a higher dose of 8 mg given once weekly compared to placebo for 36 weeks.

The primary endpoint of the trial was percent change in weight from baseline to Week 36. The multi-center, randomized, double-blind, placebo-controlled clinical trial was conducted in China by Hengrui. The clinical trial enrolled participants aged 18 to 65 years with a BMI between 24 and 40, without T2D. Participants were randomized 3:1 to receive either 8 mg of ribupatide or placebo.

**Design of Phase 2 clinical trial investigating 8 mg dose of ribupatide**




*Placebo matches volume change with each dose step-up
PBO = Placebo; QW = once weekly

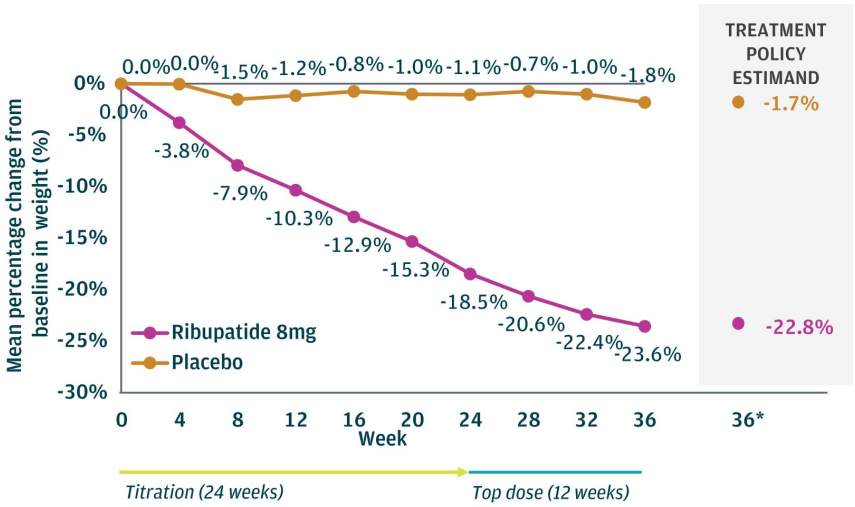
*Demographics and baseline measures*

The trial enrolled 61 participants with an average age of 34 years and 68.9% were female. The average weight and BMI of participants was 84.6 kg and 31.3, respectively.

*Efficacy data*

The clinical trial achieved the primary endpoint of percent change in weight from baseline to Week 36. Participants being treated with ribupatide lost a mean percentage of 23.6% based on the efficacy estimand compared to a 1.8% reduction with placebo, and 22.8% based on the treatment policy estimand from baseline at Week 36 in the ribupatide cohort compared to an average of 1.7% decrease in the placebo cohort. Participants randomized to ribupatide lost weight throughout the 36-weeks of treatment with no observed plateau, indicating the potential for greater weight loss over a longer duration of treatment.

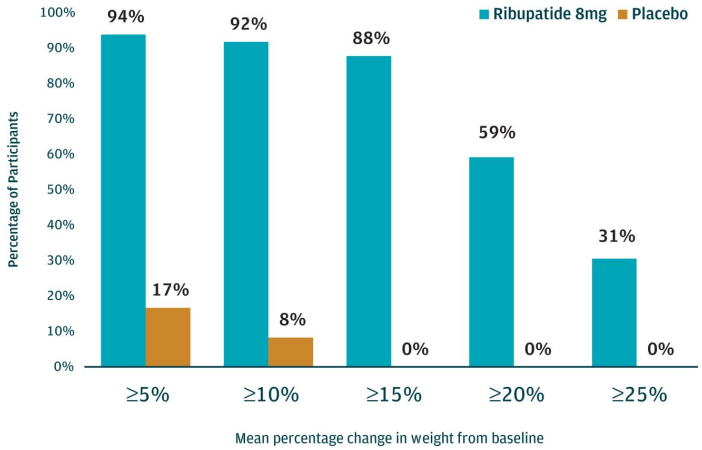
**Mean percentage change in weight loss from baseline to Week 36**




Primary estimand: efficacy estimand

The proportion of participants achieving different thresholds of weight loss was also assessed. Fifty-nine percent of participants treated with ribupatide achieved a 20% or greater weight reduction in baseline weight and 31% achieved 25% or greater reduction in baseline weight. In the placebo cohort, 8% of participants achieved 10% or greater weight loss and none achieved the 15% or greater threshold. Nearly all (94%) of participants treated with ribupatide achieved at least a 5% reduction in baseline weight, compared to 17% of participants given placebo.

**Proportion of participants achieving thresholds of weight loss in Phase 2 (8 mg) trial of ribupatide**




*Safety and tolerability data*

Ribupatide was generally well-tolerated with most AEs being mild or moderate. Three serious AEs were observed, two in the ribupatide cohort (4.1%) and one in the placebo cohort (8.3%).

The most common AEs were diarrhea, alopecia, nausea, injection site reaction, upper respiratory infection. The GI-related side effects are consistent with GLP-1-based obesity management medications. Additionally, alopecia, which was primarily mild, resolved and observed at a single trial site in this clinical trial, is a known side effect of significant weight loss. Approximately 57% of patients experience alopecia following bariatric surgery. Overall, the tolerability profile observed in this trial is consistent with the GLP-1 obesity management medications. Lastly, injection site reactions, which were primarily mild and of which none led to treatment modification or discontinuation, are not uncommon with injectable therapies.

**Summary of adverse events in Phase 2 (8 mg) trial of ribupatide**

| N, incidence% | Placebo N = 12 | Ribupatide 8mg N = 49 |
|---|---|---|
| Treatment emergent AEs(1) | 10 (83.3) | 45 (91.8) |
| Mild | 6 (50.0) | 34 (69.4) |
| Moderate | 3 (25.0) | 9 (18.4) |
| Severe | 1 (8.3) | 2 (4.1) |
| Most Common (≥ 20%) | | |
| Diarrhea | 0 | 13 (26.5) |
| Alopecia | 0 | 13 (26.5) |
| Nausea | 0 | 12 (24.5) |
| Injection site reaction | 0 | 12 (24.5) |
| Upper respiratory infection | 1 (8.3) | 12 (24.5) |
| Vomiting | 0 | 10 (20.4) |

No participants discontinued treatment due to treatment-related AEs

(1) Treatment-emergent SAEs observed in this trial in the ribupatide arms were jaw fracture and borderline serous tumor of ovary, which were assessed by the investigator as not related and possibly related to ribupatide treatment, respectively.

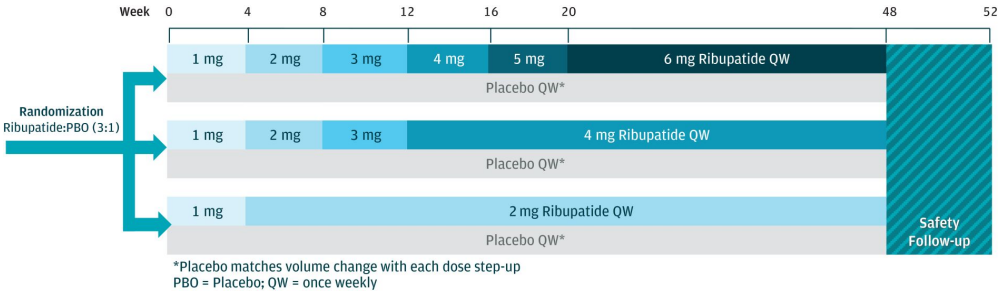
***Phase 3 obesity clinical trial in China (up to 6 mg):***

*Trial Design*

Ribupatide was investigated in a Phase 3 clinical trial of adults with obesity or overweight and at least one weight-related comorbidity, excluding T2D. The trial was conducted by Hengrui in China. The multi-center, randomized, double-blind, placebo-controlled trial investigated three dose levels of ribupatide, 2 mg, 4 mg and 6 mg, given once weekly compared to placebo for 48 weeks, including up to 20 weeks of up titration to reach the top dose. Participants in each cohort were randomized 3:1 to receive either ribupatide or placebo, as outlined in the figure below.

The co-primary endpoints of the clinical trial were percent change in weight from baseline to Week 48 and proportion of participants with weight loss of 5% or greater from baseline to Week 48. Several secondary endpoints of the trial measured change in weight-related health measures from baseline to Week 48, including: proportion of participants with 10% or greater weight loss, proportion of participants with 15% or greater weight loss, waist circumference, weight, BMI, systolic blood pressure, diastolic blood pressure, total cholesterol, low density lipoprotein, triglycerides, high density lipoprotein, fasting plasma glucose, HbA1c, fasting serum insulin and quality of life scores using a short-form health survey. Secondary endpoints also included measures of safety and tolerability.

**Design of Phase 3 clinical trial of ribupatide**




*Demographics and baseline measures*

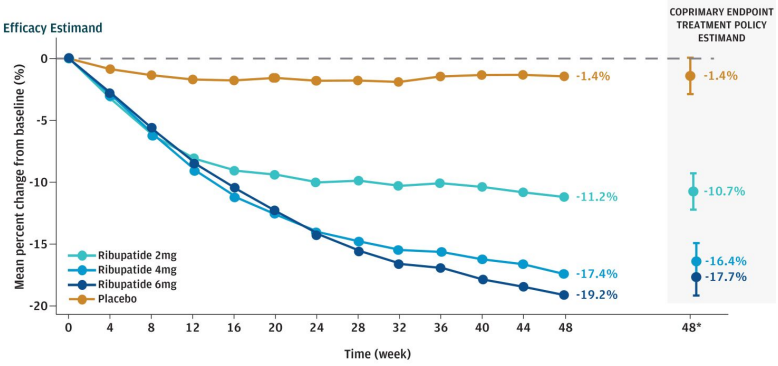
The clinical trial enrolled 567 participants with an average age of 34.4 years and 54.5% female. The average weight at baseline was 93.0 kg and the average BMI was 33.3.

*Efficacy data*

The clinical trial met both co-primary endpoints of percent change in body weight from baseline to Week 48 and proportion of participants with weight loss of 5% or greater from baseline to Week 48.

Based on the treatment policy estimand analysis, treatment with ribupatide resulted in a mean 10.7% reduction in weight from baseline with 2 mg, 16.4% with 4 mg, and 17.7% with 6 mg, compared to 1.4% with placebo. Based on the efficacy estimand, treatment with ribupatide resulted in a 11.2% mean reduction in weight with 2 mg, 17.4% with 4 mg, and 19.2% with 6 mg, compared to 1.4% with placebo. Weight loss in the 4 mg and 6 mg groups continued to decline through all time points in the 48-week trial with no observed plateau, indicating the potential for greater weight loss over a longer period of time.

**Mean percentage change in weight from baseline to Week 48 in Phase 3 clinical trial of ribupatide**

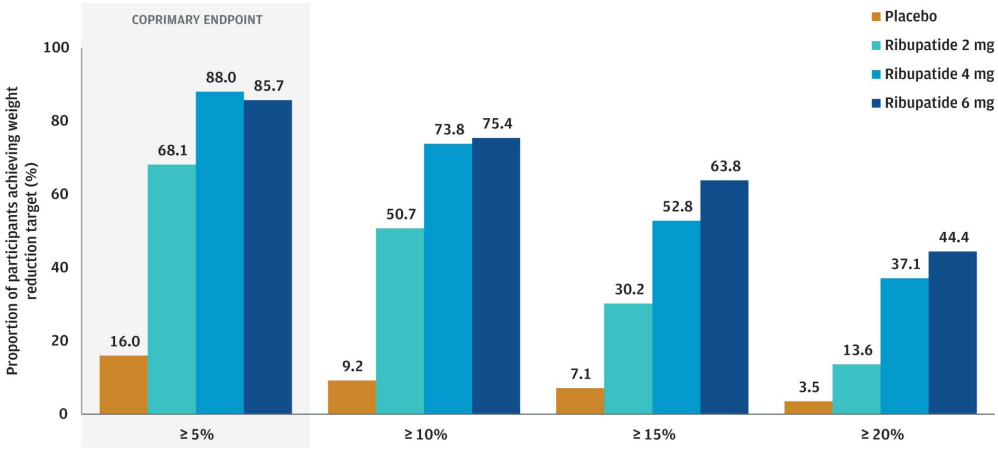



*Primary estimand: efficacy estimand*

Based on the treatment policy estimand, 68.1% of participants in the 2 mg ribupatide treatment group, 88% in the 4 mg treatment group, and 85.7% of participants in the 6 mg treatment group achieved a 5% or greater reduction in baseline weight, compared to 16% of participants in the placebo group. Based on the efficacy

estimand, 69.7% of participants in the 2 mg treatment group and 90.8% of participants in both the 4 mg and 6 mg treatment groups achieved a 5% or greater reduction in baseline weight. In the highest dose group, 75.4% of participants achieved 10% or greater, 63.8% achieved 15% or greater and 44.4% achieved 20% or greater reduction in weight from baseline to Week 48, compared to 9.2%, 7.1% and 3.5% of participants on placebo, respectively.

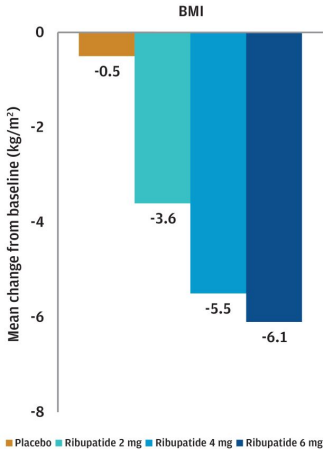
**Categorical weight loss achieved from baseline to Week 48 in Phase 3 clinical trial of ribupatide**




*Primary estimand: treatment policy estimand*

Participants also achieved a decrease in BMI from baseline to Week 48 of 3.6, 5.5, and 6.1 with 2 mg, 4 mg, and 6 mg, respectively, compared to 0.5 for placebo based on the treatment policy estimand. Improvements were seen in cardiometabolic risk factors over baseline compared to placebo at Week 48 for all ribupatide dose levels. Cardiometabolic risk factors assessed include systolic blood pressure, diastolic blood pressure, triglyceride, total cholesterol, low density lipoprotein cholesterol, non-high density lipoprotein cholesterol, glycated hemoglobin A1c, HOMA-IR and high sensitivity C reactive protein.

***Mean change in BMI from baseline to Week 48 in Phase 3 clinical trial of ribupatide***




*Safety and tolerability data*

The overall tolerability results observed in this clinical trial were consistent with the GLP-1-based class of therapies and previous clinical trials of ribupatide. Ribupatide was found to be generally well-tolerated with most treatment-emergent AEs, or TEAEs, being mild or moderate. The most common were GI-related. Most TEAEs were observed in the first weeks of titration and stabilized at the 3 mg dose level.

**Safety summary of ribupatide Phase 3 clinical trial**

| | Ribupatide 2 mg (N=142) | Ribupatide 4 mg (N=141) | Ribupatide 6 mg (N=141) | Placebo (N=143) |
|---|---|---|---|---|
| **TEAE**[1] | 130 (91.5) | 129 (91.5) | 132 (93.6) | 128 (89.5) |
| TEAE leading to treatment discontinuation | 1 (0.7) | 1 (0.7) | 2 (1.4) | 0 |
| Treatment-related TEAEs leading to treatment discontinuation | 1 (0.7) | 0 | 2 (1.4) | 0 |
| **SAE** | 2 (1.4) | 7 (5.0) | 6 (4.3) | 8 (5.6) |
| Treatment-related SAE[2] | 2 (1.4) | 1 (0.7) | 2 (1.4) | 0 |
| **Gastrointestinal disorders with ≥5% frequency in any arm** | | | | |
| Nausea | 23 (16.2) | 24 (17.0) | 38 (27.0) | 7 (4.9) |
| Diarrhea | 42 (29.6) | 45 (31.9) | 50 (35.5) | 10 (7.0) |
| Vomiting | 20 (14.1) | 27 (19.1) | 34 (24.1) | 3 (2.1) |

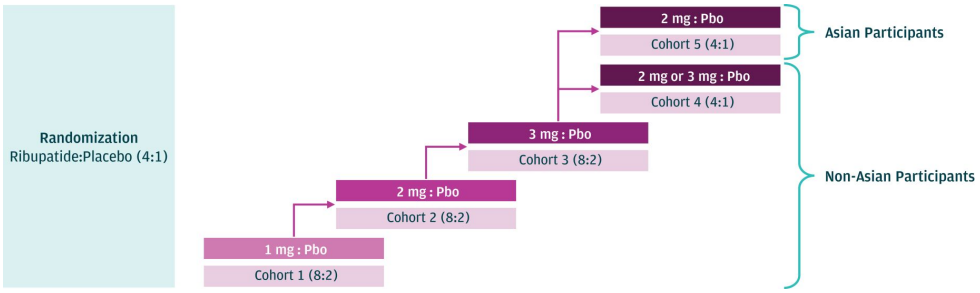
(1) Treatment-related TEAEs leading to treatment discontinuation in this trial were (1) electrocardiogram decreased T-wave amplitude, dizziness, excessive sweating and sinus arrhythmia, (2) facial paralysis, (3) nausea and vomiting and (4) acute cholecystitis.

(2) Treatment-related SAEs observed in this trial were gastroenteritis, impaired gastric emptying, abortion missed and acute cholecystitis, all of which were assessed by the investigator as possibly related to ribupatide treatment.

*Phase 1 SAD PK trial in non-Asian and Asian participants*

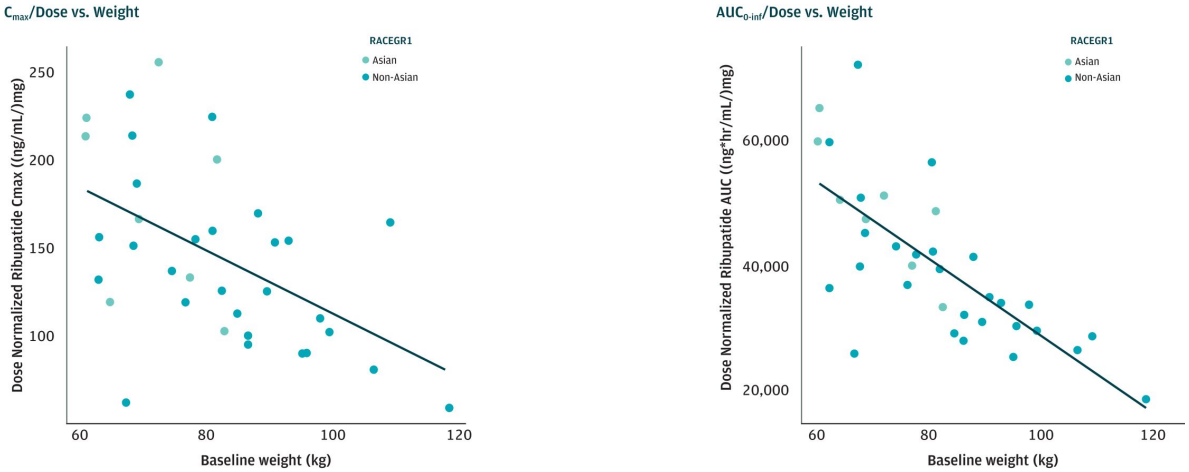
To support our global Phase 3 clinical program, we completed a Phase 1 PK bridging trial of ribupatide in non-Asian and Asian participants in Australia. The single-center, randomized, double-blind, placebo-controlled Phase 1 SAD trial enrolled 49 healthy adults with a BMI of 22.6 to 34.0 to investigate the safety, tolerability and PK of a single dose, without titration, of ribupatide in Asian and non-Asian participants. Three cohorts of non-Asian participants were randomized 4:1 to receive either 1 mg, 2 mg, 3 mg of ribupatide or placebo. In cohort 4, non-Asian participants were randomized 4:1 to receive 2 mg or 3 mg or ribupatide to placebo. In cohort 5, Asian participants were randomized 4:1 to receive either 2 mg of ribupatide or placebo.

**Design of the Phase 1 SAD PK trial in non-Asian/Asian participants**




Results showed that PK of ribupatide correlated with weight for both Asian and non-Asian participants, demonstrating that Asian heritage was not a significant covariate for ribupatide PK.

**PK correlates with weight in both Asian and non-Asian participants**




Cmax = maximum concentration; AUC = area under the curve, a measure of total systemic exposure to study drug over time

The safety results of ribupatide observed in this clinical trial were consistent with the GLP-1-based class of therapies. No SAEs, TEAEs leading to study discontinuation or serious TEAEs were observed and the most common AEs were decreased appetite, nausea and vomiting.

**Safety summary of Phase 1 bridging study of ribupatide**

| Parameter, n (%) | Placebo (N=10) | Ribupatide 1 mg Non-Asian (N=8) | Ribupatide 2 mg Non-Asian (N=12) | Ribupatide 2 mg Asian (N=8) | Ribupatide 3 mg Non-Asian (N=11) | Ribupatide Total (N=39) | All (N=49) |
|---|---|---|---|---|---|---|---|
| Participants with at least one TEAE | 7 (70.0) | 6 (75.5) | 12 (100) | 7 (87.5) | 11 (100) | 36 (92.3) | 43 (87.8) |
| Treatment-Related TEAE | 4 (40.0) | 5 (62.5) | 11 (91.7) | 6 (75.0) | 10 (90.9) | 32 (82.1) | 36 (73.5) |
| Serious TEAE | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Treatment-Related Serious TEAE | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| TEAE leading to withdrawal from study | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Most Common TEAE (≥10% in Ribupatide Total)** | | | | | | | |
| Decreased appetite | 1 (10.0) | 5 (62.5) | 8 (66.7) | 5 (62.5) | 9 (81.8) | 27 (69.2) | 28 (57.1) |
| Nausea | 0 | 2 (25.0) | 9 (75.0) | 6 (75.0) | 7 (63.6) | 24 (61.5) | 24 (49.0) |
| Headache | 2 (20.0) | 1 (12.5) | 3 (25.0) | 4 (50.0) | 5 (45.5) | 13 (33.3) | 15 (30.6) |
| Vomiting | 0 | 0 | 6 (50.0) | 3 (37.5) | 5 (45.5) | 14 (35.9) | 14 (28.6) |
| Dizziness | 0 | 0 | 4 (33.3) | 1 (12.5) | 3 (27.3) | 8 (20.5) | 8 (16.3) |
| Abdominal pain | 1 (10.0) | 0 | 2 (16.7) | 0 | 3 (27.3) | 5 (12.8) | 6 (12.2) |
| GERD | 0 | 0 | 1 (8.3) | 0 | 3 (27.3) | 4 (10.3) | 4 (8.2) |
| Myalgia | 0 | 0 | 2 (16.7) | 0 | 2 (18.2) | 4 (10.3) | 4 (8.2) |

*KaiNETIC: Our global Phase 3 program*

We initiated a global Phase 3 program, KaiNETIC, that consists of three Phase 3 clinical trials, to evaluate doses of up to 10 mg of ribupatide for the treatment of adults with obesity or overweight over 76 weeks. We believe that the range of doses being evaluated will enable personalized dosing to meet patients where they are in their treatment journey.

**Design of Phase 3 KaiNETIC trials**


Participants in each trial will receive ribupatide up to 10 mg administered over 76 weeks as shown in the figure above. The plateau in GI-related AEs from Hengrui's Phase 3 and Phase 2 clinical trials at doses of 3 mg or higher, as shown in the table below, suggests the potential for dosing higher than 8 mg to achieve further weight loss, which informed our decision to evaluate up to 10 mg in our global Phase 3 program.

**Study participant characteristics and safety summary of Hengrui trials of ribupatide**

| Study | Ribupatide-201 (24W) | | | | | Ribupatide-203 (36W) | | Ribupatide-301 (48W) | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Dose (n) | Placebo (n=49) | 1 mg (n=50) | 3 mg (n=51) | 4.5 mg (n=50) | 6 mg (n=49) | Placebo (n=12) | 8 mg (n=49) | Placebo (n=143) | 2 mg (n=142) | 4 mg (n=141) | 6 mg (n=141) |
| Mean age, yr (SD) | 35.3 (9.3) | 32.7 (8.3) | 34.9 (8.8) | 34.9 (7.0) | 33.3 (7.9) | 29.6 (7.9) | 35.0 (9.0) | 34.2 (8.5) | 34.5 (8.5) | 34.3 (8.6) | 34.7 (7.9) |
| Female, % | 51 | 52 | 53 | 52 | 51 | 75 | 67 | 54 | 55 | 55 | 54 |
| Mean BMI (SD) | 31.9 (3.0) | 32.2 (2.8) | 33.0 (3.3) | 32.3 (3.2) | 31.9 (2.9) | 32.5 (4.1) | 31.1 (3.5) | 33.9 (4.9) | 33.3 (4.7) | 33.1 (4.4) | 33.1 (3.8) |
| Mean weight, kg (SD) | 91.3 (15.2) | 91.9 (12.1) | 91.7 (14.3) | 92.8 (13.4) | 90.0 (13.4) | 85.3 (13.6) | 84.5 (14.2) | 94.5 (19.0) | 92.8 (17.1) | 92.4 (17.0) | 92.2 (15.8) |
| Efficacy - % Change in weight from baseline to end of treatment, % (95% confidence interval) | | | | | | | | | | | |
| Treatment policy | -0.1 (-2.0, 1.8) | -5.4 (-7.3, -3.5) | -13.4 (-15.2, -11.5) | -14.0 (-15.9, -12.1) | -16.8 (-18.8, -14.9) | -1.7 (-5.9, 2.4) | -22.8 (-24.7, -20.9) | -1.4 (-2.9, 0.1) | -10.7 (-12.2, -9.3) | -16.4 (-17.9, -14.9) | -17.7 (-19.2, -16.2) |
| Placebo-adjusted | NA | -5.3 (-8.0, -2.6) | -13.2 (-15.9, -10.5) | -13.9 (-16.6, -11.2) | -16.7 (-19.4, -14.0) | NA | -21.1 (-25.6, -16.6) | NA | -9.3 (-11.4, -7.3) | -15.0 (-17.1, -12.9) | -16.3 (-18.4, -14.2) |
| GI AE | | | | | | | | | | | |
| **Nausea, %** | 8.2 | **16.3** | **27.5** | **32.0** | **32.7** | 0 | **24.5** | 4.9 | **16.2** | **17.0** | **27.0** |
| **Vomit, %** | 2.0 | **6.1** | **19.6** | **22.0** | **28.6** | 0 | **20.4** | 2.1 | **14.1** | **19.1** | **24.1** |
| **Diarrhea, %** | 8.2 | **10.2** | **33.3** | **30.0** | **32.7** | 0 | **26.5** | 7.0 | **29.6** | **31.9** | **35.5** |
| Discontinued trial | 4.1 | 4.0 | 0 | 0 | 4.1 | 25.0 | 16.3 | 7.0 | 7.0 | 4.3 | 7.1 |
| Discontinued treatment | 4.1 | 4.0 | 2.0 | 2.0 | 4.1 | 25.0 | 16.3 | 9.1 | 9.2 | 9.2 | 9.9 |
| Discontinued treatment due to AE | 2.0 | 2.0 | 2.0 | 0 | 0 | 0 | 0 | 0 | 0.7 | 0 | 1.4 |

*SD = standard deviation*

We initiated our first global double-blind, randomized, placebo-controlled Phase 3 clinical trial, KaiNETIC-1, in December 2025, which is designed to enroll 2,340 participants with a BMI of 30+ or a BMI of 27+ with a comorbidity, excluding T2D. The primary endpoint of this trial is percentage change in weight from baseline at Week 76, and key secondary endpoints include percentage of participants with ≥5%, ≥10%, ≥15%, ≥20%, and ≥25% reduction in body weight, changes in waist circumference and absolute body weight and changes in cardiometabolic risk factors such as systolic blood pressure and lipid parameters. We will also evaluate ribupatide 8 mg and 10 mg in a pre-defined subgroup of participants with BMI 35+ as a key secondary endpoint. Participants will be randomized to a dose of 4 mg, 6 mg, 8 mg, 10 mg or placebo, with dose titration for up to 24 weeks and a maintenance dose of at least 52 weeks as shown above. We plan to enroll patients in certain regions, including the U.S., Europe, South America and Australia. We expect to report topline data from KaiNETIC-1 in 2028.

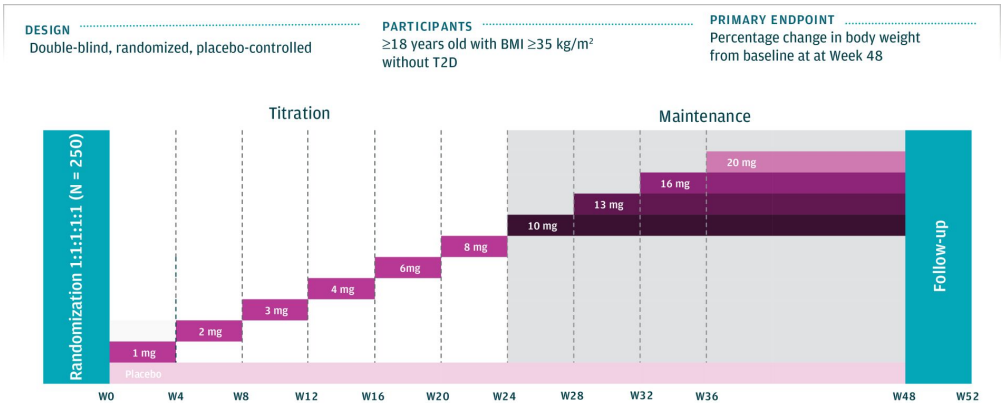
Our second global double-blind, randomized, placebo-controlled Phase 3 clinical trial, KaiNETIC-2, was initiated in January 2026. This trial is expected to enroll 1,156 participants with a BMI of 27+ and T2D. The co-primary endpoints of this trial are percentage change in weight from baseline and percentage change in HbA1c from baseline at Week 76, and key secondary endpoints include percentage of participants with ≥5%, ≥10%, ≥15%, ≥20%, and ≥25% reduction in body weight, changes in waist circumference and absolute body weight and changes in cardiometabolic risk factors such as systolic blood pressure and lipid parameters. We will also evaluate ribupatide 8 mg and 10 mg in a pre-defined subgroup of participants with BMI 35+ as a key secondary endpoint. Participants will be randomized to a dose of 4 mg, 6 mg, 8 mg, 10 mg or placebo, with dose titration for up to 24 weeks and a maintenance dose of at least 52 weeks as shown above. We plan to enroll patients in certain regions, including the U.S., Europe, South America and Australia. We expect to report topline data from KaiNETIC-2 in 2028.

Our third global double-blind and open label, randomized, active- and placebo-controlled Phase 3 clinical trial, KaiNETIC-3, was also initiated in December 2025. This trial is expected to enroll 1,200 adults with a BMI of 35+ with no T2D. The co-primary endpoints of this trial are percentage change in weight from baseline compared to placebo and percentage change in weight from baseline compared to semaglutide 2.4 mg at Week 76. Participants will be randomized to a dose of 8 mg, 10 mg, placebo or semaglutide 2.4 mg (with the semaglutide arm being open label), with dose titration for up to 24 weeks and a maintenance dose of at least 52 weeks as

shown above. We plan to enroll patients in certain regions, including the U.S. Europe and Australia. We expect to report topline data from KaiNETIC-3 in 2028.

To evaluate the potential to achieve greater weight loss with higher doses of ribupatide, we have also initiated a Phase 2b clinical trial to evaluate doses up to 20 mg of ribupatide in adults living with obesity. We initiated the randomized, double-blind, placebo-controlled Phase 2b clinical trial in March 2026 and expect to report topline results from this trial in 2027. This trial is expected to enroll 250 adults with a BMI of 35+ with no T2D. The primary endpoint of this trial is percentage change in weight from baseline compared to placebo at Week 48.

**Design of Phase 2b high dose trial of ribupatide**




***Oral ribupatide: Potential for franchise expansion with oral option providing highly differentiated tolerability and compelling weight***

Oral ribupatide (also known as KAI-9531-T and being developed by Hengrui in Greater China as HRS9531-T) is an oral formulation of our GLP-1/GIP receptor dual agonist that we believe has the potential to deliver competitive weight loss among orals with highly differentiated tolerability. Because it is an oral version of our extensively studied injectable ribupatide product candidate, we believe oral ribupatide may also have certain regulatory, development and commercial advantages, including increased speed to market and cost efficiencies.

Subject to discussions with the FDA and other regulatory agencies, we plan to initiate global Phase 3 trials of oral ribupatide as early as the first half of 2027. A next-generation formulation of oral ribupatide with enhanced bioavailability is also being evaluated in a Phase 1 clinical trial conducted by Hengrui in China.

*Unmet need: improved tolerability with compelling weight loss in an oral*

Oral treatments are projected to represent approximately 20% of the obesity therapeutic market by 2030 due to their convenience. Clinical data for oral semaglutide and orforglipron have demonstrated relatively modest efficacy with tolerability challenges, in particular, higher rates of GI-related AEs and treatment discontinuations than observed with injectable GLP-1-based therapies. We believe oral therapies that can demonstrate a differentiated clinical profile can capture a significant market opportunity.

*Our solution: Oral ribupatide*

We are expanding our ribupatide franchise with a once-daily oral tablet formulation, oral ribupatide. Based on initial Hengrui clinical data, we believe oral ribupatide has the potential for highly differentiated tolerability

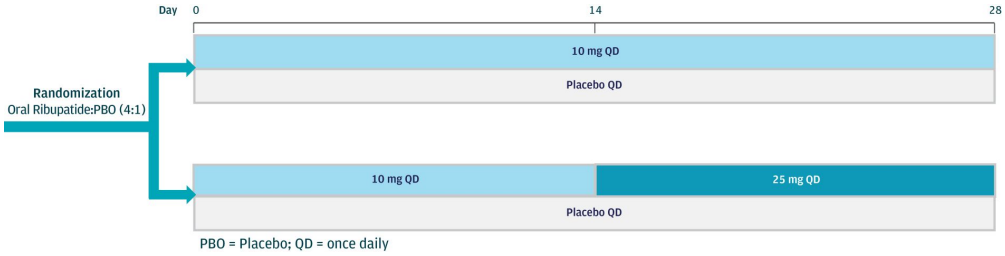
among oral treatments with compelling weight loss, representing an attractive clinical profile. We believe oral ribupatide may also have certain regulatory, development and commercial advantages, including increased speed to market and cost efficiencies.

Oral peptide delivery faces significant challenges due to the harsh gastrointestinal environment, resulting in low bioavailability and thus high variability. Key obstacles include denaturation by low stomach pH, degradation by digestive enzymes and poor intestinal permeability. To address these challenges, oral ribupatide is formulated with permeability enhancers including SNAC (sodium N-(8-[2-hydroxybenzoyl]amino)caprylate), which is designed to protect ribupatide from the gastrointestinal environment and enhance its absorption by temporarily disrupting membrane barrier function and facilitating transcellular transport.

*Phase 1 clinical trial in healthy participants*

Hengrui completed a randomized, double-blind, placebo-controlled MAD Phase 1 clinical trial that enrolled 40 healthy participants with a BMI of 24 to 35. Participants were 100% male with a mean age of 32.1 years, weight of 80.4 kg, BMI of 27.9 and HbA1c of 5.4%. Participants were randomized 4:1 to receive either oral ribupatide or placebo for four weeks. Participants in the oral ribupatide cohorts received 10 mg once daily for the first 14 days. One cohort remained at 10 mg once daily for the remaining 14 days and one cohort stepped up to 25 mg once daily after day 14.

**Design of Phase 1 MAD clinical trial of oral ribupatide**



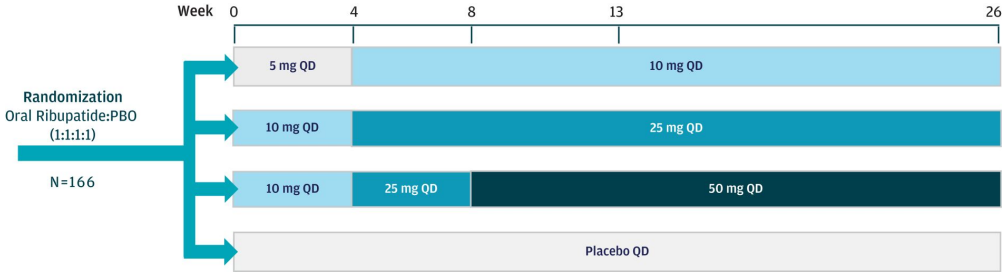

Participants receiving 10 mg of oral ribupatide for four weeks lost a mean of 4.7% of their weight from baseline at Day 29 based on the treatment policy estimand. Those participants in the cohort receiving 10 mg/25 mg lost a mean of 5.4% of their weight from baseline to Day 29. Participants receiving placebo lost 1.9% of their weight from baseline to Day 29.

Oral ribupatide was well-tolerated in the Phase 1 MAD trial. All AEs were mild-to-moderate and no serious AEs were observed. The most common GI-related AEs in participants treated with ribupatide (10 mg and 10/25 mg, respectively) were nausea (12.5% and 18.8%) vs. 0% with placebo, and vomiting (6.3 and 6.3%) vs. 0.0% with placebo.

*Phase 2 clinical trial of participants with obesity and without T2D*

Oral ribupatide was evaluated in a multi-center, randomized, double-blind, placebo-controlled Phase 2 clinical trial in participants with obesity (defined as BMI of 28+ in China) and without T2D. The trial enrolled 166 participants who were randomized in equal ratio to receive once-daily oral ribupatide 10 mg, 25 mg, 50 mg or placebo. The titration schedule for each dose level is outlined in the figure below with all participants reaching and maintaining their highest dose by Week 8.

**Design of Phase 2 clinical trial investigating up to 50 mg dose of oral ribupatide**




PBO = Placebo; QD = once daily

The primary endpoint of the trial was percent change from baseline in body weight at Week 26. Secondary endpoints included percentage of subjects with greater than 5%, 10% and 15% reduction in weight from baseline and change from baseline in cardiometabolic risk factors such as systolic blood pressure and lipid parameters, as well as measures of safety and tolerability.

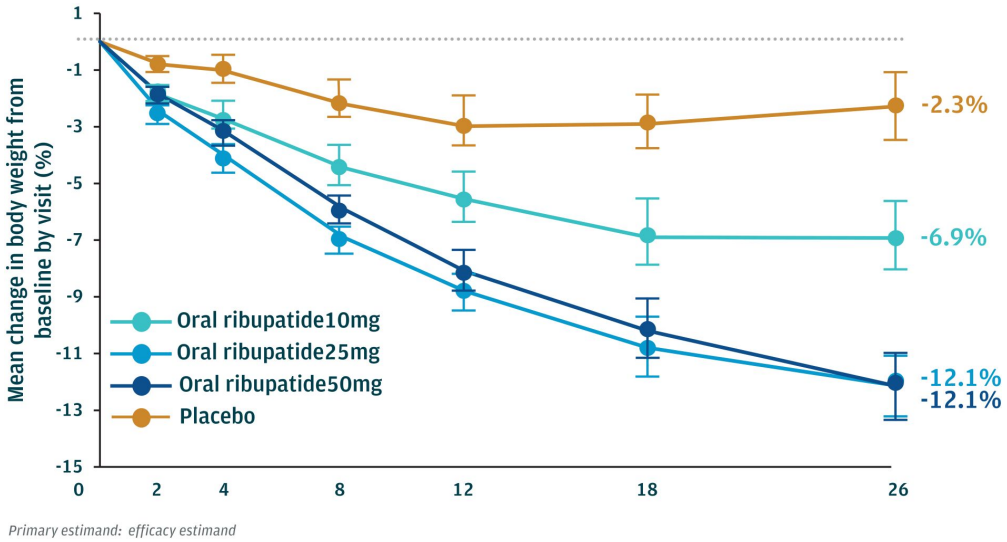
*Demographics and baseline measures*

The trial enrolled 166 participants with an average age of 33.8 years and of whom 63.3% were female. The average weight and BMI of the participants were 92.6 kg and 33.3, respectively. The inclusion criteria included a BMI measure of 28 to 40 with weight change ≤5% in the last 3 months.

*Efficacy data*

The Phase 2 clinical trial met the primary endpoint of percent change from baseline in body weight at Week 26. Based on the efficacy estimand at Week 26, participants taking oral ribupatide achieved a mean reduction of body weight from baseline of 6.9% (10 mg), 12.1% (25 mg) and 12.1% (50 mg), compared to 2.3% with placebo. Based on the treatment policy estimand at Week 26, participants taking oral ribupatide achieved a mean reduction of body weight from baseline of 6.7% (10 mg), 11.9% (25 mg) and 11.4% (50 mg) from baseline compared to 2.1% with placebo.

**Mean percentage change in body weight from baseline at Week 26 in Phase 2 clinical trial of oral ribupatide**




For the 25 mg and 50 mg cohorts, weight loss continued throughout the 26 weeks of the trial, with no observed plateau, indicating the potential for further weight loss with longer treatment duration.

The proportion of participants who achieved prespecified weight reduction targets at Week 26 was also assessed. At the 25 mg dose, 59.1% of participants achieved at least 10% weight loss and 38.6% of participants achieved at least 15% weight loss at Week 26. At the 50 mg dose, 52.5% of participants achieved at least 10% weight loss and 37.5% of participants achieved at least 15% weight loss at Week 26.

*Safety and tolerability data*

Most treatment-emergent adverse events were mild to moderate and gastrointestinal-related. Low gastrointestinal-related adverse event rates were observed. Rates of vomiting were 2.4% at 10 mg, 11.4% at 25 mg and 7.5% at 50 mg, while nausea was 11.9% at 10 mg, 22.7% at 25 mg and 20.0% at 50 mg, consistent with the results of the Phase 1 trial previously conducted by Hengrui in China.

No permanent treatment discontinuations or down-titrations due to nausea, vomiting, diarrhea or constipation were reported in participants taking oral ribupatide. All incidences of nausea, vomiting, diarrhea and constipation observed in the trial were mild, except one case of moderate diarrhea.

**Summary of adverse events in Phase 2 clinical trial of oral ribupatide**

| | Oral Ribupatide | | | | Placebo (N=40) |
|---|---|---|---|---|---|
| | 10mg (N=42) | 25mg (N=44) | 50mg (N=40) | Total (N=126) | |
| TEAEs[1] | 35 (83.3) | 37 (84.1) | 32 (80.0) | 104 (82.5) | 32 (80.0) |
| Mild | 28 (66.7) | 27 (61.4) | 26 (65.0) | 81 (64.3) | 24 (60.0) |
| Moderate | 7 (16.7) | 9 (20.5) | 6 (15.0) | 22 (17.5) | 8 (20.0) |
| Severe | 0 | 1[1] (2.3) | 0 | 1 (0.8) | 0 |
| Discontinued treatment early due to AEs[2] | 0 | 0 | 1 (2.5) | 1 (0.8) | 0 |
| Nausea | 5 (11.9) | 10 (22.7) | 8 (20.0) | 23 (18.3) | 3 (7.5) |
| Diarrhea | 2 (4.8) | 9 (20.5) | 2 (5.0) | 13 (10.3) | 2 (5.0) |
| Vomiting | 1 (2.4) | 5 (11.4) | 3 (7.5) | 9 (7.1) | 0 |

(1) Treatment-emergent SAEs observed in this trial in the oral ribupatide arms were (a) gallstones with acute cholecystitis, which was assessed by the investigator as possibly related to oral ribupatide treatment, and (b) benign ovarian germ cell teratoma and (c) right tonsillar mass, which were assessed by the investigator as not related to oral ribupatide treatment

(2) Discontinuation due to a worsening of pre-existing ventricular premature contractions, which was assessed by the investigator as possibly unrelated to oral ribupatide treatment

*Ongoing clinical trials and next steps*

A next-generation formulation of oral ribupatide with enhanced bioavailability is also being evaluated in a Phase 1 clinical trial conducted by Hengrui in China. Depending on the results of this trial, we may elect to further develop this next-generation formulation of oral ribupatide. We and Hengrui are also exploring additional oral formulations of ribupatide to enhance bioavailability. Under the Hengrui License Agreement, we have exclusive worldwide (outside of Greater China) development and commercialization rights to any daily oral formulation of ribupatide.

Subject to discussions with the FDA and other regulatory agencies, we plan to initiate global Phase 3 trials of oral ribupatide as early as the first half of 2027.

***KAI-7535: Potential for competitive clinical profile in an oral small molecule***

KAI-7535 (also being developed by Hengrui in Greater China as HRS-7535) is a novel small molecule GLP-1 receptor agonist being developed as a once-daily oral treatment for obesity or overweight. We initiated a global Phase 2 clinical trial of KAI-7535 in April 2026. A Phase 3 clinical trial in adults living with obesity or overweight conducted by Hengrui is ongoing in China.

In a Phase 2 clinical trial conducted by Hengrui in China evaluating doses ranging from 30 mg to 180 mg, treatment with 180 mg of HRS-7535 demonstrated a 9.5% (8.1% placebo-adjusted) mean percent reduction from baseline weight at the 180 mg dose at Week 36, based on the efficacy estimand. Using a treatment policy estimand analysis, treatment with HRS-7535 resulted in a mean 8.8% reduction in weight with 180 mg, compared to 1.4% with placebo. In order to explore the potential of KAI-7535 as an oral treatment for patients

living with obesity or overweight, a *post-hoc*, exploratory analysis of participants with detectable drug concentrations at all post-baseline visits was conducted showing that treatment with 180 mg resulted in a 15.0% weight loss from baseline at Week 36 based on the efficacy estimand. Treatment-emergent AEs reported in this trial were primarily mild or moderate in severity, and mainly GI-related, which were consistent with the oral GLP-1 class.

*Unmet need: Improved clinical profile in an oral small molecule*

Oral treatments are projected to represent approximately 20% of the obesity therapeutic market by 2030 due to their convenience and improved scalability. Clinical data for oral semaglutide and orforglipron have demonstrated relatively modest efficacy with tolerability challenges, in particular, higher rates of GI-related AEs and treatment discontinuations than observed with injectable GLP-1-based therapies. There is a significant need to improve upon the clinical profile of existing oral treatments. We believe that oral small molecule treatments will play a meaningful role in the treatment of obesity worldwide driven by their convenience and improved scalability.

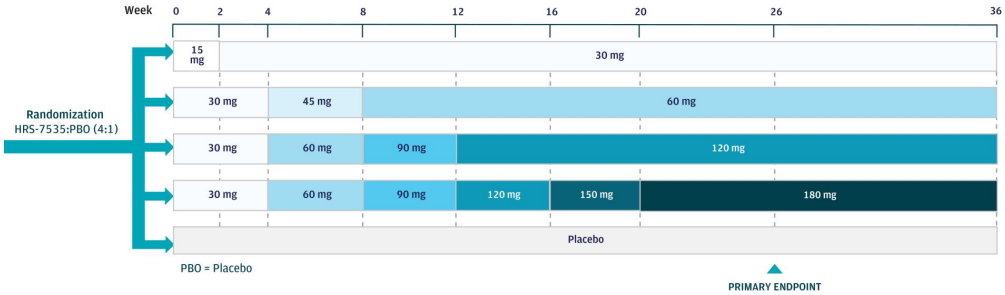
*Our solution*

We believe that KAI-7535 has the potential to improve upon the clinical profile of existing oral treatments, and is designed to offer a competitive weight loss and tolerability profile compared to other oral GLP-1 therapies.

*Phase 2 dose-ranging clinical trial in participants with obesity*

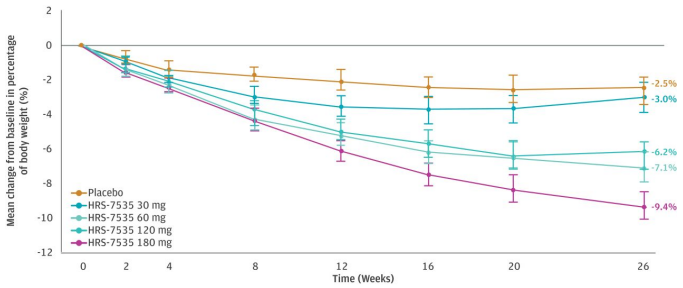
HRS-7535 was studied in a Phase 2 dose-ranging clinical trial conducted by Hengrui in China in participants with obesity. The randomized, double-blind, placebo-controlled trial enrolled 235 adults with a BMI of 28 to 40 without a diagnosis of T2D. The participants were 48.5% female and at baseline had a mean age of 33.5 years, weight of 91.6 kg and BMI of 32.5. Participants were randomized 4:1 to receiving HRS-7535 (30 mg, 60 mg, 120 mg or 180 mg) or placebo once daily for 26 weeks. All HRS-7535 cohorts underwent titration to reach the highest dose. Participants were on the highest dose for 34, 18, 14 and 6 weeks for the 30 mg, 60 mg, 120 mg and 180 mg doses, respectively. The primary endpoint of the trial was percentage change from baseline in weight at Week 26.

**Design of Phase 2 clinical trial of HRS-7535 in participants with obesity**




Significant weight loss was observed at Week 26 in the three highest dose cohorts. Participants lost a mean of 7.1%, 6.2% and 9.4% of their weight from baseline to Week 26 in the 60 mg, 120 mg and 180 mg cohorts, respectively, compared to a 2.5% loss with placebo based on the efficacy estimand.

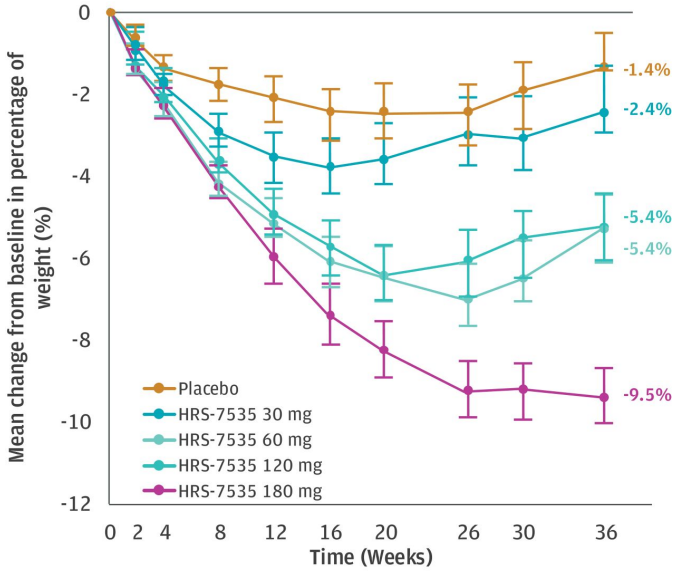
**Primary endpoint—Mean percentage change in weight from baseline to Week 26 in HRS-7535 Phase 2 trial**




*Primary estimand: efficacy estimand*

In a mandatory 10 week extension period, participants lost a mean of 5.4%, 5.4%, and 9.5% of their weight from baseline in the 60 mg, 120 mg and 180 mg cohorts, respectively, compared to a mean reduction of 2.5% with placebo, at Week 36, based on the efficacy estimand.

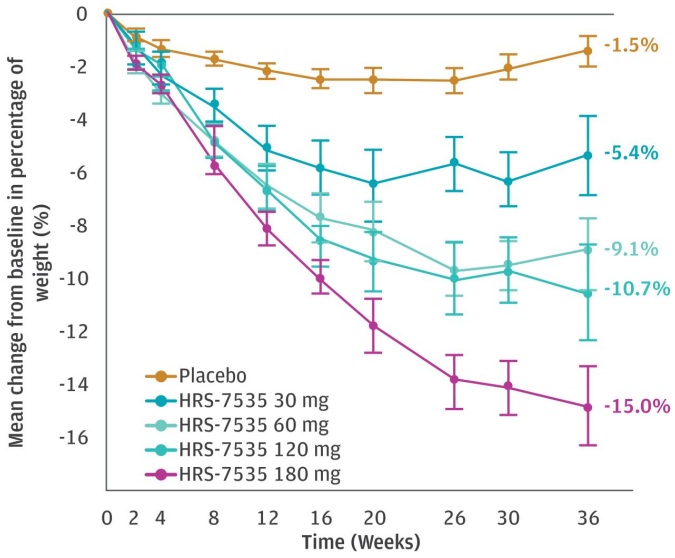
**Mean percentage change in weight from baseline to Week 36 in HRS-7535 Phase 2 trial**




*Primary estimand: efficacy estimand*

Unexpected weight increase were observed in some cohorts beginning around Week 16. We further investigated this result and observed that, based on a PK analysis, approximately 65% of participants had at least one post-baseline visit without detectable levels of study drug in their system. We conducted a *post-hoc*, exploratory analysis to assess the treatment effect excluding those participants with at least one post-baseline visit with drug PK below the limit of quantification, which we refer to as the PK-detectable population. In this analysis, PK-detectable population participants lost a mean of 9.1%, 10.7% and 15.0% of their body weight from baseline to Week 36 in the 60 mg, 120 mg and 180 mg cohorts, respectively, compared to a mean reduction of 1.5% for placebo, based on the efficacy estimand.

**Mean change from baseline in percentage of body weight over 36 weeks (*post-hoc* analysis excluding subjects with ≥1 times PK value BLQ) in HRS-7535 Phase 2 trial**




*BLQ: Below lower-limitation of quantification*
*Primary estimand: efficacy estimand*

HRS-7535 was generally well-tolerated in the clinical trial with most AEs being mild or moderate. One death occurred during the study, which was deemed not related to treatment as the participant was involved in a physical altercation and died of resulting wounds. The most common AEs were GI-related, including nausea, vomiting and diarrhea, which is consistent with the GLP-1-based class.

**Safety results overview of HRS-7535 Phase 2 trial**

| | HRS-7535 | | | | Placebo (N=46) |
|---|---|---|---|---|---|
| | 30 mg (N=48) | 60 mg (N=47) | 120 mg (N=46) | 180 mg (N=48) | |
| Any TEAE | 45 (93.8) | 45 (95.7) | 43 (93.5) | 47 (97.9) | 42 (91.3) |
| Mild | 27 (56.3) | 34 (72.3) | 23 (50.0) | 24 (50.0) | 32 (69.6) |
| Moderate | 16 (33.3) | 10 (21.3) | 19 (41.3) | 21 (43.8) | 9 (19.6) |
| Severe | 2 (4.2) | 1 (2.1) | 1 (2.2) | 2 (4.2) | 1 (2.2) |
| Serious adverse events | 1 (2.1) | 2 (4.3) | 0 | 3 (6.3) | 1 (2.2) |
| Treatment discontinuation due to TEAE | 1 (2.1) | 1 (2.1) | 0 | 3 (6.3) | 0 |
| Death | 1 (2.1) | 0 | 0 | 0 | 0 |
| Gastrointestinal disorders | 17 (35.4) | 23 (48.9) | 29 (63.0) | 31 (64.6) | 7 (15.2) |
| Nausea | 8 (16.7) | 16 (34.0) | 19 (41.3) | 28 (58.3) | 2 (4.3) |
| Vomiting | 9 (18.8) | 14 (29.8) | 18 (39.1) | 21 (43.8) | 1 (2.2) |
| Diarrhea | 9 (18.8) | 10 (21.3) | 12 (26.1) | 9 (18.8) | 4 (8.7) |

Similar safety results were seen between the PK-detectable population and participants with at least one postbaseline visit with drug PK below the limit of quantification, referred to as the non-PK-detectable population in the chart below.

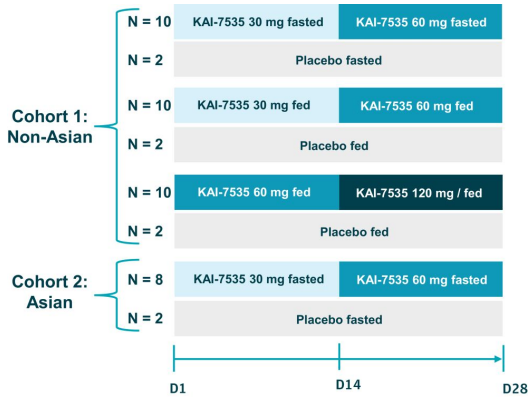
**Safety data for PK-detectable and non-PK-detectable populations**

| | HRS-7535 | | | | | | | | Placebo (N=46) |
|---|---|---|---|---|---|---|---|---|---|
| | 30 mg | | 60 mg | | 120 mg | | 180 mg | | |
| AE | PK Detectable (N=15) | Other (N=33) | PK Detectable (N=18) | Other (N=29) | PK Detectable (N=12) | Other (N=34) | PK Detectable (N=21) | Other (N=27) | |
| Nausea | 2 (13.3) | 6 (18.2 | 6 (33.3) | 10 (34.5) | 5 (41.7) | 14 (41.2) | 13 (61.9) | 15 (55.6) | 2 (4.3) |
| Vomiting | 2 (13.3) | 7 (21.2) | 5 (27.8) | 9 (31.0) | 4 (33.3) | 14 (41.2) | 9 (42.9) | 12 (44.4) | 1 (2.2) |
| Diarrhea | 1 (6.7) | 8 (24.2) | 6 (33.3) | 4 (13.8) | 2 (16.7) | 10 (29.4) | 3 (14.3) | 6 (22.2) | 4 (8.7) |

*Phase 1 SAD PK trial in non-Asian and Asian participants*

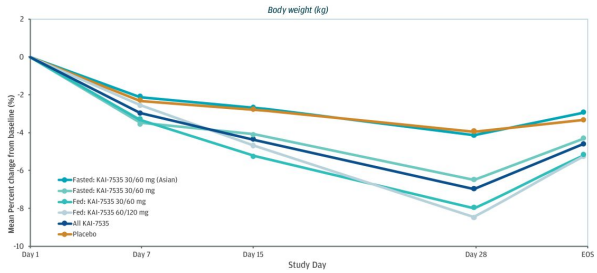
To support our global Phase 2 clinical program, we completed a Phase 1 PK bridging trial of KAI-7535 in non-Asian and Asian participants in Australia. The single-center, randomized, double-blind, placebo-controlled Phase 1 SAD trial enrolled 43 healthy adults with an average BMI of 30.3 to investigate the safety, tolerability, PK and food effect of a single dose, without titration, of KAI-7535 in Asian and non-Asian participants. In cohort 1, participants of non-Asian descent were randomized 4:1 to one of three KAI-7535 dose escalation sequences or to placebo. The active sequences included: 30 mg once daily under fasted conditions for 14 days followed by 60 mg fasted for 14 days; 30 mg once daily under fed conditions for 14 days followed by 60 mg fed for 14 days; and 60 mg once daily under fed conditions for 14 days followed by 120 mg fed for 14 days. In cohort 2, participants of Asian descent were randomized to KAI-7535 and placebo under fasted conditions. Participants assigned to KAI-7535 received 30 mg once daily under fasted conditions for 14 days followed by 60 mg fasted for 14 days.

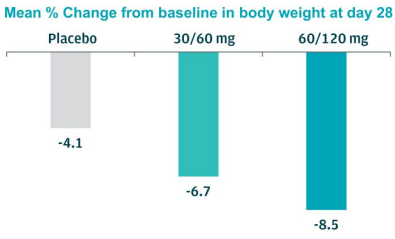
**Design of the Phase 1 SAD PK trial in non-Asian/Asian participants**




In the KAI-7535 treated groups, mean percent weight loss from baseline was 7.1% at Day 28 compared to 4.1% weight loss in the placebo group. In addition, results showed that the PK of KAI-7535 correlated with the participant's weight for both Asian and non-Asian participants, demonstrating that Asian heritage was not a significant covariate for the PK of KAI-7535.

**Mean Percent change in body weight (kg) from baseline over time**




KAI-7535 was generally well-tolerated with the most common TEAEs being GI in nature. No SAEs, TEAEs leading to study discontinuation or serious TEAEs were observed. No safety concerns for hepatotoxicity or pancreatitis were observed.

**Safety summary of Phase 1 PK bridging study of KAI-7535**

| Adverse event, N(%) | KAI-7535 | | | | | Placebo (N=8) |
|---|---|---|---|---|---|---|
| | Fasted | | Fed | | All (N=35) | |
| | 30/60 mg (Asian) (N=6) | 30/60 mg (N=10) | 30/60 mg (N=10) | 60/120 mg (N=9) | | |
| **TEAEs** | 5 (83.3) | 9 (90.0) | 10 (100) | 9 (100) | 33 (94.3) | 6 (75.0) |
| Serious TEAEs | 0 | 0 | 0 | 0 | 0 | 0 |
| TEAEs leading to dose reduction | 0 | 1 (10.0) | 0 | 0 | 1 (2.9) | 0 |
| TEAEs leading to treatment discontinuation | 0 | 0 | 0 | 0 | 0 | 0 |
| **TEAE by maximum severity:** | | | | | | |
| Severe | 0 | 0 | 0 | 0 | 0 | 0 |
| Moderate | 2 (33.3) | 4 (40.0) | 6 (60.0) | 3 (33.3) | 15 (42.9) | 1 (12.5) |
| Mild | 3 (50.0) | 5 (50.0) | 4 (40.0) | 6 (66.7) | 18 (51.4) | 5 (62.5) |
| **GI TEAEs:** | 4 (66.7) | 9 (90.0) | 10 (100) | 8 (88.9) | 31 (88.6) | 3 (37.5) |
| Nausea | 3 (50.0) | 7 (70.0) | 9 (90.0) | 7 (77.8) | 26 (74.3) | 0 |
| Constipation | 2 (33.3) | 0 | 3 (30.0) | 3 (33.3) | 8 (22.9) | 2 (25.0) |
| Vomiting | 0 | 2 (20.0) | 3 (30.0) | 1 (11.1) | 6 (17.1) | 0 |
| Diarrhea | 2 (33.3) | 1 (10.0) | 1 (10.0) | 1 (11.1) | 5 (14.3) | 0 |

*Liver safety results*

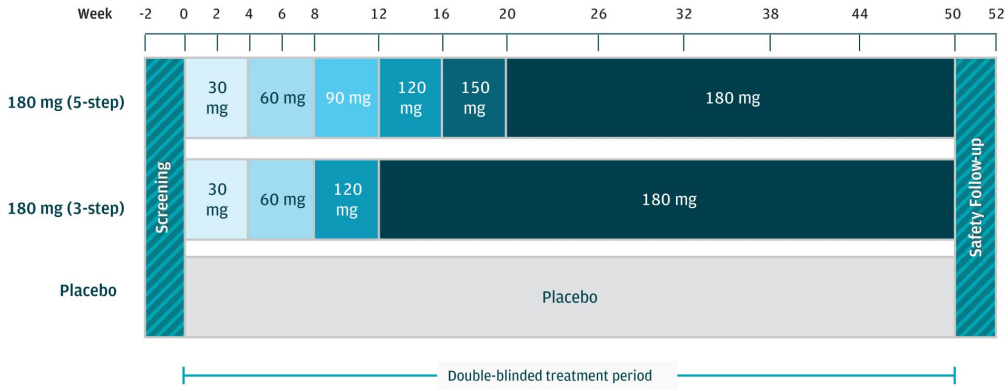
Certain other small molecule GLP-1 agonists, such as lotiglipron, were associated with liver safety findings. To that end, KAI-7535 was designed by Hengrui to mitigate the risk of liver safety issues. Mitigation efforts included extensive nonclinical studies designed to ensure all metabolites were non-reactive and stable, and that there are no major human metabolites (>10% of parent). *In vitro* liver toxicity studies did not show any significant liver signal while nonclinical toxicology studies, including those in cynomolgus monkeys dosed out to 9 months, demonstrated the absence of liver safety findings. As of December 2025, this nonclinical work has translated into the absence of liver safety findings in over 1,200 participants dosed with KAI-7535 out to 52 weeks.

*Ongoing clinical trials and next steps*

Based on the results of the Phase 2 clinical trial, Hengrui is conducting a randomized, double-blind, placebo-controlled Phase 3 clinical trial in China in non-diabetic adults living with obesity or overweight and one or

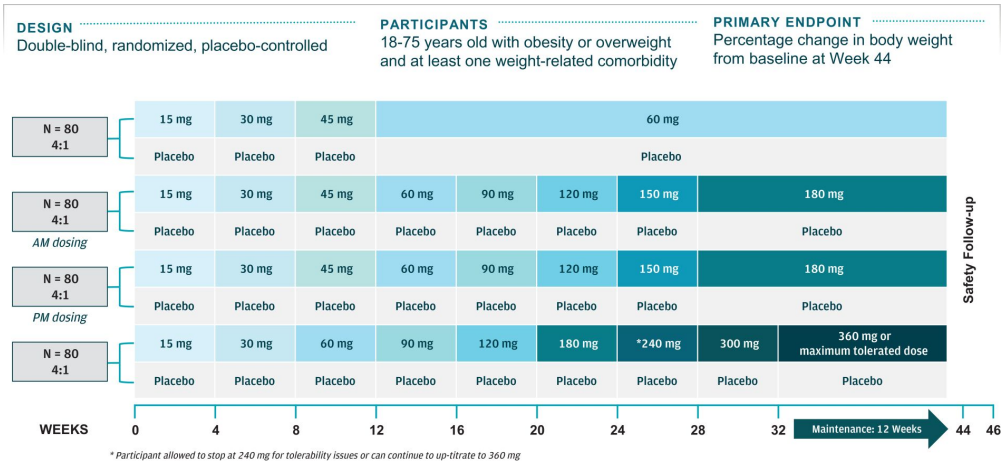
more weight-related concomitant disease. The trial enrolled 556 participants to receive 180 mg of HRS-7535 or placebo. The trial will test a 5-step and 3-step titration scheme to reach the 180 mg dose in 20 weeks or 12 weeks, respectively. The primary endpoint of the trial will be percentage change from baseline in weight at Week 50. Topline results from this 50-week trial are anticipated in 2026.

**Design of Phase 3 clinical trial of HRS-7535**




We initiated a double-blind, randomized, placebo-controlled Phase 2 trial of KAI-7535 in April 2026. This trial is expected to enroll approximately 320 participants with a BMI of 30+ or a BMI of 27+ with at least one co-morbidity (which may include T2D). Participants will receive either placebo or doses up to 360 mg of KAI-7535 administered over a period of 44 weeks. We expect to report topline results from this trial in 2027.

**Design of global Phase 2 clinical trial of KAI-7535**




***KAI-4729: GLP-1/GIP/Glucagon tri-agonist injectable***

We are advancing KAI-4729 (also being developed by Hengrui in Greater China as HRS-4729), a once-weekly injectable GLP-1/GIP/glucagon receptor tri-agonist, which was designed to improve upon the existing tri-agonist

profile. We believe KAI-4729's combination of the proven GLP-1/GIP mechanism with the addition of glucagon agonism has the potential to result in greater weight reduction than currently marketed treatments with improved liver fat reduction and a differentiated tolerability profile.

KAI-4729 was designed to have augmented potency on the GLP-1 receptor compared to reference drug retatrutide, a GLP-1/GIP/glucagon receptor tri-agonist in development by Eli Lilly. Preclinical *in vitro* head-to-head cell-based receptor potency data suggests the potential for superior potency for KAI-4729 compared to reference drug retatrutide on the GLP-1 receptor and similar potency on the GIP and glucagon receptors. Additionally, results from testing of KAI-4729 in a nonclinical animal model of obesity suggests the potential for superior weight loss compared to reference drug retatrutide.

Hengrui is conducting an ongoing Phase 1 single ascending dose, or SAD, and MAD trial of HRS-4729 in China.

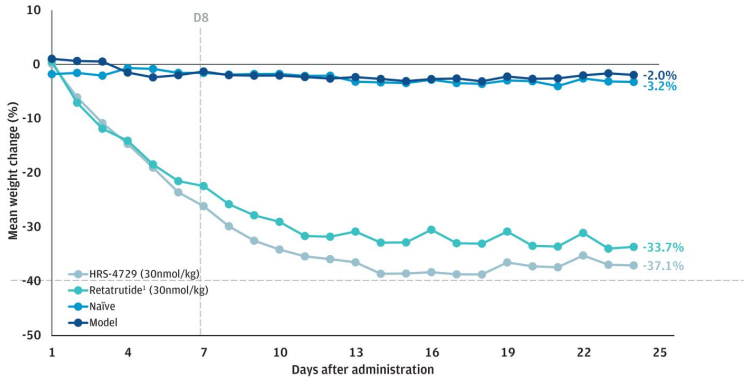
We intend to initiate a global Phase 1 clinical trial of KAI-4729 in 2026 and expect to report topline results from this trial in 2027.

*Nonclinical data*

Nonclinical studies show that HRS-4729 had significant potency in activating the GLP-1 receptor. Hengrui evaluated the agonistic activities of HRS-4729 and the reference drug retatrutide on GLP-1, GIP and glucagon receptors in human, rodent and cynomolgus monkey GLP-1, GIP and glucagon cell lines, respectively, using the time-resolved fluorescence energy transfer (TR-FRET) method with cyclic adenosine monophosphate (cAMP) production as the detection indicator. In this nonclinical study, the agonistic activity of HRS-4729 on the human GLP-1 receptor was 1.6 times that of retatrutide, while the agonistic activity of HRS-4729 on the human GIP and glucagon receptors was comparable to that of retatrutide. The results show that HRS-4729 was more potent than native GLP-1 and retatrutide. This result was also seen when investigating the potency of activation of the glucagon receptor, with HRS-4729 showing greater potency than retatrutide. This evaluation was conducted in an *in vitro* cell-based receptor potency study and HRS-4729 may perform differently in *in vivo* studies. The PK profile of HRS-4729 was examined in monkeys and the Tmax was 8 to 20 hours and the half-life was approximately 60 hours.

In nonclinical studies of HRS-4729 in a diet-induced obesity, or DIO, mouse model, percent weight change was greater with HRS-4729 compared to reference drug retatrutide at the same dose level. The increased loss in weight occurred approximately seven days after administration and was sustained through the 25-day study.

**Mean percentage change in weight in diet-induced mouse model of obesity**

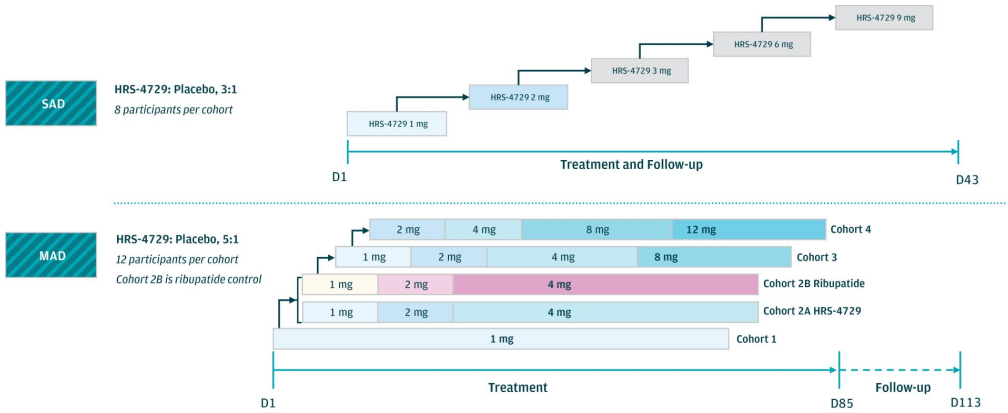



[1] *Retatrutide re-synthesized in-house using publicly available information and tested head-to-head*

*Ongoing clinical trials and next steps*

A Phase 1 clinical trial of HRS-4729 is currently being conducted in China by Hengrui. The randomized, double-blind, placebo-controlled SAD and MAD Phase 1 trial is planned to enroll 100 healthy participants with a BMI of 19 to 40. Participants in the SAD portion of the trial will be randomized 3:1 to receive a single dose of HRS-4729 at 1 mg, 2 mg, 3 mg, 6 mg, and 9 mg or placebo. There will be eight participants per dose cohort. The MAD portion of the trial is expected to enroll 12 participants per cohort who will be randomized 5:1 to receive once-weekly HRS-4729, ribupatide or placebo for 85 days. The 4 mg ribupatide dose is serving as an active comparator arm. The four maintenance doses of HRS-4729 that will be investigated are 1 mg, 4 mg, 8 mg or 12 mg. The primary endpoint of the clinical trial will be measures of safety and tolerability.

**Design of SAD and MAD portions of the Phase 1 clinical trial of HRS-4729**




Additionally, we intend to initiate a global Phase 1 clinical trial of KAI-4729 in 2026, with topline results expected in 2027.

***Additional value creating opportunities for our portfolio***

GLP-1-based therapies have generated positive clinical data in patients with obstructive sleep apnea, or OSA; heart failure with preserved ejection fraction, or HFpEF; metabolic dysfunction-associated steatohepatitis, or MASH; osteoarthritis; and atherosclerotic cardiovascular disease, or ASCVD. As a result of their significant impact on obesity, overweight and obesity-related complications and diseases, the potential application of GLP-1-based therapies in a variety of other diseases continues to grow. While we are focused on obesity first, Hengrui has also generated significant data in our programs in other indications. For instance, Hengrui is currently evaluating ribupatide in a Phase 2 clinical trial for polycystic ovary syndrome, Phase 2 clinical trial for HFpEF, Phase 3 clinical trial in T2D, OSA as well as in other indications. We may in the future expand the evaluation of ribupatide and our other product candidates to these additional indications to create further value.

## Manufacturing

We do not have any manufacturing facilities and we currently rely on third party vendors, including Hengrui, for manufacturing of drug product and drug substance for our clinical trials. Given the past supply issues that have occurred with GLP-1 therapies, we implemented a supply chain strategy to support scalability for the potential

needs of commercial products. We currently have a strategy to support sufficient ribupatide drug substance and drug product to supply our global clinical development program for both injectable ribupatide and oral ribupatide, including sourcing initial clinical trial material from Hengrui to support rapid initiation of clinical trials. We are evaluating potential high-capacity, long-term supply agreements with third-party manufacturers to meet commercial demand, if approved, with the option to leverage Hengrui's manufacturing capacity to provide significant flexibility and scale. We believe that our planned manufacturing capabilities will also be able to scale to support a commercial launch of ribupatide, if regulatory approval is achieved. For our other programs, we have sufficient supply from Hengrui to support ongoing and planned Phase 1 and Phase 2 clinical trials until our supply chain to manufacture those products is fully operational. While our partnership with Hengrui has the potential to include significant clinical and commercial product supply, we have established relationships with a network of drug substance and drug product manufacturers outside of China to provide a geographically and geopolitically diverse manufacturing footprint.

We are continually working with our manufacturing vendors to optimize manufacturing processes with the goal of increasing speed, reducing costs, and increasing the resiliency of the supply chain through the creation of stable stockpiles of materials and reducing failure points. For ribupatide, we have completed technology transfers into our selected vendors and have completed multiple GMP campaigns for both drug substance and drug product. For KAI-7535, we have initiated the technology transfer process at our initial drug substance vendor and are working with our drug product formulation partner to develop and manufacture the dosage strengths required for use in global clinical trials. We are also evaluating processes designed to ensure that the commercial cost of goods sold for any approved product candidate will support a robust margin profile at full commercial scale. Should any of our current or future manufacturing partners become unavailable to us for any reason, we believe that there are a number of potential replacements, although we may incur delays and increased costs in identifying, qualifying and transferring manufacturing know-how to such replacements.

Given the large and growing population that could be eligible for obesity and obesity-related disease treatments, we are building a stable, diversified network of drug substance and drug product suppliers that we believe can be scaled to meet a potentially significant global demand.

## Hengrui license and collaboration agreement

On May 15, 2024, we entered into a License and Collaboration Agreement, or the Hengrui License Agreement, with Hengrui, pursuant to which Hengrui granted us (a) an exclusive, royalty-bearing, sublicensable license under certain intellectual property rights controlled by Hengrui to develop, manufacture and commercialize products comprising ribupatide, KAI-7535, KAI-4729, and certain derivatives of the foregoing, or the Licensed Products, for the treatment, prevention, or diagnosis of any and all indications, diseases, or conditions worldwide, excluding China, Hong Kong, Macau, and Taiwan, or the Territory, and (b) a non-exclusive right to pre-clinically develop and manufacture the Licensed Products outside of the Territory solely for the development or commercialization of such Licensed Products in the Territory, subject to certain restrictions. We granted Hengrui a non-exclusive, sublicensable license under certain intellectual property rights controlled by us solely to the extent necessary to develop, manufacture and commercialize Licensed Products outside of the Territory, to conduct Hengrui's obligations under the Hengrui License Agreement, and to pre-clinically develop and manufacture Licensed Products in the Territory solely for development or commercialization of such compounds or products outside of the Territory. Hengrui also granted us a right of first refusal to negotiate and obtain an exclusive license to develop, manufacture and commercialize in the Territory up to three other product candidates under development by Hengrui for the treatment of type 2 diabetes and obesity. In addition, if Hengrui notifies us that it wishes to initiate a registrational trial for a combination product that combines a Licensed Product with one or more other active ingredients proprietary to Hengrui and that it wishes to license such combination product to us in the Territory, and unless we are already developing a similar combination product, we may either elect to (i) negotiate

an exclusive license from Hengrui to develop, manufacture and commercialize such combination product (or such other active ingredient) in the Territory or (ii) not negotiate an exclusive license from Hengrui and pay Hengrui a fee ranging from a low eight-figure amount for the first three of combination products proposed by Hengrui for which there is a valid claim in a Licensed Patent in the U.S. and certain other major market countries covering the Licensed Product contained in such combination product to a mid seven-figure amount for each subsequent combination product. If Hengrui fails to complete a registrational trial for such combination product, other than in the event of a serious unexpected adverse event, Hengrui will refund us for such combination product fee, subject to certain other exceptions. In addition, if we elect to receive rights to develop certain new forms of the Licensed Products developed by Hengrui, we must make option exercise payments of either a mid-seven figure amount or low-eight figure amount depending on the Licensed Product for each new form of such Licensed Product.

We are obligated to use commercially reasonable efforts to (i) develop and obtain marketing authorization for at least four Licensed Products in the Territory, including by achieving certain regulatory milestone obligations within specified timelines, and (ii) commercialize the Licensed Products for which we have received marketing authorization in the Territory. As partial consideration for the license granted to us by Hengrui, we paid Hengrui an upfront payment of $100 million, issued Hengrui 5,677,603 shares of our preferred stock, valued at approximately $96.4 million at the time of issuance, and paid Hengrui a technology transfer payment of $10.0 million. We are obligated to pay Hengrui (A) clinical and regulatory milestone payments of up to an aggregate of $200.0 million, (B) commercial milestone payments of up to an aggregate of $5.725 billion, and (C) tiered royalties ranging from mid-single-digit to low-tens percentage of net sales of Licensed Products by us, our affiliates or sublicensees, subject to certain customary reductions. Our obligation to pay Hengrui royalties will commence, on a Licensed Product-by-Licensed Product and country-by-country basis, on the first commercial sale of such Licensed Product in such country and expire on the latest of the expiration of the last-to-expire Hengrui licensed patent covering such Licensed Product in such country, expiration of all regulatory exclusivity for such Licensed Product in such country, and ten years following the first commercial sale of such Licensed Product in such country, or the Royalty Term.

Until May 15, 2026, (i) we are restricted from developing or commercializing any product that contains a GLP-1 receptor agonist for the treatment of obesity or diabetes anywhere in the world (subject to certain exceptions in the event of our change of control), except for Licensed Products in the Territory or pre-clinical development and manufacture outside the Territory but for use in the Territory, and (ii) Hengrui is restricted from developing or commercializing any such products in the Territory, except for pre-clinical development and manufacture of Licensed Products for use outside the Territory. Unless earlier terminated, the Hengrui License Agreement will expire on a Licensed Product-by-Licensed Product and country by country basis upon the expiration of the Royalty Term for such Licensed Product in such country and in its entirety upon the expiration of all Royalty Terms. We may terminate the Hengrui License Agreement for any reason or no reason upon advanced written notice to Hengrui. Hengrui may terminate the Hengrui License Agreement if we or our sublicensees challenge the patents licensed to us by Hengrui, and either we or Hengrui may terminate the Hengrui License Agreement in the event of the other party's material breach or insolvency, subject to certain notice and cure periods.

## Intellectual property

We strive to protect the proprietary technologies that we believe are important to our business, including by pursuing and maintaining patent protection intended to cover our product candidates and their methods of use, as well as other inventions that are important to our business. In addition to patent protection, we also rely on trade secrets to protect aspects of our business that we do not consider appropriate for patent protection.

Our commercial success depends in part on our ability to obtain and maintain patent and other proprietary protection for commercially important technologies, inventions and know-how related to our business, defend

and enforce our intellectual property rights, particularly our patent rights, preserve the confidentiality of our trade secrets and operate without infringing valid and enforceable intellectual property rights of others.

The patent positions for biotechnology companies like us are generally uncertain and can involve complex legal, scientific and factual issues. In addition, the coverage claimed in a patent application can be significantly reduced before a patent is issued, and its scope can be reinterpreted and even challenged after issuance. As a result, we cannot guarantee that any of our product candidates will receive protection from or remain protected by enforceable patents. 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.

***Patents***

Our patent portfolio includes patents and applications in-licensed from Hengrui, as discussed in more detail above. We cannot be certain that any of the patent filings in our portfolio will provide meaningful protection for any product we ultimately attempt to commercialize.

As of December 31, 2025, the patent rights in-licensed under the Hengrui License Agreement include:

- For our GLP-1/GIP receptor dual agonist program, our in-licensed portfolio includes 6 patent families directed to GLP-1/GIP agonists, injectable and oral formulations, and methods of treating GLP-1 associated diseases or disorders, including obesity and Type 2 diabetes. These patent families relate to ribupatide. The GLP-1/GIP agonist composition of matter family includes 1 allowed application in the United States, and applications are allowed, granted, or pending in 15 ex-U.S. jurisdictions, including certain major market countries such as Australia, Canada, Europe and Japan. Excluding any potentially available patent term adjustments or extensions and assuming payment of appropriate maintenance, renewal, annuity and other governmental fees, any patents that may issue from this family are expected to have a statutory expiration date in 2041.
- For our GLP-1 receptor agonist program, our in-licensed portfolio includes 9 patent families directed to GLP-1 agonists, salt and crystalline forms, and oral formulations, methods of making GLP-1 agonists and their intermediates, and methods of treating GLP-1 associated diseases or disorders, including obesity and Type 2 diabetes. These patent families relate to KAI-7535. The GLP-1 agonist composition of matter family includes 3 granted patents in the United States. Additionally, 1 application is pending in the U.S., and applications are granted, allowed, or pending in 14 ex-U.S. jurisdictions, including certain major market countries such as Australia, Canada, Europe and Japan. Excluding any patent term adjustments or extensions and assuming payment of appropriate maintenance, renewal, annuity and other governmental fees, any patents that have or may issue from this family have a statutory expiration date in 2041.
- For our GLP-1/GIP/glucagon receptor tri-agonist program, our in-licensed portfolio includes a patent family directed to GLP-1/GIP/GCG agonists and methods of treating GLP-1 associated diseases or disorders, including obesity and Type 2 diabetes. This patent family relates to KAI-4729 and includes one pending international PCT application. Excluding any patent term adjustments or extensions and assuming payment of appropriate maintenance, renewal, annuity and other governmental fees, any patents that issue from this family will have a statutory expiration date in 2044.

See the section entitled “Business—Hengrui license and collaboration agreement” for additional information on our rights under the Hengrui License Agreement.

***Trade secrets***

In addition to patents, we rely on trade secrets and know-how to develop and maintain our competitive position. We typically rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. We protect trade secrets and know-how by establishing confidentiality agreements and invention assignment agreements with our employees, consultants, scientific advisors, contractors and partners. These agreements generally provide that all confidential information developed or made known during the course of an individual or entity's relationship with us must be kept confidential during and after the relationship. These agreements also generally provide that all inventions resulting from work performed for us or relating to our business and conceived or completed during the period of employment or assignment, as applicable, shall be our exclusive property. In addition, we take other appropriate precautions, such as physical and technological security measures, to guard against misappropriation of our proprietary information by third parties.

***Trademarks***

As of November 30, 2025, we have three allowed trademark applications in the United States, and one more that the USPTO recently approved for publication for our corporate name and slogan. In addition, our registered trademark portfolio contains 15 trademark registrations in foreign jurisdictions, including Australia, the European Union, New Zealand, and the United Kingdom, and an additional 17 pending or published applications in Canada, Japan, Mexico, New Zealand, Saudi Arabia, and the United Arab Emirates.

## Sales and marketing

As a clinical stage company, we do not currently maintain a commercial organization or distribution network. If one or more of our product candidates are approved, we may commercialize them ourselves by selectively building commercial functions, or we may rely in whole or in part on third parties for sales, marketing and distribution. We intend to continue evaluating opportunities to work with partners that could support the development and potential commercialization of our product candidates. Any commercialization activities, whether conducted independently or with partners, will be focused on key markets in order to maximize the worldwide commercial potential of our product candidates.

## Competition

The biopharmaceutical industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our, knowledge, experience and scientific resources provide us with competitive advantages, we face competition from many different sources, including commercial and clinical stage biopharmaceutical companies, academic institutions, government agencies and private and public research institutions. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future.

Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical studies, clinical trials, regulatory approvals and marketing approved products than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Our competitors may succeed in developing therapies that are more effective, better tolerated or less costly than any which we are developing, which could reduce our commercial opportunity. Even if we obtain regulatory approval for any of our product candidates, our competitors may succeed in obtaining regulatory approvals for their products earlier than we do. We will also face competition from these third parties in recruiting and retaining qualified

scientific and management personnel, in establishing clinical trial sites and patient registration for clinical trials, and in acquiring and in-licensing technologies and products complementary to our programs or advantageous to our business.

The key competitive factors affecting the success of each of our product candidates, if approved, are likely to be its efficacy, safety, tolerability, frequency and route of administration, convenience and price, the level of branded and generic competition and the availability of coverage and reimbursement from government and other third-party payors.

Our product candidates, if approved, will compete against therapies that are already approved and marketed for obesity, including semaglutide (Wegovy®) and liraglutide (Saxenda®) from Novo Nordisk A/S, and tirzepatide (Zepbound™) from Eli Lilly and Company. In addition, we are aware of active programs at Aardvark Therapeutics, Inc., Altimmune, Inc., Amgen Inc., Ascletis Pharma Inc., AstraZeneca PLC, Boehringer Ingelheim International GmbH, BrightGene Pharmaceutical Co., Ltd., Eli Lilly and Company, Corxel Pharmaceuticals, F. Hoffmann-La Roche Ltd, Gan & Lee Pharmaceuticals, Gubra, Hanmi Pharmaceutical Co., Ltd., Hansoh Pharmaceutical Group Company Limited, Innovent Biologics, Inc., Merck & Co., Novo Nordisk A/S, Pfizer Inc., Regeneron Pharmaceuticals Inc., Regor Therapeutics Group, Sciwind Biosciences Co., Ltd., Structure Therapeutics Inc., Verdiva Bio Limited, Viking Therapeutics, Inc., and Zealand Pharma A/S. We may also face competition from compounding facilities manufacturing, tirzepatide and semaglutide, the active ingredients in Zepbound™ and Wegovy®, respectively.

## Government regulation

The FDA and other regulatory authorities at federal, state, and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring, and post-approval reporting of pharmaceutical product candidates such as those we are developing. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources.

### *Review and approval of drugs and biologics in the United States*

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or the FDCA, and its implementing regulations, and biologics under the FDCA, the Public Health Service Act, or the PHSA, and their implementing regulations. Drugs and biologics also are subject to other federal, state, local and foreign statutes and regulations. The process required by the FDA before new drug and biologic product candidates may be marketed in the United States generally involves the following:

- completion of nonclinical or preclinical laboratory tests, animal studies and formulation studies, with certain studies conducted in accordance with Good Laboratory Practice regulations, or GLPs, and other applicable regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- approval by an independent institutional review board, or IRB, or ethics committee at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with Good Clinical Practice regulations, or GCPs, to evaluate the safety and effectiveness of a proposed drug candidate, and the safety, purity and potency of a proposed biological product candidate, for its intended use and proposed doses;

- preparation and submission to the FDA of a New Drug Application, or NDA, for a drug or BLA for a biologic, after completion of all pivotal trials;
- a determination by the FDA within 60 days of its receipt of an NDA or BLA to file the application for review;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug or biologic is produced to assess compliance with current Good Manufacturing Practice requirements, or cGMPs, to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity;
- satisfactory completion of potential inspection of selected clinical investigation sites to assess compliance with GCPs; and
- FDA review and approval of the NDA or BLA to permit commercial marketing of the product for particular indications for use in the United States.

Once a product candidate is identified for development, it enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies. An IND sponsor must submit, among other things, the results of the preclinical tests, together with manufacturing information and analytical data, to the FDA as part of an IND. An IND is a request for authorization from the FDA to administer an investigational product to humans. An IND will also include a protocol detailing, among other things, the objectives of the clinical trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated, if the trial includes an efficacy evaluation. Some preclinical testing may continue even after the IND is submitted. The IND becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, places the IND on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding questions or concerns before the clinical trial can begin. Clinical holds also may be imposed by the FDA at any time before or during clinical trials due to safety concerns or non-compliance with FDA requirements, in which case clinical trials may not begin or continue until the FDA notifies the sponsor that the hold has been lifted. FDA may also place a trial on a partial clinical hold. A partial clinical hold is a delay or suspension of only part of the clinical work requested or ongoing under the IND. No more than 30 days after imposition of a clinical hold or partial clinical hold, the FDA will provide the sponsor a written explanation of the basis for the hold. Following issuance of a clinical hold or partial clinical hold, an investigation (or full investigation in the case of a partial clinical hold) may only begin or resume after the FDA has notified the sponsor that the investigation may proceed.

Clinical trials involve the administration of the investigational product to human subjects, and must be conducted under the supervision of one or more qualified investigators in accordance with GCPs, which include, among other things, the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. Clinical trials must be conducted under protocols detailing, among other things, the objectives of the trial, dosing procedures, subject selection and exclusion criteria and the safety and effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND, and a separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. While the IND is active, progress reports summarizing the results of the clinical trials and nonclinical studies performed since the last progress report, among other information, must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and investigators for serious and unexpected suspected adverse reactions, findings from other studies suggesting a significant risk to humans exposed to the same or similar drugs or biologics or, in the case of drug-device or biologic-device combination products, the device component, findings from animal or *in vitro* testing suggesting a significant risk to humans, and any clinically important increased incidence of a serious suspected adverse reaction compared to that listed in the protocol or investigator brochure. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information.

Furthermore, an independent IRB or ethics committee at each institution participating in the clinical trial must review and approve each protocol before a clinical trial commences at that institution and must also approve the information regarding the trial and the consent form that must be provided to each trial subject or his or her legal representative, monitor the study until completed and otherwise comply with IRB regulations. The FDA or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the investigational product has been associated with unexpected serious harm to patients. In addition, some clinical trials are overseen by an independent group of qualified experts organized by the sponsor, known as a data safety monitoring board or committee. Depending on its charter, this group may determine whether a trial may move forward at designated check points based on access to certain data from the trial. There are also requirements governing the registration of certain clinical trials and reporting of clinical trial results to public registries, including clinicaltrials.gov.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- ***Phase 1***: The product candidate is initially introduced into healthy human subjects or, in certain indications, patients with the target disease or condition, and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion and, if possible, to gain an early indication of its effectiveness and to determine maximal dosage.
- ***Phase 2***: The product candidate is administered to a limited patient population with a specified disease or condition to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product candidate for specific targeted diseases, and to determine dosage tolerance and appropriate dosage.
- ***Phase 3***: The product candidate is administered to an expanded patient population to further evaluate dosage, to provide substantial evidence of efficacy, or purity and potency, and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk-benefit ratio of the product candidate and provide an adequate basis for product labeling.

Post-approval trials, sometimes referred to as Phase 4 studies, may be conducted after initial regulatory approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA or BLA.

Concurrent with clinical trials, companies often complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the product candidate and finalize a process for manufacturing the product in commercial quantities in accordance with cGMPs. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final product. In addition, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

*NDA and BLA review and approval process*

Assuming satisfactory completion of all required testing in accordance with applicable regulatory requirements, the results of product development, including among other things, results from nonclinical studies and clinical trials, are submitted to the FDA as part of an NDA or BLA requesting approval to market the product candidate for one or more indications. The NDA or BLA must include all relevant data available from preclinical and

clinical studies, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. Data can come from company-sponsored clinical studies, or from a number of alternative sources, such as studies initiated by investigators or other third parties. The submission of an NDA or BLA requires payment of a substantial user fee to FDA, and the sponsor of an approved NDA or BLA is also subject to an annual program fee. A waiver of certain user fees may be obtained under certain limited circumstances.

The FDA conducts a preliminary review of all NDAs and BLAs within the first 60 days after submission, before accepting them for filing, to determine whether they are sufficiently complete to permit substantive review. The FDA may refuse to file any NDA or BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the NDA or BLA must be resubmitted with the additional information before FDA will review the application. Once filed, the FDA reviews a BLA to determine, among other things, whether the product is safe, pure and potent for its intended use, and an NDA to determine, among other things, whether the product is safe and effective for its intended use. As part of the NDA and BLA review, FDA also evaluates whether the manufacturing of the products is cGMP-compliant to assure and preserve the product's identity, strength, quality, and purity. Under the Prescription Drug User Fee Act, or PDUFA, guidelines that are currently in effect, the FDA has a goal of ten months for a standard review and six months for priority review from the date of "filing" of an original NDA or BLA to review and act on the submission. A standard review typically takes twelve months, and a priority review typically takes eight months, from the date the NDA or BLA is submitted to the FDA because the FDA has approximately two months to make a "filing" decision. The FDA does not always meet its PDUFA goal dates. The review process can be significantly extended by FDA requests for additional information or clarification, the applicant's submission of additional information, or other reasons. The review process may also take more than one cycle or FDA could fail to meet the PDUFA goal date.

The FDA may refer an application for a novel biologic or drug, to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and may provide a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

During its review of an NDA or BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. In addition, the FDA will typically inspect one or more clinical trial sites to assure compliance with GCPs and the integrity of the clinical data submitted. After the FDA evaluates an NDA or BLA and conducts inspections of manufacturing facilities where the investigational product will be produced, the FDA may issue an approval letter or a Complete Response Letter, or CRL. An approval letter authorizes commercial marketing of the product with prescribing information for specific indications. A CRL indicates that the review cycle for the application is complete, and the application will not be approved in its present form. A CRL usually describes the specific deficiencies in the application identified by the FDA and may include requirements to conduct additional clinical trials, or other significant, costly, and time-consuming requirements related to clinical data, nonclinical studies or manufacturing. If a CRL is issued, the sponsor must resubmit the NDA or BLA, addressing all of the deficiencies identified in the letter, or withdraw the application. The FDA has committed in most cases to reviewing such resubmissions in two or six months depending on the type of information included. Even if such data and information are submitted, the FDA may decide that the application does not satisfy the criteria for approval and issue an additional complete response letter.

If the FDA approves a product, it may limit the approved indications for use for the product; require that contraindications, warnings or precautions be included in the product's labeling; require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess the product's safety or effectiveness or

safety, purity, and potency after approval; require testing and surveillance programs to monitor the product after commercialization; or impose other conditions, including distribution restrictions or other risk management mechanisms, including a risk evaluation and mitigation strategy, or REMS, which can materially affect the potential market and profitability of the product. If the FDA concludes a REMS is needed, the sponsor of the NDA or BLA must submit a proposed REMS in connection with the application. The FDA will not approve the application without an approved REMS, if one is required. A REMS could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of commercial products.

In addition, the Pediatric Research Equity Act, or PREA, requires a sponsor to conduct pediatric clinical trials for most biologics and drugs, for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration. Under PREA, original NDAs and BLAs and certain supplements must contain a pediatric assessment unless the sponsor has received a deferral or waiver. The required assessment must evaluate the safety and effectiveness, or safety, purity, and potency, of the product for the claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product is deemed safe and effective, or safe, pure and potent. The sponsor may request or FDA may grant a waiver or deferral of pediatric clinical trials for some or all of the pediatric subpopulations. A deferral may be granted for several reasons, including a finding that the drug or biologic is ready for approval for use in adults before pediatric clinical trials are complete or that additional data need to be collected before the pediatric clinical trials begin.

***Expedited development and review programs***

The FDA has a number of programs intended to expedite the development or review of a marketing application for an investigational product. For example, the fast track designation program is intended to expedite or facilitate the process for developing and reviewing product candidates that meet certain criteria. Specifically, investigational drugs and biologics are eligible for fast track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. The sponsor of a fast track product candidate has opportunities for more frequent interactions with the applicable FDA review team during product development and, once a marketing application is submitted, the application may be eligible for priority review. With regard to a fast track product candidate, the FDA may consider for review sections of the application on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the application, the FDA agrees to accept sections of the applications and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA or BLA.

A product candidate intended to treat a serious or life-threatening disease or condition may also be eligible for breakthrough therapy designation to expedite its development and review. A product candidate can receive breakthrough therapy designation if preliminary clinical evidence indicates that the product candidate, alone or in combination with one or more other drugs or biologics, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the fast track program features, as well as more intensive FDA interaction and guidance beginning as early as Phase 1 and an organizational commitment to expedite the development and review of the product candidate, including involvement of senior managers.

Any product candidate submitted to the FDA for approval may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. An NDA or BLA is eligible for priority review if the product candidate is designed to treat a serious condition, and if approved, would

provide a significant improvement in safety or efficacy compared to available therapies. The FDA endeavors to review applications with priority review designations within six months of the filing date as compared to ten months for review of NDAs or BLAs with a standard review designation under its current PDUFA review goals.

In 2025, the FDA created a new voucher program called the Commissioner's National Priority Voucher, or CNPV, with the goal of radically expediting the drug and biological product review and approval process. The agency may award a CNPV to a company or specific product candidate that demonstrates alignment with certain national health priorities. The FDA aims to take action on a marketing application for which a CNPV is used within one to two months after the filing date.

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

***Post-approval requirements***

Drugs and biologics manufactured and distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual program fees for any marketed products. Drug and biologic manufacturers and other entities involved in the manufacture and distribution of approved drugs and biologics are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP requirements, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

Once an approval is granted, the FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information, imposition of requirements for post-market studies or clinical studies to assess new safety risks, or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters, or untitled letters;
- clinical holds on ongoing or planned clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of approvals;
- product seizure or detention, or refusal to permit the import or export of products;

- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information;
- issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

In addition, the FDA closely regulates the marketing, labeling, advertising and promotion of products that are placed on the market. Drugs and biologics may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may legally prescribe commercially-available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products.

***Combination products***

Certain of our injectable product candidates are being developed together with an injector device, which will render them combination products with a device component. Specifically, under regulations issued by the FDA, a combination product may include:

- a product comprised of two or more regulated components that are physically, chemically, or otherwise combined or mixed and produced as a single entity;
- two or more separate products packaged together in a single package or as a unit and composed of drug and device products, device and biological products, biological and drug products or biological products, drug products and device products;
- a drug, or device, or biological product packaged separately that according to its investigational plan or proposed labeling is intended for use only with an individually specified drug, or device, or biological product where both are required to achieve the intended use, indication, or effect and where upon approval of the proposed product, the labeling of the other product would need to be updated (e.g., to reflect a change in intended use, dosage form, strength, route of administration, or significant change in dose); or
- an investigational drug, or device, or biological product packaged separately that according to its proposed labeling is for use only with another individually specified investigational drug, device, or biological product where both are required to achieve the intended use, indication, or effect.

Under the FDCA and its implementing regulations, the FDA is charged with assigning a center with primary jurisdiction, or a lead center, for review of a combination product. The designation of a lead center generally eliminates the need to receive approvals from more than one FDA center for combination products, although it does not preclude consultations by the lead center with another FDA center. The determination of which center will be the lead center is based on the "primary mode of action" of the combination product. The FDA has established an Office of Combination Products to address issues regarding combination products and provide more certainty to the regulatory review process. This office is responsible for developing guidance and regulations to clarify the regulation of combination products, and for assigning the FDA center that will have primary jurisdiction for review of a combination product where the jurisdiction is unclear or in dispute.

Following approval of a combination product, each component of a combination product retains its regulatory status (as a biologic, drug or device, for example) and is subject to the requirements established by the FDA for that type of component.

A combination product candidate with a drug primary mode of action, as we expect our combination products to be regulated, generally would be reviewed and approved pursuant to a NDA. In reviewing the NDA for such a product, however, FDA reviewers in the drug center could consult with their counterparts in the device center to ensure that the drug and device component of the combination product candidate, as applicable, met all requirements applicable to its category. In addition, under FDA regulations, combination products are subject to the cGMP requirements applicable to each component within the combination. We believe our combination product candidates are likely to be reviewed by the FDA under a NDA.

***Hatch-Waxman amendments***

Section 505 of the FDCA describes three types of marketing applications that may be submitted to the FDA to request marketing authorization for a drug product (not a biologic). A Section 505(b)(1) NDA is an application that contains full reports of investigations of safety and efficacy. A 505(b)(2) NDA is an application that contains full reports of investigations of safety and efficacy but where at least some of the information required for approval comes from investigations that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. This regulatory pathway enables the applicant to rely, in part, on the FDA's prior findings of safety and efficacy for an existing product, or published literature, in support of its application. Section 505(j) establishes an abbreviated approval process for a generic version of approved drug products through the submission of an Abbreviated New Drug Application, or ANDA. An ANDA provides for marketing of a generic drug product that has the same active ingredients, dosage form, strength, route of administration, labeling, performance characteristics and intended use, among other things, to a previously approved product, known as a reference listed drug, or RLD. ANDAs are termed "abbreviated" because they are generally not required to include preclinical (animal) and clinical (human) data to establish safety and efficacy. Instead, generic applicants must scientifically demonstrate that their product is bioequivalent to, or performs in the same manner as, the RLD through in vitro, in vivo, or other testing. The generic version must deliver the same amount of active ingredient(s) into a subject's bloodstream in the same amount of time as the RLD, and pursuant to state law, a generic product can often be substituted by pharmacists under prescriptions written for the RLD.

***Non-patent exclusivity***

The Hatch-Waxman Amendments also established periods of non-patent exclusivity for an RLD, which preclude the FDA from approving (or in some cases accepting) an ANDA or 505(b)(2) application referencing such RLD until the applicable period(s) of non-patent exclusivity for the RLD has expired. For example, the Hatch-Waxman Amendments established a period of five years of exclusivity for a new drug containing a new chemical entity, or NCE. For the purposes of this provision, an NCE is a drug that contains no active moiety that has previously been approved by the FDA in any other NDA. An active moiety is the molecule or ion responsible for the physiological or pharmacological action of the drug substance. In cases where such NCE exclusivity has been granted, an ANDA may not be filed with the FDA until the expiration of five years after approval of the RLD, unless the submission is accompanied by a Paragraph IV certification, which states the proposed generic drug will not infringe one or more of the already approved product's listed patents or that such patents are invalid or unenforceable, in which case the applicant may submit its application four years following the RLD's approval.

The FDCA also provides for a period of three years of exclusivity for non-NCE drugs if the NDA or NDA supplement includes reports of one or more new clinical investigations, other than bioavailability or

bioequivalence studies, that were conducted by or for the applicant and are essential to the approval of the application or supplement. This three-year exclusivity period often protects changes to a previously approved drug product, such as a new dosage form, route of administration, combination or indication, but it generally would not protect the originally approved product from generic competition. Unlike five-year NCE exclusivity, an award of three-year exclusivity does not block the FDA from accepting ANDA or 505(b)(2) applications; it only prevents FDA from approving them.

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

***Hatch-Waxman patent certification and the 30-month stay***

In seeking approval of an NDA or a supplement thereto, NDA sponsors are required to list with the FDA each patent with claims that cover the applicant's product or an approved method of using the product. Upon approval, each of the patents listed by the NDA sponsor is published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Upon submission of an ANDA or 505(b)(2) NDA, an applicant is required to certify to the FDA concerning any patents listed for the RLD in the Orange Book that:

- no patent information on the drug product that is the subject of the application has been submitted to the FDA;
- such patent has expired;
- the date on which such patent expires; or
- such patent is invalid, unenforceable or will not be infringed upon by the manufacture, use, or sale of the drug product for which the application is submitted.

Generally, the ANDA or 505(b)(2) NDA cannot be approved until all listed patents have expired, except where the ANDA or 505(b)(2) NDA applicant challenges a listed patent through the last type of certification, also known as a paragraph IV certification. If the applicant does not challenge the listed patents or indicates that it is not seeking approval of a patented method of use, the ANDA or 505(b)(2) NDA application will not be approved until all of the listed patents claiming the referenced product have expired. If the ANDA or 505(b)(2) NDA applicant has provided a paragraph IV certification the applicant must send notice of the paragraph IV certification to the NDA and patent holders once the application 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. If the paragraph IV certification is challenged by an NDA holder or the patent owner(s) asserts a patent challenge to the paragraph IV certification, the FDA may not approve that application until the earlier of 30 months from the receipt of the notice of the paragraph IV certification, the expiration of the patent, when the infringement case concerning each such patent was favorably decided in the applicant's favor or settled, or such shorter or longer period as may be ordered by a court. This prohibition is generally referred to as the 30-month stay. In instances where an ANDA or 505(b)(2) NDA applicant files a paragraph IV certification, the NDA holder or patent owner(s) regularly take action to trigger the 30-month stay, recognizing that the related patent litigation may take many months or years to resolve. Thus, approval of an ANDA or 505(b)(2) NDA could be delayed for a significant period of time depending on the patent certification the applicant makes and the RLD sponsor's decision to initiate patent litigation.

***Biosimilars and exclusivity***

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, created an abbreviated approval pathway in the PHSA for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through, as applicable, analytical studies, animal studies, and a clinical study or studies. Interchangeability means that a product is biosimilar to the reference product and can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing that applicant's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product. The BPCIA also established an exclusivity period for biosimilars approved as interchangeable products. Substitution at the pharmacy level of biosimilar products deemed to be interchangeable is governed by state pharmacy law. We expect our product candidates to be reviewed through the NDA, not the BLA pathway, unless pending litigation against the FDA results in a change to the treatment of our product candidates as biologics.

A biological product can also obtain pediatric exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity protection. This six-month exclusivity, which runs from the end of other exclusivity protection, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study.

***Rest of the world regulation***

For other countries outside of the United States, such as those in Europe, Latin America or Asia, the requirements governing product development, the conduct of clinical trials, product marketing, product licensing, pricing and reimbursement can vary from country to country. Failure to comply with applicable foreign regulatory requirements may subject sponsors, manufacturers or marketers of pharmaceutical products to, among other things, fines, suspension or withdrawal of regulatory authorizations and approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

***Review and approval of medicinal products in the European Union***

In order to market any product outside of the United States, a company must also comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, or MA, commercial sales and distribution of products. Whether or not it obtains FDA approval for a product, an applicant will need to obtain the necessary approvals by the comparable foreign regulatory authorities before it can commence clinical trials or marketing of the product in those countries or jurisdictions. Specifically, the process governing approval of medicinal products in the EU generally follows similar lines as in the United States. It entails satisfactory completion of preclinical studies and adequate and well-controlled clinical trials to establish the safety and

efficacy of the product for each proposed indication. It also requires the submission to the relevant competent authorities of a MA application, or MAA, and granting of a MA by these authorities before the product can be marketed and sold in the EU.

*Non-clinical studies and clinical trials*

Similarly to the United States, the various phases of non-clinical and clinical research in the EU are subject to significant regulatory controls.

Non-clinical studies are performed to demonstrate the health or environmental safety of new chemical or biological substances. Non-clinical (pharmaco-toxicological) studies must be conducted in compliance with the principles of good laboratory practice, or GLP, as set forth in EU Directive 2004/10/EC (unless otherwise justified for certain particular medicinal products, e.g., radio-pharmaceutical precursors for radio-labeling purposes). In particular, non-clinical studies, both in vitro and in vivo, must be planned, performed, monitored, recorded, reported and archived in accordance with the GLP principles, which define a set of rules and criteria for a quality system for the organizational process and the conditions for non-clinical studies. These GLP standards reflect the Organization for Economic Co-operation and Development requirements.

Clinical trials of medicinal products in the EU must be conducted in accordance with EU and national regulations and the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use, or ICH, guidelines on Good Clinical Practices, or GCP, as well as the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. If the sponsor of the clinical trial is not established within the EU, it must appoint an EU entity to act as its legal representative. The sponsor must take out a clinical trial insurance policy, and in most EU member states, the sponsor is liable to provide ‘no fault’ compensation to any study subject injured in the clinical trial.

The regulatory landscape related to clinical trials in the EU has been subject to recent changes. The EU Clinical Trials Regulation, or CTR, which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. Unlike directives, the CTR is directly applicable in all EU member states without the need for member states to further implement it into national law. The CTR notably harmonizes the assessment and supervision processes for clinical trials throughout the EU via a Clinical Trials Information System, which contains a centralized EU portal and database.

While the EU Clinical Trials Directive required a separate clinical trial application, or CTA, to be submitted in each member state in which the clinical trial takes place, to both the competent national health authority and an independent ethics committee, much like the FDA and IRB respectively, the CTR introduces a centralized process and only requires the submission of a single application for multi-center trials. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each member state, leading to a single decision per member state. The CTA must include, among other things, a copy of the trial protocol and an investigational medicinal product dossier containing information about the manufacture and quality of the medicinal product under investigation. The assessment procedure of the CTA has been harmonized as well, including a joint assessment by all member states concerned, and a separate assessment by each member state with respect to specific requirements related to its own territory, including ethics rules. Each member state’s decision is communicated to the sponsor via the centralized EU portal. Once the CTA is approved, clinical study development may proceed.

The CTR transition period ended on January 31, 2025, and all clinical trials (and related applications) are now fully subject to the provisions of the CTR.

Medicines used in clinical trials must be manufactured in accordance with Good Manufacturing Practice, or GMP. Other national and EU-wide regulatory requirements may also apply.

*Marketing authorization*

In order to market our product candidates in the EU and many other foreign jurisdictions, we must obtain separate regulatory approvals. More concretely, in the EU, medicinal product candidates can only be commercialized after obtaining a MA. To obtain a MA, an applicant must submit an MAA either under a centralized procedure administered by the European Medicines Agency, or EMA, or one of the procedures administered by competent authorities in the EU member states (decentralized procedure or mutual recognition procedure) for obtaining a MA in multiple EU member states.

“Centralized MAs” are issued by the European Commission through the centralized procedure based on the opinion of the Committee for Medicinal Products for Human Use, or CHMP, of the European Medicines Agency, or EMA, and are valid throughout the EU. Pursuant to Regulation (EC) No 726/2004, the centralized procedure is compulsory for specific products, including for medicines produced by certain biotechnological processes, products designated as orphan medicinal products, advanced therapy medicinal products (gene therapy, somatic cell therapy and tissue-engineered products) and products with a new active substance indicated for the treatment of certain diseases, including products for the treatment of HIV, AIDS, cancer, diabetes, neurodegenerative diseases, auto-immune and other immune dysfunctions and viral diseases. The centralized procedure is optional for products containing a new active substance not yet authorized in the EU, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU.

Under the centralized procedure, the maximum timeframe for the evaluation of an MAA by the EMA is 210 days, excluding clock stops, when additional information or written or oral explanation is to be provided by the applicant in response to questions asked by the CHMP. Clock stops may extend the timeframe of evaluation of an MAA considerably beyond 210 days. Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is of major interest from a public health perspective and in particular from the point of view of therapeutic innovation. If the CHMP accepts such request, the time limit of 210 days will be reduced to 150 days, excluding clock stops, but it is possible that the CHMP can revert to the standard time limit for the centralized procedure if it considers that it is no longer appropriate to conduct an accelerated assessment. At the end of this period, the CHMP provides a scientific opinion on whether or not a marketing authorization should be granted in relation to a medicinal product. Within 67 days from the date of the CHMP opinion, the European Commission will adopt its final decision on the MAA.

“National MAs” are issued by the competent authorities of the EU member states, only cover their respective territory, and are available for product candidates not falling within the mandatory scope of the centralized procedure. Where a product has already been authorized for marketing in an EU member state, this national MA can be recognized in another member state through the mutual recognition procedure. If the product has not received a national MA in any member state at the time of application, it can be approved simultaneously in various member states through the decentralized procedure. Under the decentralized procedure an identical dossier is submitted to the competent authorities of each of the member states in which the MA is sought, one of which is selected by the applicant as the reference member state.

*Periods of authorization and renewals*

A MA has an initial validity of five years. The MA may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the relevant EU member state for a nationally authorized product. To this end, the MA holder must provide the EMA or the competent authority with a consolidated version of the file in respect of quality, safety and efficacy, including all variations introduced since the MA was granted, at least nine months before the MA ceases to be valid. Once renewed, the MA is valid for an unlimited period, unless the European Commission or the competent authorities of the

relevant member states decide, on justified grounds relating to pharmacovigilance, to proceed with one further five year renewal period. Any authorization which is not followed by the actual placing of the medicinal product on the EU market (for centrally-authorized products) or on the market of the authorizing EU member state (for nationally-authorized products) within three years after authorization ceases to be valid (the so-called “sunset clause”).

*Data and market exclusivity*

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

*Pediatric development*

Regulation (EC) No 1901/2006 provides that prior to obtaining a MA in the EU, applicants have to demonstrate compliance with all measures included in a pediatric investigation plan, or PIP, agreed with the EMA’s Pediatric Committee, or PDCO, and covering all subsets of the pediatric population, unless the PDCO has granted (1) a product-specific waiver, (2) a class waiver or (3) a deferral for one or more of the measures included in the PIP. The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the product for which a MA is being sought. Products that are granted a MA with the results of the pediatric clinical trials conducted in accordance with the PIP are eligible for a six-month extension of the protection under a SPC provided an application for such extension is made at the same time as filing the SPC application for the product, or at any point up to two years before the SPC expires, even where the trial results are negative. In the case of orphan medicinal products, a two-year extension of the orphan market exclusivity may be available. This pediatric reward is subject to specific conditions and is not automatically available when data in compliance with the PIP are developed and submitted.

*Post-approval requirements*

Similar to the United States, both MA holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA, the European Commission and/or the competent regulatory authorities of the member states. The holder of a MA must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance, or QPPV, who is responsible for the establishment and maintenance of that system, and oversees the safety profiles of medicinal products and any emerging safety concerns. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports, or PSURs.

All new MAA must include a risk management plan, or RMP, describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product.

The regulatory authorities may also impose specific obligations as a condition of the MA. Such risk-minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies.

The advertising and promotion of medicinal products is also subject to laws concerning promotion of medicinal products, interactions with physicians, misleading and comparative advertising and unfair commercial practices. All advertising and promotional activities for the product must be consistent with the approved summary of product characteristics, and therefore all off-label promotion is prohibited. Direct-to-consumer advertising of prescription medicines is also prohibited in the EU. Although general requirements for advertising and promotion of medicinal products are established under EU directives, the details are governed by regulations in each member state and can differ from one country to another.

The aforementioned EU rules are generally applicable in the European Economic Area, or EEA, which consists of the 27 EU member states plus Norway, Liechtenstein and Iceland.

Failure to comply with EU and member state laws that apply to the conduct of clinical trials, manufacturing approval, MA of medicinal products and marketing of such products, both before and after grant of the MA, manufacturing of pharmaceutical products, statutory health insurance, bribery and anti-corruption or with other applicable regulatory requirements may result in administrative, civil or criminal penalties. These penalties could include delays or refusal to authorize the conduct of clinical trials, or to grant MA, product withdrawals and recalls, product seizures, suspension, withdrawal or variation of the MA, total or partial suspension of production, distribution, manufacturing or clinical trials, operating restrictions, injunctions, suspension of licenses, fines and criminal penalties.

*Reform of the regulatory framework in the European Union*

The EU pharmaceutical legislation is currently undergoing a complete review process, in the context of the Pharmaceutical Strategy for Europe initiative, launched by the European Commission in November 2020. The European Commission's proposal for revision of several legislative instruments related to medicinal products (reduction of the duration of regulatory data protection, revising the eligibility for expedited pathways, etc.) was published on April 26, 2023. The European Parliament and Council of the EU have reached a political agreement on the proposed revisions in December 2025. Following positive votes by member states and the European Parliament on the provisional agreement in March 2026, the proposed revisions (affecting the duration of regulatory data protection and market protection, including for orphan medicinal products, revising the eligibility for expedited pathways, etc.) must now be formally adopted by the Ministers of Health in the Employment, Social Policy, Health and Consumer Affairs Council and the European Parliament Plenary, currently anticipated in the second half of 2026. The proposed changes are not expected to become applicable before 2028.

*Brexit and the regulatory framework in the United Kingdom*

Following the end of the Brexit transition period on January 1, 2021 and the implementation of the Windsor Framework on January 1, 2025, the United Kingdom, or UK, is not generally subject to EU laws in respect of medicines. The EU laws that have been transposed into UK law through secondary legislation remain applicable in the UK. However, new legislation such as the (EU) CTR is not generally applicable in the UK.

Under the Medicines and Medical Devices Act 2021, the Secretary of State or an 'appropriate authority' have delegated powers to amend or supplement existing regulations in the area of medicinal products and medical devices. This allows new rules to be introduced in the future by way of secondary legislation, which aims to allow flexibility in addressing regulatory gaps and future changes in the fields of human medicines, clinical trials and medical devices.

As of January 1, 2021, the Medicines and Healthcare products Regulatory Agency, or MHRA, is the UK's standalone medicines and medical devices regulator. As a result of the Northern Ireland Protocol, different rules applied in Northern Ireland than in England, Wales, and Scotland (together, "Great Britain", or GB), which continued to follow the EU regulatory regime. However, on January 1, 2025 an arrangement called the "Windsor Framework" came into effect and reintegrated Northern Ireland under the regulatory authority of the MHRA with respect to medicinal products. The Windsor Framework removes EU licensing processes and EU labeling and serialization requirements in relation to Northern Ireland and introduces a UK-wide licensing process for medicines.

The UK regulatory framework in relation to clinical trials is governed by the Medicines for Human Use (Clinical Trials) Regulations 2004, as amended, which is derived from the EU Clinical Trials Directive, as implemented into UK national law through secondary legislation. On April 28, 2025, the UK adopted an amendment to the UK clinical trials regulations intended to support a more streamlined and flexible regulation of clinical trials, removing unnecessary administrative burdens on trial sponsors, whilst protecting the interests of trial participants. It also intends to bring the UK regulatory framework for clinical trials, which is still based on the EU Clinical Trials Directive, into closer alignment with the (EU) CTR. The amendment will become applicable on April 28, 2026 following a one-year transition period.

MAs in the UK are governed by the Human Medicines Regulations (SI 2012/1916), as amended. In order to use the centralized procedure to obtain an MA that will be valid throughout the EEA, companies must be established in the EEA. Therefore, after Brexit, companies established in the UK can no longer use the EU centralized procedure and instead an EEA entity must hold any centralized MAs. In order to obtain a UK MA to commercialize products in the UK, an applicant must be established in the UK and must follow one of the UK national authorization procedures or one of the remaining post-Brexit international cooperation procedures. Applications are governed by the Human Medicines Regulations (SI 2012/1916) and are made electronically through the MHRA Submissions Portal. The MHRA has introduced changes to national licensing procedures, including procedures to prioritize access to new medicines that will benefit patients, a 150-day assessment (subject to clock-stops) and a rolling review procedure. The rolling-review procedure permits the separate or joint submission of quality, non-clinical, and clinical data to the MHRA which can be reviewed on a rolling basis. After an application under the rolling-review procedure has been validated, the decision should be received within 100 days (subject to clock-stops). In addition, since January 1, 2024, the MHRA may rely on the International Recognition Procedure, or IRP, when reviewing certain types of MAAs. Pursuant to the IRP, the MHRA will take into account the expertise and decision-making of trusted regulatory partners (e.g. the regulatory authorities in Australia, Canada, Switzerland, Singapore, Japan, the U.S.A. and the EU). The MHRA will conduct a targeted assessment of IRP applications but retains the authority to reject applications if the evidence provided is considered insufficiently robust. The IRP allows medicinal products approved by such trusted regulatory partners that meet certain criteria to undergo a fast-tracked MHRA review to obtain and/or update an MA in the UK. Applications should be decided within a maximum of 60 days if there are no major objections identified that cannot be resolved within such 60 day period and the approval from the trusted regulatory partner selected has been granted within the previous 2 years or if there are such major objections identified or such approval has not been granted within the previous 2 years within 110 days. Applicants can submit initial MAAs to the IRP but the procedure can also be used throughout the lifecycle of a product for post-authorization procedures including line extensions, variations and renewals.

In the UK, the initial duration of an MA is five years and following renewal will be valid for an unlimited period, unless the MHRA decides on justified grounds relating to pharmacovigilance to proceed with only one additional five-year renewal. Any authorization which is not followed by the actual placing of the medicine on the market in the UK within three (3) years shall cease to be in force.

The UK has an initiative known as the Innovative Licensing and Access Pathway, or ILAP, which has similar aims to the EU PRIME scheme but significant differences. ILAP can be entered into earlier, notably during non-clinical development. The MHRA and, notably, the National Institute for Health and Care Excellence (the body responsible for assessing which medicines should be funded by the NHS in England) will assist with the development of a target development profile for medications accepted into ILAP.

***Other healthcare laws***

Pharmaceutical companies are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business, which may constrain the financial arrangements and relationships through which we conduct research, as well as sell, market and distribute any products for which we obtain marketing approval. Such laws include, without limitation, federal and state anti-kickback, fraud and abuse, false claims, and physician and other health care provider transparency laws and regulations. Violation of any of these laws or any other governmental regulations that apply include, without limitation, administrative, civil and criminal penalties, damages, fines, disgorgement, the curtailment or restructuring of operations, additional reporting requirements and/or oversight if the manufacturer becomes subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, exclusion from participation in federal and state healthcare programs and imprisonment.

Moreover, analogous state and foreign laws and regulations may be broader in scope than the provisions described above and may apply regardless of payor. These laws and regulations may differ from one another in significant ways, thus further complicating compliance efforts. For instance, in the EU, many EU member states have adopted specific anti-gift statutes that further limit commercial practices for medicinal products, in particular vis-à-vis healthcare professionals and organizations. Additionally, there has been a recent trend of increased regulation of payments and transfers of value provided to healthcare professionals or entities and many EU member states have adopted national “Sunshine Acts” which impose reporting and transparency requirements (often on an annual basis), similar to the requirements in the United States, on pharmaceutical companies. Certain countries also mandate implementation of commercial compliance programs, or require disclosure of marketing expenditures and pricing information. Violation of any of such laws or any other governmental regulations that apply may result in penalties, including, without limitation, significant administrative, civil and criminal penalties, damages, fines, disgorgement, additional reporting obligations and oversight if a manufacturer becomes subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, the curtailment or restructuring of operations, exclusion from participation in governmental healthcare programs and imprisonment.

***Coverage and reimbursement***

Sales of any product depend, in part, on the extent to which such product will be covered by third-party payors, such as federal, state, and foreign government healthcare programs, commercial insurance and managed healthcare organizations, and the level of reimbursement for such product by third-party payors. Decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. These third-party payors are increasingly reducing reimbursements for medical products, drugs, and services. In addition, the U.S. government, state legislatures, and foreign governments have continued

implementing cost-containment programs, including price controls, restrictions on coverage and 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 sales of any product. Decreases in third-party reimbursement for any product or a decision by a third-party payor not to cover a product could reduce physician usage and patient demand and also have a material adverse effect on sales. As a result, our success could depend on the ability and willingness of patients to pay out-of-pocket for our products, if approved.

In addition, in many countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country. In the EU, governments influence the price of products through their pricing and reimbursement rules and control of national healthcare systems that fund a large part of the cost of those products to consumers. Member states are free to restrict the range of pharmaceutical products for which their national health insurance systems provide reimbursement, and to control the prices and reimbursement levels of pharmaceutical products for human use. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed to by the government. Member states may approve a specific price or level of reimbursement for the pharmaceutical product, or alternatively adopt a system of direct or indirect controls on the profitability of the company responsible for placing the pharmaceutical product on the market, including volume-based arrangements, caps and reference pricing mechanisms. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product to currently available therapies. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. The downward pressure on healthcare costs in general, particularly prescription products, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross border imports from low-priced markets exert a commercial pressure on pricing within a country.

***Healthcare reform***

The United States government and other governments have shown significant interest in pursuing health care reform. Any government-adopted reform measures could adversely impact the pricing of health care products and services in the United States or internationally and the amount of reimbursement available from governmental agencies or other third-party payors. For example, the Patient Protection and Affordable Care Act (the ACA) which was enacted in the United States in 2010, substantially changed the way healthcare is financed by both governmental and private insurers, and significantly affected the pharmaceutical industry. The ACA contains a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement adjustments and changes to fraud and abuse laws. For example, the ACA:

- increased the minimum level of Medicaid rebates payable by manufacturers of brand name drugs from 15.1% to 23.1% of the average manufacturer price;
- expanded the manufacturer Medicaid rebate obligation to drugs paid by Medicaid managed care organizations; and
- imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell “branded prescription drugs” to specified federal government programs.

Since its enactment, there have been judicial, executive, and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the United States Supreme Court dismissed the most recent judicial challenge to the ACA without specifically ruling on the constitutionality of the ACA. Thus, the ACA will remain in force in its current

form. Other legislative changes have been proposed and adopted since the ACA was enacted, including reductions of Medicare payments to providers through 2032. The American Rescue Plan Act of 2021 eliminated the statutory cap on drug manufacturers' Medicaid drug rebate liability, which began on January 1, 2024. Elimination of this cap may require pharmaceutical manufacturers to pay more in rebates than they receive from the sale of products, which could have a material impact on our business.

Most significantly, on August 16, 2022, the Inflation Reduction Act of 2022 (IRA) was signed into law. Among other things, the IRA (i) directs HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare, and subject drug manufacturers to civil monetary penalties and a potential excise tax by offering a price that is not equal to or less than the negotiated "maximum fair price" for such drugs and biologics under the law, and (ii) imposes rebates with respect to certain drugs and biologics covered under Medicare Part B or Medicare Part D to penalize price increases that outpace inflation. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. These provisions took effect progressively starting in fiscal year 2023. The Centers for Medicare & Medicaid Services, or CMS, published the negotiated prices for the initial ten drugs, which went into effect in January 2026, and the subsequent 15 drugs, which will first be effective in 2027, as well as the next 15 drugs that will be subject to price negotiation, although the Medicare drug price negotiation program is currently subject to legal challenges. The impact of these judicial challenges and any future healthcare measures and agency rules implemented by the government on us and the pharmaceutical industry as a whole is unclear. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product candidates, if approved.

The One Big Beautiful Bill Act, which was enacted in July 2025, imposes significant reductions in the funding of the Medicaid program. Such reductions are expected to decrease the number of persons enrolled in Medicaid and reduce the services covered by Medicaid, which could adversely affect our sales of any product candidate that we commercialize.

The Trump administration is also pursuing a two-fold strategy to reduce drug costs in the U.S. While it is unclear whether and how the Trump proposals will be implemented, the Trump policies are likely to have a negative impact on the pharmaceutical industry and on our ability to receive adequate revenues for our product candidates, if approved. On the one hand, President Trump has threatened to impose significant tariffs on pharmaceutical manufacturers that do not adopt pricing policies such as most favored nation pricing, which would tie the price for drugs in the U.S. to the lowest price in a group of other countries. In response, multiple manufacturers have reportedly entered into confidential pricing agreements with the federal government. On the other hand, the Trump administration is pursuing traditional regulatory pathways to impose drug pricing policies, although final regulations have not yet been published. Even regulatory proposals or executive actions that are ultimately deemed unlawful could negatively impact the U.S. pharmaceutical sector and our business. In addition, pharmaceutical pricing and marketing has long been the subject of considerable discussion in Congress and among policymakers, and it is possible that Congress could enact additional laws that negatively affect the pharmaceutical industry.

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 healthcare products and services, which could result in reduced demand for our product candidates, if approved, or additional pricing pressures.

Similar political, economic and regulatory developments are occurring in the EU and may affect the ability of pharmaceutical companies to profitably commercialize their products. In addition to continuing pressure on prices and cost containment measures, legislative developments at the EU or member state level may result in significant additional requirements or obstacles. The delivery of healthcare in the EU, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than EU, law and policy. National governments and health service

providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most EU member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing EU and national regulatory burdens on those wishing to develop and market products, this could restrict or regulate post-approval activities and affect the ability of pharmaceutical companies to commercialize their products. In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies.

In the EU, potential reductions in prices and changes in reimbursement levels could be the result of different factors, including reference pricing systems, parallel distribution and parallel trade. It could also result from the application of external reference pricing mechanisms, which consist of arbitrage between low-priced and high-priced countries. Reductions in the pricing of our medicinal products in one EU member state could affect the price in other EU member states and, thus, have a negative impact on our financial results.

Health Technology Assessment, or HTA, of medicinal products in the EU is an essential element of the pricing and reimbursement decision-making process in a number of EU member states. The outcome of HTA has a direct impact on the pricing and reimbursement status granted to the medicinal product. A negative HTA by a leading and recognized HTA body concerning a medicinal product could undermine the prospects to obtain reimbursement for such product not only in the EU member state in which the negative assessment was issued, but also in other EU member states.

In 2011, Directive 2011/24/EU was adopted at the EU level. This Directive establishes a voluntary network of national authorities or bodies responsible for HTA in the individual EU member states. The network facilitates and supports the exchange of scientific information concerning HTAs. Further to this, on December 13, 2021, Regulation No 2021/2282 on HTA, amending Directive 2011/24/EU, was adopted. The Regulation entered into force in January 2022 and has been applicable since January 2025, with phased implementation based on the type of product, i.e. oncology and advanced therapy medicinal products as of 2025, orphan medicinal products as of 2028, and all other new medicinal products by 2030. The Regulation intends to boost cooperation among EU member states in assessing health technologies, including new medicinal products, and provide the basis for cooperation at the EU level for joint clinical assessments in these areas. It will permit EU member states to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the highest potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU member states will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technology, and making decisions on pricing and reimbursement.

***Data privacy and security laws***

Numerous state, federal, and foreign laws, regulations and standards govern the collection, use, access to, confidentiality, and security of health-related and other personal information, including clinical trial data, and could apply now or in the future to our operations or the operations of our partners. In the United States, numerous federal and state laws and regulations, including data breach notification laws, health information privacy and security laws, and consumer protection laws and regulations, govern the collection, use, disclosure, and protection of health-related and other personal information. Further, to the extent we collect personal data from individuals outside of the United States, through clinical trials or otherwise, we could be subject to foreign laws, such as the GDPR and China's Personal Information Protection Law, which govern the privacy and security of personal data, including health-related data. Privacy and security laws, regulations and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties and restrictions on

data processing. In China, the data privacy and security laws regime comprise the Cyber Security Law (CSL), the Personal Information Protection Law (PIPL) and the Data Security Law (DSL) and their implementing regulations. The PIPL, which applies extra-territorially, establishes a comprehensive framework for the collection and processing of personal information, defining “personal information” and “sensitive personal information” (which includes medical and health information), requiring a lawful basis for processing, mandating purpose limitation, data minimization, transparency and individual rights, and imposing restrictions on cross-border transfers by requiring a data export mechanism to be relied on, such as entering into standard contractual clauses, obtaining a certification or passing a regulator-led security assessment, unless exemptions apply. The CSL and DSL impose network and data security obligations, data classification and graded protection requirements, data localization for critical information infrastructure operators and security assessments for important data.

## Employees and human capital resources

As of December 31, 2025 we had 145 full-time employees and no part-time employees. Of our full-time employees, 98 employees are engaged in research and development activities and 47 are engaged in general and administrative activities. None of our employees is represented by a labor union or covered by 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 employees. We believe our success depends on our ability to attract, retain, develop and motivate diverse highly skilled personnel. In particular, we depend upon the personal efforts and abilities of the principal members of our senior management to partner effectively as a team, and to provide strategic direction, develop our business, manage our operations and maintain a cohesive and stable work environment. We also rely on qualified managers and skilled employees, such as clinical, scientific and medical personnel, with expertise in drug development and the regulatory approval process in order to operate our business successfully.

Our compensation program is designed to retain, motivate and, as needed, attract highly qualified employees. Accordingly, we use a mix of competitive base salary, cash-based annual incentive compensation, performance-based equity compensation awards and other employee benefits.

## Facilities

Our principal office is located at 180 Third Avenue, 4th Floor, Waltham, Massachusetts 02451, where we occupy approximately 39,500 square feet of office space under a lease that currently expires in 2032. We believe that our facilities are sufficient to meet our current needs and that suitable additional space will be available as and when needed.

## Legal proceedings

We are not subject to any material legal proceedings. From time to time, we may be subject to various legal proceedings and claims that arise in the ordinary course of our business activities. Regardless of the outcome, litigation can have a material adverse effect on us because of defense and settlement costs, diversion of management resources, and other factors.

# Management

## Executive officers and directors

The following table sets forth the name, age and position of each of our executive officers and directors as of March 31, 2026.

| Name | Age | Position |
|---|---|---|
| ***Executive Officers*** | | |
| Ronald C. Renaud, Jr. | 57 | President, Chief Executive Officer and Director |
| Scott Akamine | 42 | Chief Legal Officer and Secretary |
| Paul Burgess | 52 | Chief Operating Officer and Chief Business Officer |
| Paula Cloghessy | 55 | Chief People Officer |
| Jamie Coleman | 49 | Chief Commercial Officer |
| Douglas Pagán | 54 | Chief Financial Officer |
| Scott Wasserman, M.D. | 56 | Chief Medical Officer |
| ***Non-Employee Directors*** | | |
| John F. Milligan, Ph.D. | 65 | Chairman |
| Frank Clyburn, Jr. | 61 | Director |
| Michael Gladstone(1) | 39 | Director |
| Christopher Hite | 59 | Director |
| Andrew Kaplan | 41 | Director |
| Adam Koppel, M.D., Ph.D. | 56 | Director |
| Yuting (Shelley) Liu, Ph.D. | 37 | Director |
| Martin Mackay, Ph.D. | 69 | Director |
| Amir Zamani, M.D.(2) | 43 | Director |

(1) Mr. Gladstone resigned from our board of directors immediately prior to the effectiveness of the registration statement of which this prospectus forms a part.
(2) Dr. Zamani resigned from our board of directors immediately prior to the effectiveness of the registration statement of which this prospectus forms a part.

## Executive officers

*Ronald C. Renaud, Jr.* has served as our President and Chief Executive Officer and a member of the board of directors since September 2024. Previously, from June 2023 to August 2024, Mr. Renaud served as president and chief executive officer and a member of the board of directors of Cerevel Therapeutics Holdings, Inc., or Cerevel (Nasdaq: CERE), a clinical-stage biopharmaceutical company, until the close of its acquisition by AbbVie Inc. From September 2022 to May 2023, Mr. Renaud was a partner at Bain Capital Life Sciences, a life sciences investment firm. Prior to Bain Capital, Mr. Renaud served as chair and chief executive officer of Translate Bio, Inc., a clinical-stage mRNA therapeutics company, from 2014 until the close of its acquisition by Sanofi in September 2021. Mr. Renaud has served as chairman of the board of directors of Upstream Bio, Inc. (Nasdaq:

UPB) and has been a member of the board of directors since November 2021. Mr. Renaud previously served on the boards of Atara Biotherapeutics, Inc. (Nasdaq: ATRA) from April 2020 until December 2022, Ikena Oncology, Inc. from March 2018 until December 2022, Chimerix, Inc. from December 2014 until June 2020, and Akebia Therapeutics, Inc. (Nasdaq: AKBA) from September 2014 until December 2018. Mr. Renaud holds a B.A. from St. Anselm College and an M.B.A. from the Marshall School of Business at the University of Southern California. We believe Mr. Renaud is qualified to serve on our board of directors because of his leadership and management experience and his extensive knowledge of the biopharmaceutical industry.

*Scott Akamine, J.D.* has served as our Chief Legal Officer and Secretary since December 2024. From May 2021 to August 2024, Mr. Akamine served as chief legal officer of Cerevel, until the close of its acquisition by AbbVie. Previously, he served as general counsel and corporate secretary of AEON Biopharma, Inc. (NYSE: AEON), a biopharmaceutical company, from August 2019 to May 2021. Prior to AEON, Mr. Akamine was the associate general counsel and interim general counsel at CoreLogic, Inc. (NYSE: CLGX), a global property information, analytics, and data-enabled services company now known as Cotality, and general counsel and corporate secretary at Incipio, LLC, a technology accessories company which was acquired by Armor Acquisition LLC. He also held legal roles of increasing responsibility at Allergan, Inc., a pharmaceutical company, until the company was acquired by Actavis plc. Mr. Akamine began his legal career as a corporate attorney at Latham & Watkins LLP. Mr. Akamine holds a B.A. from Chapman University and a J.D. from Pepperdine University School of Law.

*Paul Burgess, J.D., M.S.* has served as our Chief Operating Officer and Chief Business Officer since September 2024. From June 2023 to August 2024, Mr. Burgess served as chief business development and strategic operations officer of Cerevel. Prior to joining Cerevel, Mr. Burgess was the chief operating officer and chief legal officer of Translate Bio, Inc., a clinical-stage mRNA therapeutics company acquired by Sanofi, from December 2019 to October 2021, when the company was sold to Sanofi, and the chief legal officer from March 2015 to December 2019. At Translate Bio, he led business development, legal, program management, quality, technical operations and partner collaborations. Prior to Translate Bio, Mr. Burgess worked in a legal role at a number of companies including Scholar Rock Holding Corporation (Nasdaq: SRRK), a clinical-stage biopharmaceutical company, Civitas Therapeutics, a biopharmaceutical company acquired by Acorda Therapeutics, Inc., BIND Therapeutics, Inc., a clinical-stage nanomedicine platform company whose assets were acquired by Pfizer Inc., and TransForm Pharmaceuticals, a pharmaceutical company acquired by Johnson & Johnson. Mr. Burgess also previously worked in the lab at Genetics Institute. Mr. Burgess holds a B.S. from Merrimack College and an M.S. in pharmacology from Northeastern University. He also holds a J.D. from Northeastern University School of Law.

*Paula Cloghessy* has served as our Chief People Officer since June 2024. Prior to joining Kailera, Ms. Cloghessy served as executive vice president and chief people officer of Seres Therapeutics, Inc. (Nasdaq: MCRB), a clinical-stage biotechnology company, from February 2022 to December 2023. Previously, Ms. Cloghessy served in roles of increasing seniority at Translate Bio, Inc., a biotechnology company acquired by Sanofi, most recently as chief people officer from June 2018 to December 2021, and previously as senior vice president, human resources from January 2017 to June 2018 and as vice president, human resources from July 2016 until December 2016. In these roles, Ms. Cloghessy was responsible for leading human resources and organizational development and performance. Prior to Translate Bio, Ms. Cloghessy held senior roles at Joule Unlimited Technologies, Inc., an alternative energy company, and Interleukin Genetics, Inc. Ms. Cloghessy holds a B.A. in psychology from University of Massachusetts, Boston.

*Jamie Coleman* has served as our Chief Commercial Officer since January 2025. Prior to joining Kailera, Ms. Coleman held roles of increasing responsibility at Eli Lilly and Company (NYSE: LLY), a global pharmaceutical company, including most recently as vice president marketing, U.S. brand leader—Zepbound, from May 2022 to January 2025, and as associate vice president, U.S. brand leader —Trulicity®, from September 2020 to May 2022. At Eli Lilly, she was responsible for brand strategy, consumer marketing, and global

commercial leadership across therapeutic areas. Additionally, she directed U.S. consumer marketing strategies for oncology treatments at Eli Lilly, and held roles at Pfizer Inc. (NYSE: PFE), a global pharmaceutical company, and ZS Associates, management consulting and technology firm, earlier in her career. Jamie holds a B.B.A. in marketing, international business and spanish from the University of Wisconsin and an M.B.A. from the University of Chicago Booth School of Business.

*Douglas Pagán* has served as our Chief Financial Officer since December 2025. Prior to joining Kailera, he served as chief financial officer and chief operating officer of Atalanta Therapeutics, a clinical-stage biotechnology company, from May 2025 to December 2025, and has served on its board of directors since January 2026. Before Atalanta, he served as chief financial officer and chief operating officer of Jnana Therapeutics, a clinical-stage biotechnology company, from April 2022 to November 2024, following its acquisition by Otsuka Pharmaceutical. Prior to Jnana, Mr. Pagán was the chief financial officer of Dicerna Pharmaceuticals, Inc., a biopharmaceutical company, from May 2020 to March 2022, following its acquisition by Novo Nordisk. Prior to Dicerna, Mr. Pagán held roles as the chief financial officer and secretary of KSQ Therapeutics, Inc., a clinical-stage biotechnology company, the chief financial officer of Paratek Pharmaceuticals, Inc. and the vice president of finance at Acceleron Pharma, Inc, a clinical-stage biopharmaceutical company later acquired by Merck. Prior to that, Mr. Pagán served in strategic and financial management roles at Biogen Idec and Bristol-Myers Squibb and worked in healthcare investment banking at J.P. Morgan, as well as in pharmaceutical operational roles at Johnson & Johnson. Mr. Pagán served on the board of directors of Ziopharm Oncology, Inc. from September 2018 to September 2020 and of Timberlyne Therapeutics Inc. from January 2025 to November 2025. Mr. Pagán holds an M.B.A. in finance & accounting from Columbia Business School and a B.S.E. in chemical engineering from Princeton University.

*Scott Wasserman, M.D.* has served as our Chief Medical Officer since October 2024. Prior to joining Kailera, Dr. Wasserman served as venture partner at Frazier Life Sciences, an investment firm focused on innovative therapeutics, from October 2023 to October 2024. Previously, Dr. Wasserman was the chief executive officer and co-founder of Latigo Biotherapeutics, Inc., a venture-backed biotechnology company, from May 2019 to June 2023. Over 14 years, Dr. Wasserman served in roles of increasing responsibility at Amgen Inc. (Nasdaq: AMGN), a multinational biopharmaceutical company, including most recently as vice president, global development therapeutic area head for bone, cardiovascular, metabolic, and neuroscience from November 2018 to May 2019. Dr. Wasserman was previously a faculty member at Stanford University in the Division of Cardiovascular Medicine where he conducted research on endothelial gene expression, and also served as a non-interventional cardiologist at the Veterans Administration Hospital in Palo Alto, CA. Dr. Wasserman holds a B.S. from Haverford College, where he graduated magna cum laude, and an M.D. from Harvard Medical School, where he graduated magna cum laude. He completed his postgraduate training in internal medicine and cardiovascular medicine at Stanford University and post-doctoral cardiovascular research at COR Therapeutics, Millennium Pharmaceuticals, and Stanford.

## Non-employee directors

*John F. Milligan, Ph.D.* has served as a member of our board of directors since September 2024. Dr. Milligan previously served as the president and chief executive officer of Gilead Sciences, Inc. (NYSE: GILD), a biopharmaceutical company, from May 2008 and March 2016, respectively, until March 2019, and spent over 29 years at Gilead in various roles since 1990. Prior to joining Gilead, Dr. Milligan was a postdoctoral research fellow at the University of California San Francisco Medical Center. Dr. Milligan has served as executive chair of the board of directors of 4D Molecular Therapeutics, Inc. (Nasdaq: FDMT) since August 2020 and as a director of PacBio, Inc. (Nasdaq: PACB) since July 2014 and chair of the board since September 2020. Dr. Milligan has served as a director at TurnCare, Inc. since January 2024. Dr. Milligan holds a B.A. in chemistry from Ohio Wesleyan University and a Ph.D. from the University of Illinois at Urbana-Champaign. We believe Dr. Milligan is

qualified to serve as a member of our board of directors based on his extensive experience and leadership roles in the biopharmaceutical industry.

*Frank Clyburn, Jr.* has served as a member of our board of directors since October 2025. Mr. Clyburn previously served as executive director and chief executive officer of International Flavors & Fragrances Inc. (NYSE: IFF), a company that creates and manufactures flavor and fragrance products, from February 2022 to February 2024. Prior to International Flavor & Fragrances, Mr. Clyburn served as executive vice president and president, human health at Merck & Co., Inc., (NYSE: MRK), a multinational pharmaceutical company, from March 2021 to January 2022. Mr. Clyburn held a variety of other leadership positions with Merck from 2008 to 2021, including leading the company's oncology and market access business. Prior to Merck, Mr. Clyburn was vice president, oncology and internal medicine of Sanofi Aventis, now known as Sanofi (Nasdaq: SNY), from 2004 to 2008, holding various positions of increasing responsibility for Sanofi Aventis and its predecessors since 1994. Mr. Clyburn has served as a member of the board of directors of Revolution Medicines, Inc. (Nasdaq: RVMD) since August 2024 and Cencora, Inc. (NYSE: COR) since October 2024, and previously served as a member of the board of directors of DuPont de Nemours, Inc. (NYSE: DD) from 2019 to 2022. Mr. Clyburn holds a B.A. from Franklin & Marshall College and an M.B.A. from Arizona State University. We believe that Mr. Clyburn's extensive expertise in the healthcare and pharmaceutical industries and leadership experience qualifies him to serve on our board of directors.

*Michael Gladstone* has served as a member of our board of directors since May 2024. Mr. Gladstone has served as a partner at Atlas Venture, a biotechnology venture capital firm, since June 2020, and he previously served as principal from May 2015 to June 2020. Prior to joining Atlas Venture in 2012, Mr. Gladstone worked at L.E.K. Consulting, a global strategy consulting firm, from December 2009 to March 2012, and previously, he conducted HIV vaccine research in the Viral Pathogenesis department of Beth Israel Deaconess Medical Center. Mr. Gladstone has served as member of the board of directors of Diagonal Therapeutics, Inc. since 2022 and Pheon Therapeutics Inc. since 2022. Mr. Gladstone was previously a board director for Third Harmonic Bio, Inc. (Nasdaq: THRD) from 2019 to August 2025, Day One Biopharmaceuticals, Inc. (Nasdaq: DAWN) from 2019 to June 2025, Versanis Bio Inc. (acquired by Eli Lilly and Company) from 2021 to August 2024, as well as Aiolos Bio, Inc. (acquired by GSK plc) from 2023 to February 2024. Mr. Gladstone holds a B.S. in biochemical sciences from Harvard University. Mr. Gladstone resigned from our board of directors immediately prior to the effectiveness of the registration statement of which this prospectus forms a part.

*Christopher Hite, J.D.* has served as a member of our board of directors since May 2025. Mr. Hite has served as chairman, partnering and investments of Royalty Pharma PLC (Nasdaq: RPRX), the largest buyer of biopharmaceutical royalties, since March 2026, and he previously served as executive vice president and vice chairman from March 2020 to March 2026. Prior to Royalty Pharma, Mr. Hite served as vice chairman and global head of healthcare at Citibank, N.A., the banking arm of Citigroup Inc. (NYSE: C), where he worked from 2008 to 2020, and global head of healthcare investment banking at Lehman Brothers, Inc. prior to joining Citigroup. Mr. Hite has served as a member of the board of directors of Vera Therapeutics, Inc. (Nasdaq: VERA) since March 2026. Mr. Hite previously served as the audit chairman on the board of directors of Acceleron Pharma Inc. until its acquisition by Merck & Co., Inc. in 2021. Mr. Hite is a member of the Board of Trustees of Lehigh University and sits on the advisory board of FasterCures, a center of the Milken Institute. Mr. Hite holds a B.S. from Lehigh University and a J.D./M.B.A. from the University of Pittsburgh. We believe that Mr. Hite's extensive financial and leadership experience qualifies him to serve on our board of directors.

*Andrew Kaplan* has served as a member of our board of directors since October 2025. Mr. Kaplan joined Bain Capital Private Equity, LP in 2009. He is a partner in the Healthcare vertical and a member of the North America Private Equity team. Prior to joining Bain Capital Private Equity, Mr. Kaplan was an investment banker with The Goldman Sachs Group, Inc. (NYSE: GS), a multinational investment bank and financial services company. He also

co-founded EngagedHealth, LLC, a post-hospitalization service for chronically ill, low-income patients aiming to improve outcomes, reduce readmissions, and save costs. Mr. Kaplan serves as a member of the board of directors of Beeline Medicines Corporation, PCI Pharma Services, QuVa Pharma, Inc., US Renal Care, Inc. and Surgery Partners (Nasdaq: SGRY). He previously served as a member of the board of directors of Beacon Health Options, now known as Carelon Behavioral Health, and InnovaCare Health. Mr. Kaplan holds a B.S. in economics from The Wharton School at the University of Pennsylvania and an M.B.A from Harvard Business School. We believe that Mr. Kaplan's experience in co-founding a healthcare company and his financial expertise qualifies him to serve on our board of directors.

*Adam Koppel, M.D., Ph.D.* has served as a member of our board of directors since April 2025. Dr. Koppel is a partner of Bain Capital Life Sciences, LP. He initially joined Bain Capital Public Equity, LP in 2003, where he was a leader within the healthcare sector until 2014. From 2014 to 2016, Dr. Koppel was executive vice president of corporate development and chief strategy officer at Biogen, Inc. (Nasdaq: BIIB). Prior to joining Bain Capital Public Equity in 2003, Dr. Koppel was an associate principal at McKinsey & Company in New Jersey where he served a variety of healthcare companies. Dr. Koppel currently serves as a member of the boards of directors of Areteia Therapeutics, Inc., Beeline Medicines Corporation, and Cardurion Pharmaceuticals, Inc., and previously served on the boards of directors of Foghorn Therapeutics, Inc. (Nasdaq: FHTX) from July 2017 to December 2024, Solid Biosciences, Inc. (Nasdaq: SLDB) from March 2017 to June 2022 and again from December 2022 to June 2024, Cerevel from September 2018 to August 2024, Aptinyx Inc. (Nasdaq: APTX) from December 2017 to May 2023, BCLS Acquisition Corp. from August 2020 to November 2022, Trevena, Inc., Dicerna Pharmaceuticals, Inc. from April 2017 to December 2021 and ViaCyte, Inc. Dr. Koppel graduated magna cum laude from Harvard University and holds an A.B. and A.M. in history and science. He holds an M.D. and Ph.D. in neuroscience from the University of Pennsylvania School of Medicine and an M.B.A. from The Wharton School at the University of Pennsylvania, where he was a Palmer Scholar. We believe that Dr. Koppel's background as an executive officer, director and equity investor in pharmaceutical companies, as well as his scientific and medical background, qualifies him to serve on our board of directors.

*Yuting (Shelley) Liu, Ph.D*. has served as a member of our board of directors since February 2026. Dr. Liu has served as the head of China business development and strategy of Jiangsu Hengrui Pharmaceuticals Co., Ltd., or Hengrui, since April 2025. Prior to Hengrui, Dr. Liu served as a partner for Boston Consulting Group, a global consulting firm, where she worked from June 2016 to April 2025, focusing on the biopharmaceutical sector. Dr. Liu holds a Ph.D. in chemical biology from Yale University and dual B.Sc. from Peking University in chemistry and molecular biology & biochemistry. We believe that Dr. Liu's extensive experience in the biopharmaceutical and healthcare industries qualifies her to serve on our board of directors.

*Martin Mackay, Ph.D*. has served as a member of our board of directors since March 2026. Dr. Mackay is a co-founder of Rallybio Corporation, or Rallybio (Nasdaq: RLYB), a clinical-stage biotechnology company, and currently serves as the chairman of its board of directors. From August 2023 to December 2024, Dr. Mackay served as executive chairman of Rallybio, and from January 2018 to August 2023, he served as chief executive officer and chairman of the board of directors of Rallybio. From March 2013 to December 2017, Dr. Mackay served as executive vice president and global head of research & development at Alexion Pharmaceuticals, Inc., a biopharmaceutical company acquired by AstraZeneca. From July 2010 to January 2013, Dr. Mackay served as president of research & development at AstraZeneca PLC (NYSE: AZN), a global biopharmaceutical company, where he led the research and development organization worldwide. Prior to AstraZeneca, Dr. Mackay worked at Pfizer, Inc. (NYSE: PFE), a global pharmaceutical company, for 15 years where he held positions of increasing responsibility, including president, head of pharmatherapeutics research and development, and senior vice president of worldwide development. Earlier in his career, Dr. Mackay held various positions at Ciba-Geigy (now Novartis) in the United Kingdom and Switzerland from 1986 to 1995. Dr. Mackay has served as a member of the board of directors of Charles River Laboratories International, Inc. (NYSE: CRL) since July 2017, Sail

Biomedicines since October 2025 and Beeline Medicines Corporation since April 2026. He previously served as a member of the board of directors of Novo Nordisk A/S (NYSE: NVO) from March 2018 to November 2025, SpringWorks Therapeutics, Inc. (Nasdaq: SWTX) from June 2024 to August 2025 and 5AM Acquisition Co. from October 2020 to April 2022. Dr. Mackay holds a BSc with First-Class Honours in microbiology from Heriot-Watt University and a Ph.D. in molecular genetics from the University of Edinburgh. We believe that Dr. Mackay's extensive experience in the biopharmaceutical and industry and leadership experience qualifies him to serve on our board of directors.

*Amir Zamani, M.D.* has served as a member of our board of directors since May 2024. Dr. Zamani joined Bain Capital Life Sciences, LP in April 2018. He is a partner and leads investments in biopharmaceutical, medical device, and diagnostics companies. Prior to joining Bain Capital, Dr. Zamani was a partner at McKinsey & Company, where he was a leader in the Biopharmaceutical and Medical Products Practice. Previously, he was a resident physician in Plastic and Reconstructive Surgery at the University of Pennsylvania. He currently serves as a board observer at Rivus Pharmaceuticals, Inc., a clinical-stage biopharmaceutical company. He previously served as a board member at Aiolos Bio, Inc. and ViaCyte, Inc., and as a board observer at Alkeus Pharmaceuticals, Inc. and Amylyx Pharmaceuticals, Inc. (Nasdaq: AMLX). Dr. Zamani holds an M.D. from The Johns Hopkins University School of Medicine, where he graduated Alpha Omega Alpha, and a B.A. in economics and a B.S. in biological sciences from Stanford University, where he graduated Phi Beta Kappa. Dr. Zamani resigned from our board of directors immediately prior to the effectiveness of the registration statement of which this prospectus forms a part.

## Board composition and election of directors

***Director independence***

Under the applicable listing rules of The Nasdaq Stock Market, or the Nasdaq rules, independent directors must comprise a majority of a listed company's board of directors within one year of the completion of its initial public offering. In addition, the Nasdaq rules require that, subject to specified exceptions, each member of a listed company's audit and compensation committees be independent and that director nominees be selected or recommended for the board's selection by independent directors constituting a majority of the independent directors or by a nominating and corporate governance committee comprised solely of independent directors. Under the Nasdaq rules, a director will only qualify as "independent" 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 and that such person is "independent" as defined under the Nasdaq rules and the rules under the Exchange Act.

Audit committee members must also satisfy the independence criteria set forth in Rule 10A-3 under the 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.

Our board of directors currently consists of ten members. Upon completion of this offering, our board of directors will consist of eight members. Based upon information requested from and provided by each director concerning his or her background, employment and affiliations, including family relationships, our board of directors has determined that all of our directors, other than our chief executive officer, Ronald C. Renaud, Jr., do not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is "independent" as that term is defined under the Nasdaq rules. including, in the case of all the members of our audit committee, the independence criteria set forth in Rule 10A-3 under the Exchange Act, and in the case of all the members of our compensation and talent

committee, the independence criteria set forth in Rule 10C-1 under the Exchange Act and are “non-employee directors” as defined in Section 16b-3 of the Exchange Act. In making these determinations, our board of directors considered the current and prior relationships that each non-employee director has with our company and all other facts and circumstances our board of directors deemed relevant in determining their independence, including the beneficial ownership of our shares by each non-employee director and the transactions described in the section titled “Certain relationships and related person transactions.”

There are no family relationships among any of our directors or executive officers.

***Classified board of directors***

In accordance with our amended and restated certificate of incorporation that will go into effect upon the closing of this offering, our board of directors will be divided into three classes with staggered, three-year terms. At each annual meeting of stockholders, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following election. Effective upon the closing of this offering, our directors will be divided among the three classes as follows:

- the Class I directors will be Mr. Hite, Dr. Koppel and Mr. Renaud, and their terms will expire at our first annual meeting of stockholders following this offering;
- the Class II directors will be Mr. Clyburn, Mr. Kaplan and Dr. Mackay, and their terms will expire at our second annual meeting of stockholders following this offering; and
- the Class III directors will be Dr. Liu and Dr. Milligan, and their terms will expire at the third annual meeting of stockholders following this offering.

Our amended and restated certificate of incorporation that will go into effect immediately after the closing of this offering will provide that the authorized number of directors may be changed only by resolution of the board of directors. Any additional directorships resulting from an increase 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. The division of our board of directors into three classes with staggered three-year terms may delay or prevent a change of our management or a change in control of our company. Our directors may be removed only for cause by the affirmative vote of the holders of at least two-thirds of our outstanding voting stock entitled to vote in the election of directors.

Our directors were elected to and currently serve on the board pursuant to an amended and restated voting agreement among us and several of our largest stockholders. See “Certain Relationships and Related Party Transactions—Amended and Restated Voting Agreement.” This agreement will terminate upon the closing of this offering, after which there will be no further contractual obligations regarding the election of our directors.

## Board leadership structure

Our board of directors is currently chaired by Dr. Milligan. Our corporate governance guidelines provide that, if the chair of the board is a member of management or does not otherwise qualify as independent, the independent directors of the board may elect a lead director. The lead director’s responsibilities include, but are not limited to: presiding over all meetings of the board of directors at which the chair is not present, including any executive sessions of the independent directors; approving board meeting schedules and agendas; and acting as the liaison between the independent directors and the chief executive officer and chair of the board. Our corporate governance guidelines further provide the flexibility for our board of directors to modify our leadership structure in the future as it deems appropriate.

## Role of the board in risk oversight

One of the key functions of our board of directors is informed oversight of our risk management process. 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. In particular, our board of directors is responsible for monitoring and assessing strategic risk exposure and our audit committee has the responsibility to consider and discuss our major financial risk and information technology risk exposures and the steps our management has taken to monitor and control these exposures, including guidelines and policies to govern the process by which risk assessment and management is undertaken. Our audit committee also monitors compliance with legal and regulatory requirements. Our nominating and corporate governance committee monitors the effectiveness of our corporate governance practices, including whether they are successful in preventing illegal or improper liability-creating conduct. Our compensation and talent committee assesses and monitors whether any of our compensation policies and programs has the potential to encourage excessive risk-taking. While each committee is responsible for evaluating certain risks and overseeing the management of such risks, our entire board of directors is regularly informed through committee reports about such risks.

## Board committees

Our board of directors has established three standing committees—audit, compensation and talent and nominating and corporate governance—each of which operates under a charter that has been approved by our board of directors. Upon our listing on the Nasdaq Global Select Market, each committee's charter will be available under the Corporate Governance section of our website at *www.kailera.com*. The reference to our website address does not constitute incorporation by reference of the information contained at or available through our website, and you should not consider it to be a part of this prospectus.

### *Audit committee*

The audit committee's responsibilities include, among other things:

- appointing, approving the compensation of, and assessing the independence of our registered public accounting firm;
- overseeing the work of our registered public accounting firm, including through the receipt and consideration of reports from such firm;
- reviewing and discussing with management and the registered public accounting firm our annual and quarterly financial statements and related disclosures;
- coordinating our board of directors' oversight of our internal control over financial reporting, and disclosure controls and procedures;
- discussing our risk assessment, risk management and cybersecurity policies;
- meeting independently with our internal auditing staff, if any, registered public accounting firm and management;
- establishing procedures for the receipt, retention and treatment of complaints;
- reviewing our corporate approval authority policy and financial approval matrix;
- reviewing and approving or ratifying any related person transactions; and

- preparing the audit committee report required by Securities Exchange Commission, or SEC, rules.

The members of our audit committee are Mr. Hite, Mr. Clyburn and Dr. Milligan. Mr. Hite serves as the chairperson of the committee. All members of our audit committee meet the requirements for financial literacy under the applicable Nasdaq rules. Our board of directors has determined that all of the audit committee members meet the independence requirements of Rule 10A-3 under the Exchange Act and the applicable Nasdaq rules. Our board of directors has determined that each of the audit committee members qualifies as an "audit committee financial expert" as defined by applicable SEC rules and has the requisite financial sophistication as defined under the applicable Nasdaq rules.

***Compensation and talent committee***

The compensation and talent committee's responsibilities include:

- reviewing and approving, or recommending for approval by the board of directors, the compensation of our Chief Executive Officer and our other executive officers;
- administering and overseeing our cash and equity incentive plans;
- reviewing and making recommendations to our board of directors with respect to director compensation;
- reviewing and discussing annually with management our "Compensation Discussion and Analysis," to the extent required;
- administering and overseeing our compliance with the compensation recovery policy required by applicable SEC and Nasdaq rules;
- overseeing our succession planning for the Chief Executive Officer and other executive officer roles;
- overseeing the evaluation of our executive officers and periodically reviewing with management our policies and practices with respect to talent management and development; and
- preparing the annual compensation and talent committee report required by SEC rules, to the extent required.

The members of our compensation and talent committee are Mr. Clyburn, Mr. Kaplan and Dr. Koppel. Mr. Clyburn serves as the chairperson of the committee. Our board of directors has determined that all of the compensation and talent committee members are independent under the applicable Nasdaq rules, including the Nasdaq rules specific to membership on the compensation and talent committee, and are currently a "non-employee director" as defined in Rule 16b-3 promulgated under the Exchange Act.

***Nominating and corporate governance committee***

The nominating and corporate governance committee's responsibilities include, among other things:

- identifying individuals qualified to become board members;
- recommending to our board of directors the persons to be nominated for election as directors and to each board committee;
- periodically reviewing the committee structure and leadership structure of our board of directors and recommending to our board of directors any proposed changes;

- developing and recommending to our board of directors corporate governance guidelines, and reviewing and recommending to our board of directors proposed changes to our corporate governance guidelines from time to time;
- coordinating our board of directors' oversight of our code of business conduct and ethics; and
- overseeing a periodic evaluation of our board of directors.

The members of our nominating and corporate governance committee are Mr. Kaplan, Mr. Hite, and Dr. Mackay. Mr. Kaplan serves as the chairperson of the committee. Our board of directors has determined that all of the nomination and corporate governance committee members are independent under the applicable Nasdaq rules and the SEC rules and regulations.

***Compensation committee interlocks and insider participation***

No member of our compensation and talent committee is or has been our current or former officer or employee. None of our executive officers served as a director or a member of a compensation and talent committee (or other committee serving an equivalent function) of any other entity.

## Code of ethics and code of conduct

We have adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. Upon our listing on the Nasdaq Global Select Market, our code of business conduct and ethics will be available under the Corporate Governance section of our website at *www.kailera.com*. In addition, we intend to post on our website all disclosures that are required by law or the Nasdaq rules concerning any amendments to, or waivers from, any provision of the code. The reference to our website address does not constitute incorporation by reference of the information contained at or available through our website, and you should not consider it to be a part of this prospectus.

# Executive and director compensation

This section discusses the material components of the executive compensation program for our executive officers who are named in the "2025 summary compensation table" below. In 2025, our "named executive officers" and their positions were as follows:

- Ronald C. Renaud, Jr., our President and Chief Executive Officer;
- Paul Burgess, our Chief Operating Officer and Chief Business Officer;
- Jamie Coleman, our Chief Commercial Officer; and
- Laurie Stelzer, our former Chief Financial Officer.

This discussion may contain forward-looking statements that are based on our current plans, considerations, expectations and determinations regarding future compensation programs. Actual compensation programs that we adopt following the completion of this offering may differ materially from the currently planned programs summarized in this discussion.

## 2025 summary compensation table

The following table sets forth information concerning the compensation of our named executive officers for the year ended December 31, 2025.

| Name and principal position | Salary($) | Bonus($) (1) | Option awards($) (2) | Non-Equity incentive plan compensation($) | All other compensation($) (3) | Total |
|---|---|---|---|---|---|---|
| Ron Renaud<br>President and Chief Executive Officer | 558,104 | — | 9,185,435 | 305,767 | — | 10,049,306 |
| Paul Burgess<br>Chief Operating Officer and Chief Business Officer | 466,472 | — | 1,697,663 | 185,868 | 17,850 | 2,367,853 |
| Jamie Coleman<br>Chief Commercial Officer | 420,599 | 310,880 | 2,757,860 | 167,178 | 12,626 | 3,669,143 |
| Laurie Stelzer<br>Former Chief Financial Officer | 350,308 | 200,000 | 2,087,267 | — | 255,758 | 2,893,333 |

(1) Amounts shown represent one-time signing bonuses paid in connection with the named executive officer's commencement of employment in 2025.

(2) Amounts reflect the full grant-date fair value of stock options granted during 2025 computed in accordance with ASC Topic 718, rather than the amounts paid to or realized by the named executive officer. The assumptions used in calculating the grant date fair value of the options reported in this column are set forth in Note 11 to the financial statements included in this prospectus. For Ms. Stelzer, the amount shown also reflects the incremental fair value, computed as of the modification date in accordance with FASB ASC Topic 718, of options that were modified in 2025 in connection with her termination of employment to provide for accelerated vesting and to extend the post-termination exercise period. See "—Separation agreement with Ms. Stelzer" below for more information.

(3) Amounts shown for Mr. Burgess and Ms. Coleman represent matching contributions under our 401(k) plan. Amount shown for Ms. Stelzer represents matching contributions under our 401(k) plan ($8,979) and severance payments and benefits paid during 2025 in connection with her termination of employment consisting of (i) continued base salary payments ($102,616), (ii) a pro-rated portion of her 2025 annual bonus ($139,636), and (iii) COBRA premiums paid on her behalf ($4,527). See "—Separation agreement with Ms. Stelzer" below for more information.

## Narrative to summary compensation table

***2025 salaries***

The named executive officers receive a base salary to compensate them for services rendered to our company. The base salary payable to each named executive officer is intended to provide a fixed component of compensation reflecting the executive's skill set, experience, role and responsibilities.

Our board of directors and compensation and talent committee may adjust base salaries from time to time in their discretion. For 2025, the base salary for each named executive officer was $550,000 for Mr. Renaud, $460,000 for Mr. Burgess, $450,000 for Ms. Coleman and $460,000 for Ms. Stelzer.

Base salaries of certain of our current named executive officers were adjusted contingent on the effectiveness of the registration statement of which this prospectus forms a part. See "Recent changes in executive compensation—Annual base salaries" below for additional information.

***2025 bonuses***

We offer our named executive officers the opportunity to earn cash bonuses to compensate them for attaining short-term company goals as approved by our board of directors. For 2025, bonuses were based upon the compensation and talent committee's determination of our achievement of certain clinical, regulatory, technical and other corporate objectives. The 2025 target bonus (expressed as a percentage of annual base salary) was 55% for Mr. Renaud and 40% for each of our other named executive officers. The actual annual cash bonuses awarded to each named executive officer for 2025 performance are set forth above in the 2025 Summary Compensation Table in the column titled "Non-Equity Incentive Plan Compensation."

The bonus target for Mr. Renaud was adjusted contingent on the effectiveness of the registration statement of which this prospectus forms a part. See "Recent changes in executive compensation—Target bonuses" below for additional information.

***Equity compensation***

We offer stock options to our employees, including our named executive officers, as the long-term incentive component of our compensation program. Our stock options generally allow employees to purchase shares of our common stock at a price equal to the fair market value of our common stock on the date of grant, as determined by the board of directors or a delegee thereof. Our stock options typically vest over four years, with certain grants to Mr. Renaud vesting over three years as to 33.33% of the underlying shares on the first anniversary of the vesting commencement date and in equal monthly installments over the following two years and with other grants to executive officers vesting as to 25% of the underlying shares on the first anniversary of the vesting commencement date and in equal monthly installments over the following three years, in each case, subject to the holder's continued employment with us. In addition to the time-based options granted to Mr. Renaud, in connection with his commencement of employment in 2024, our board of directors granted him a performance-based stock option that was eligible to vest as to 100% if the FDA authorized the Company's commencement of its Phase 3 trial for ribupatide on or prior to December 31, 2025, 66.66% if such authorization occurred after December 31, 2025 but on or before March 31, 2026 and 0% if such authorization occurred after March 31, 2026. This option vested in full in September 2025. Certain of the stock options we grant to employees are intended to qualify as "incentive stock options" to the extent permitted under the U.S. Internal Revenue Code of 1986, as amended.

The following table sets forth the stock options granted to our named executive officers in the 2025 fiscal year.

| Named executive officer | 2025 stock options granted |
|---|---|
| Ron Renaud | 1,773,089 |
| Paul Burgess | 325,491 |
| Jamie Coleman | 625,897 |

See “Outstanding equity awards at fiscal year-end” table and “Separation agreement with Ms. Stelzer” below for a discussion of the treatment of Ms. Stelzer’s option awards in connection with her termination of employment.

In connection with this offering, we adopted the 2026 Incentive Award Plan, referred to below as the 2026 Plan, in order to facilitate the grant of cash and equity incentives to directors, employees (including our named executive officers) and consultants of our company and certain of its affiliates and to enable our company and certain of its affiliates to obtain and retain services of these individuals, which is essential to our long-term success. The 2026 Plan will be effective on the effective date of the registration statement of which this prospectus forms a part. For additional information about the 2026 Plan, please see the section titled “Equity incentive plan” below.

Additionally, see “Recent changes in executive compensation—Equity awards to named executive officers” below for a description of the option awards granted to our named executive officers contingent on the effectiveness of the registration statement of which this prospectus forms a part.

***Other elements of compensation***

*Retirement plans*

We currently maintain a 401(k) retirement savings plan for our employees, including our named executive officers, who satisfy certain eligibility requirements. Our current named executive officers are eligible to participate in the 401(k) plan on the same terms as other full-time employees. The Code allows eligible employees to defer a portion of their compensation, within prescribed limits, on a pre-tax basis through contributions to the 401(k) plan. Currently, we match contributions made by participants in the 401(k) plan up to a specified percentage of the employee contributions, and these matching contributions are fully vested as of the date on which the contribution is made. We believe that providing a vehicle for tax-deferred retirement savings though our 401(k) plan, and making fully vested matching contributions, adds to the overall desirability of our executive compensation package and further incentivizes our employees, including our named executive officers, in accordance with our compensation policies.

*Employee benefits and perquisites*

*Health/Welfare Plans.* All of our full-time employees, including our named executive officers, are eligible to participate in our health and welfare plans, including:

- medical, dental and vision benefits;
- medical and dependent care flexible spending accounts;
- short-term and long-term disability insurance; and
- life insurance.

We believe the benefits described above are necessary and appropriate to provide a competitive compensation package to our named executive officers.

***No tax gross-ups***

We do not make gross-up payments to cover our named executive officers' personal income taxes that may pertain to any of the compensation or perquisites paid or provided by our company.

## Outstanding equity awards at fiscal year-end

The following table summarizes the number of shares of common stock underlying outstanding equity incentive plan awards for each named executive officer as of December 31, 2025.

| Name | Vesting commencement date | Number of securities underlying unexercised options (#) exercisable | Number of securities underlying unexercised options (#) unexercisable (6) | Option exercise price ($) | Option expiration date |
|---|---|---|---|---|---|
| Ron Renaud | 9/9/2024(1) | 356,609 | 499,311 | 5.25 | 9/19/2034 |
| | 9/9/2024(2) | 427,960 | — | 5.25 | 9/19/2034 |
| | 12/9/2024(1) | 191,425 | 382,907 | 5.25 | 12/9/2034 |
| | 12/9/2024(2) | 287,166 | — | 5.25 | 12/9/2034 |
| | 11/5/2025(1) | — | 294,649 | 7.24 | 11/5/2035 |
| | 11/5/2025(3) | 147,324 | — | 7.24 | 11/5/2035 |
| | 11/5/2025(4) | — | 1,331,116 | 7.24 | 11/5/2035 |
| Paul Burgess | 9/16/2024(4) | 89,158 | 196,149 | 5.25 | 9/19/2034 |
| | 12/9/2024(4) | 47,861 | 143,583 | 5.25 | 12/9/2034 |
| | 11/5/2025(4) | — | 325,491 | 7.24 | 11/5/2035 |
| Jamie Coleman | 1/27/2025(4) | — | 357,563 | 5.40 | 2/27/2035 |
| | 11/5/2025(4) | — | 268,334 | 7.24 | 11/5/2035 |
| Laurie Stelzer | 1/8/2025(5) | 119,188 | — | 5.40 | 10/12/2026 |
| | 11/5/2025(3) | 24,554 | — | 7.24 | 10/12/2026 |

(1) The option vests as to 33% of the shares on the first anniversary of the vesting commencement date and as to the remaining shares in 24 substantially equal monthly installments thereafter, subject to the named executive officer's continued employment with us through the applicable vesting dates.

(2) The option was subject to the performance vesting condition described above under "Equity compensation." The performance condition was satisfied in September 2025 and the option vested in full.

(3) The option was fully vested at grant.

(4) The option vests as to 25% of the shares on the first anniversary of the vesting commencement date and as to the remaining shares in 36 substantially equal monthly installments thereafter, subject to the named executive officer's continued employment with us through the applicable vesting dates.

(5) Ms. Stelzer terminated employment with us in October 2025. As part of her separation agreement, 25% of Ms. Stelzer's unvested options were accelerated and the remaining options were forfeited. The number of shares shown represents the accelerated portion of the option. In addition, the post-termination exercise period of her vested options was extended to the first anniversary of her termination date. See "Separation agreement with Ms. Stelzer" below for more information.

(6) For all named executive officers, the options are subject to double trigger vesting acceleration in connection with the named executive officer's termination of employment by us without cause or the named executive officer's resignation for good reason, in either case, following a change in control, or full vesting in the event the option is not assumed, continued or substituted by the acquirer in the change in control. In addition, with respect to the unvested options held by Mr. Renaud, a pro-rated portion of the next monthly vesting tranche is subject to acceleration in connection with his termination without cause or resignation for good reason.

## Executive compensation arrangements

We have entered into an employment agreement with each of our named executive officers in connection with the named executive officer's commencement of employment with us. Each employment agreement establishes an annual base salary, target annual bonus opportunity and eligibility for benefits for the named executive officer and provides for an initial stock option grant.

Under each employment agreement, if we terminated Messrs. Renaud or Burgess or Ms. Coleman without "cause" or if such named executive officer resigned for "good reason" (each as defined in the applicable employment agreement), subject to the named executive officer's execution and nonrevocation of a release of claims and continued compliance with restrictive covenants, the named executive officer would be entitled to receive (i) base salary continuation for a period of twelve months (twenty-four months for Mr. Renaud); (ii) payment for any earned but unpaid annual bonus for the prior fiscal year; (iii) a pro-rated payment for any annual bonus for the fiscal year in which termination occurs (which, for Mr. Renaud, is not less than a pro-rated amount of his target bonus); and (iv) payment for continued health coverage pursuant to COBRA for up to twelve months (eighteen months for Mr. Renaud). In addition, following a termination without "cause" or resignation for "good reason," Mr. Renaud would also be entitled to receive accelerated vesting of a pro-rated portion of the next vesting tranche of his outstanding time-based option awards.

Messrs. Renaud and Burgess and Ms. Coleman are required to provide 30 days notice (60 days for Mr. Renaud) in the event of their resignation without good reason.

Under the separate restrictive covenant agreement with each of Messrs. Renaud and Burgess and Ms. Coleman, each named executive officer has agreed to refrain from competing with us while employed and following termination of employment for a period of one year (subject, in certain instances, to our obligation to pay garden leave or other compensation) and from soliciting our employees or consultants to terminate their relationship with us and from inducing our customers, clients, vendors, suppliers or other business partners to terminate or diminish their relationship with us, in each case, while employed and following a termination of employment for any reason for a period of one year (two years for Mr. Renaud).

Contingent on the effectiveness of the registration statement of which this prospectus forms a part, we entered into amended and restated employment agreements with our current named executive officers. See "Recent changes in executive compensation—Executive employment agreements" below for additional information.

***Separation agreement with Ms. Stelzer***

We entered into a separation agreement with Ms. Stelzer in connection with her termination of employment in October 2025. Pursuant to the separation agreement and subject to her execution of a release of claims and continued compliance with certain restrictive covenants, we agreed to pay Ms. Stelzer the severance benefits set forth in her employment agreement, consisting of continued base salary payments for 12 months, a pro-rated annual bonus for 2025 based on actual performance under the bonus plan for the year, and 12 months of COBRA premium payments. In addition, Ms. Stelzer received accelerated vesting of 25% of her outstanding options as of the termination date, an extension of the post-termination exercise period of her vested options to the first anniversary of her employment termination date and an additional fully vested option grant. Ms. Stelzer was available to provide advisory and transition services for 60 days following her termination date.

## Recent changes in executive compensation

In anticipation of this offering and contingent on the effectiveness of the registration statement of which this prospectus forms a part, our board of directors approved certain changes to our current named executive officers' compensation arrangements to better align their compensation levels with peer group practices. These include adjusting annual base salaries and target bonus opportunities and entering into amended and restated employment agreements, each as described in more detail below.

***Annual base salaries***

Our board of directors approved, contingent on the effectiveness of the registration statement of which this prospectus forms a part, increases to the annual base salaries of certain of our named executive officers, effective upon the closing of this offering, as follows: Mr. Renaud, $675,000; and Mr. Burgess, $515,000.

***Target bonuses***

Our board of directors approved, contingent on the effectiveness of the registration statement of which this prospectus forms a part, an increase to the target bonus amount for Mr. Renaud that will become effective upon the closing of this offering. The new target bonus amount is set at 60% of base salary.

***Executive employment agreements***

We entered into amended and restated employment agreements with each of our current named executive officers that will supersede the named executive officer's prior employment agreement with us contingent on the effectiveness of the registration statement of which this prospectus forms a part.

The amended and restated employment agreements are for indefinite terms and entitle the named executive officers to the annual base salaries and annual target bonus opportunities described above. Each amended and restated employment agreement is substantially the same as the prior employment agreements with us as described above under "Executive compensation arrangements," except if we terminate Messrs. Renaud or Burgess or Ms. Coleman without "cause" or they resign for "good reason" (each as defined below) during the period beginning three months prior to the date of a change in control and ending on (and including) the date that is twelve months following the date of a change in control, such named executive officer is entitled to receive, in lieu of the severance benefits described above under "Executive compensation arrangements", and subject to the named executive officer's execution and nonrevocation of a release of claims and continued compliance with restrictive covenants, (i) an amount equal to the sum of (x) twelve months (twenty-four months for Mr. Renaud) of base salary and (y) the named executive officer's then-current target bonus; (ii) payment for any earned but unpaid annual bonus for the prior fiscal year; (iii) payment for continued health coverage pursuant to COBRA for up to twelve months (twenty-four months for Mr. Renaud); and (iv) accelerated vesting of the named executive officer's outstanding time-based equity awards, with any such awards that vest based on the attainment of performance-vesting conditions being governed by the terms of the applicable award agreement.

For purposes of the amended and restated employment agreements, "cause" generally means, subject to certain notice and cure rights, the named executive officer's (i) willful and repeated refusal to comply with a lawful directive of our board of directors or the named executive officer's supervisor (other than due to physical or mental incapacity); (ii) gross negligence or willful misconduct in the performance of the named executive officer's duties and responsibilities; (iii) use of illegal drugs (whether or not at the workplace) or other similar conduct, even if not in conjunction with the named executive officer's duties to us, which could reasonably be expected to, or which does, cause us public disgrace or disrepute or material economic harm; (iv) material and willful breach of the agreement, any restrictive covenant agreement or any written policy or code of ethics or business conduct, in each case, applicable to the named executive officer's position, as in effect from time to time, of which the named executive officer has received prior written notice; (v) indictment for (or procedural equivalent thereof), or plea of guilty or nolo contendere to a felony or any crime involving moral turpitude (other than, in each case, a traffic related offense); or (vi) fraud, theft, embezzlement, unlawful harassment or other intentional misconduct that is or could reasonably be expected to be materially harmful to the business interests or reputation of us.

For purposes of the amended and restated employment agreements, "good reason" generally means, subject to certain notice and cure rights, (i) any diminution in the base salary or target bonus, unless such diminution is no greater than 10% and applied across-the-board to all similarly-situated executives on a proportionate basis; (ii) any material diminution in the named executive officer's titles, authority, duties or responsibilities; (iii) a permanent reassignment of the named executive officer's primary office to a location more than thirty-five miles away from the named executive officer's then-current principal place of employment (provided that "good reason" shall not exist pursuant to this clause (iii) if the named executive officer is permitted to work remotely, in which case, any material adverse change to this remote work arrangement shall constitute "good reason"); or (iv) a material breach by the Company of the agreement, any restrictive covenant agreement or any documents governing the named executive officer's equity awards.

***Equity awards to named executive officers***

Contingent on the effectiveness of the registration statement of which this prospectus forms a part, the board granted options to purchase shares of common stock to our named executive officers as follows:

| Named executive officer | Time-Based Options | Market Condition Options |
|---|---|---|
| Ron Renaud | 300,000 | 300,000 |
| Paul Burgess | 100,000 | 100,000 |
| Jamie Coleman | 75,000 | 75,000 |

The time-based options will vest as to 25% of the underlying shares on the first anniversary of the effective date of the registration statement of which this prospectus forms a part and in equal monthly installments over the following three years, subject to continued employment with us through each applicable vesting date and accelerated vesting under the employment agreements as described above.

The market condition options will vest based on our achieving a stock price equal to or greater than $40 per share based on the average closing price during any 30 consecutive calendar day period during the period beginning six months after this offering and ending on the four-year anniversary of the offering, subject to continued employment with us through the vesting date.

## Director compensation

***2025 director compensation table***

| Name | Fees earned or paid in cash($) (1) | Option awards($)(2) | Total($) |
|---|---|---|---|
| John F. Milligan, Ph.D. | 75,000 | 1,636,775 | 1,711,775 |
| Frank Clyburn, Jr. | 5,096 | 887,681 | 892,777 |
| Michael Gladstone(3) | — | — | — |
| Christopher Hite | 17,836 | 773,898 | 791,734 |
| Andrew Kaplan | — | — | — |
| Adam Koppel, M.D., Ph.D. | — | — | — |
| Amir Zamani, M.D.(4) | — | — | — |

(1) Amounts shown represent annual cash fees earned for service on our board during 2025. Mr. Gladstone, Mr. Kaplan, Dr. Koppel and Dr. Zamani are affiliated with our principal stockholders and did not earn compensation for service on our board during 2025.
(2) Amounts reflect the full grant date fair value of stock options granted during 2025 computed in accordance with ASC Topic 718, rather than the amounts paid to or realized by the director. The assumptions used in calculating the grant date fair value of the options reported in this column are set forth in Note 11 to the financial statements included in this prospectus.
(3) Mr. Gladstone resigned from our board of directors immediately prior to the effectiveness of the registration statement of which this prospectus forms a part.
(4) Dr. Zamani resigned from our board of directors immediately prior to the effectiveness of the registration statement of which this prospectus forms a part.

The table below shows the aggregate numbers of option awards (exercisable and unexercisable) held as of December 31, 2025 by each non-employee director who was serving as of December 31, 2025. These options vest as of 25% of the shares underlying the option on the first anniversary of the grant date and as to the remaining shares in 36 substantially equal monthly installments thereafter.

| Name | Options outstanding at fiscal year end |
|---|---|
| John F. Milligan, Ph.D. | 599,124 |
| Frank Clyburn, Jr. | 170,194 |
| Michael Gladstone(1) | — |
| Christopher Hite | 170,194 |
| Andrew Kaplan | — |
| Adam Koppel, M.D., Ph.D. | — |
| Amir Zamani, M.D.(2) | — |

(1) Mr. Gladstone resigned from our board of directors immediately prior to the effectiveness of the registration statement of which this prospectus forms a part.
(2) Dr. Zamani resigned from our board of directors immediately prior to the effectiveness of the registration statement of which this prospectus forms a part.

***Non-Employee Director Compensation Program***

In connection with this offering, our board of directors and stockholders approved a compensation program for our non-employee directors under which each non-employee director will receive the following amounts for their services on our board of directors:

- Upon the director's initial election or appointment to our board of directors that occurs after our initial public offering, an option to purchase a number of shares of our common stock having an aggregate grant date fair value of $800,000 (as determined under the program);
- If the director has served on our board of directors for at least six months as of the date of an annual meeting of stockholders and will continue to serve as a director immediately following such meeting, an option to purchase a number of shares of our common stock on the date of the annual meeting having an aggregate grant date fair value of $400,000 (as determined under the program);
- An annual director fee of $40,000; and
- If the director serves as lead independent director or chair or on a committee of our board of directors, an additional annual fee as follows:
    - Chair of the board: $35,000;
    - Chair of the audit committee: $20,000;
    - Audit committee member other than the chair, $10,000;
    - Chair of the compensation and talent committee, $15,000;
    - Compensation and talent committee member other than the chair, $7,500;
    - Chair of the nominating and corporate governance committee, $10,000; and
    - Nominating and corporate governance committee member other than the chair, $5,000.

Director fees under the program will be payable in arrears in four equal quarterly installments not later than the fifteenth day following the final day of each calendar quarter, provided that the amount of each payment will be prorated for any portion of a quarter that a director is not serving on our board and no fee will be payable in respect of any period prior to the effective date of this offering.

Stock options granted to our non-employee directors under the program will have an exercise price equal to the fair market value of our common stock on the date of grant and will expire not later than ten years after the date of grant. The stock options granted upon a director's initial election or appointment will vest in three substantially equal annual installments following the date of grant. The stock options granted annually to directors will vest in a single installment on the earlier of the day before the next annual meeting or the first anniversary of the date of grant. In addition, all unvested stock options will vest in full upon the occurrence of a change in control.

Contingent on the effectiveness of the registration statement of which this prospectus forms a part, each non-employee director who will continue as a director following this offering (other than Dr. Liu who declined receipt of director compensation) will receive an option to purchase 38,300 shares of common stock, which option will vest on the first anniversary of the effective date of the registration statement of which this prospectus forms a part.

## Equity incentive plans

***2026 incentive award plan***

We adopted, and our stockholders approved, the 2026 Incentive Award Plan, or the 2026 Plan, under which we may grant cash and equity incentive awards to eligible service providers in order to attract, motivate and retain the talent for which we compete. The material terms of the 2026 Plan are summarized below.

*Eligibility and Administration***.** Our employees, consultants and directors, and employees, consultants and directors of our subsidiaries will be eligible to receive awards under the 2026 Plan. We expect that the 2026 Plan will be administered by our board of directors with respect to awards to non-employee directors and by our compensation and talent committee with respect to other participants, each of which may delegate its duties and responsibilities to committees of our directors and/or officers (referred to collectively as the plan administrator below), subject to certain limitations that may be imposed under Section 16 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and/or stock exchange rules, as applicable. The plan administrator will have the authority to make all determinations and interpretations under, prescribe all forms for use with, and adopt rules for the administration of, the 2026 Plan, subject to its express terms and conditions. The plan administrator will also set the terms and conditions of all awards under the 2026 Plan, including any vesting and vesting acceleration conditions.

*Limitation on Awards and Shares Available***.** The number of shares initially available for issuance under awards granted pursuant to the 2026 Plan will be 14,011,037 shares. The number of shares initially available for issuance will be increased on January 1 of each calendar year beginning on and including January 1, 2027 and ending on and including January 1, 2036, by an amount equal to the lesser of (a) 5% of the aggregate number of shares of common stock outstanding on the final day of the immediately preceding calendar year, and (b) such smaller number of shares as determined by the plan administrator. No more than 30,000,000 shares of common stock may be subject to awards granted as, or issued upon the exercise of, incentive stock options under the 2026 Plan. Shares issued under the 2026 Plan may be authorized but unissued shares, or treasury shares.

If an award under the 2026 Plan or 2024 Plan expires, lapses or is terminated, exchanged for or settled for cash, surrendered, repurchased, cancelled without having been fully exercised or forfeited, any shares subject

to such award may, to the extent of such forfeiture, expiration or cash settlement, be used again for new grants under the 2026 Plan. Further, shares delivered to us to satisfy the applicable exercise or purchase price of an award under the 2026 Plan or the 2024 Plan and/or to satisfy any applicable tax withholding obligations (including shares retained by us from the award under the 2026 Plan or the 2024 Plan being exercised or purchased and/or creating the tax obligation) will become or again be available for award grants under the 2026 Plan. The payment of dividend equivalents in cash in conjunction with any awards under the 2026 Plan or 2024 Plan will not reduce the shares available for grant under the 2026 Plan.

Awards granted under the 2026 Plan upon the assumption of, or in substitution for, awards authorized or outstanding under a qualifying equity plan maintained by an entity with which we enter into a merger or similar corporate transaction will not reduce the shares available for grant under the 2026 Plan.

*Director Compensation*. The 2026 Plan provides that the plan administrator may establish compensation for non-employee directors from time to time; provided that the sum of any cash compensation or other compensation and the value (as determined in accordance with FASB ASC 718, or any successor thereto) of any equity awards granted as compensation for services as a non-employee director during any fiscal year of the Company may not exceed $750,000, increased to $1,000,000 in the fiscal year in which the 2026 Plan's effective date occurs or in the fiscal year of a non-employee director's initial service as a non-employee director (in each case, excluding any compensation awarded prior to the 2026 Plan's effective date). Consulting fees or other compensation we may pay or provide to any non-employee director for services in addition to the services normally performed by a non-employee director shall not be included in calculating compliance with such limits. The plan administrator may, however, make exceptions to such limits on director compensation in extraordinary circumstances, subject to the limitations in the 2026 Plan.

*Awards***.** The 2026 Plan provides for the grant of stock options, including incentive stock options, or ISOs, and nonqualified stock options, or NSOs, restricted stock, dividend equivalents, restricted stock units, or RSUs, performance shares, other incentive awards, stock appreciation rights, or SARs, and cash awards. Certain awards under the 2026 Plan may constitute or provide for a deferral of compensation, subject to Section 409A of the Code, which may impose additional requirements on the terms and conditions of such awards. All awards under the 2026 Plan will be set forth in award agreements, which will detail all terms and conditions of the awards, including any applicable vesting and payment terms and post-termination exercise limitations. Awards other than cash awards generally will be settled in shares of our common stock, but the plan administrator may provide for cash settlement of any award. A brief description of each award type follows.

- Stock Options. Stock options provide for the purchase of shares of our common stock in the future at an exercise price set on the grant date. ISOs, by contrast to NSOs, may provide tax deferral beyond exercise and favorable capital gains tax treatment to their holders if certain holding period and other requirements of the Code are satisfied. The exercise price of a stock option may not be less than 100% of the fair market value of the underlying share on the date of grant (or 110% in the case of ISOs granted to certain significant stockholders), except with respect to certain substitute options granted in connection with a corporate transaction. The term of a stock option may not be longer than ten years (or five years in the case of ISOs granted to certain significant stockholders). Vesting conditions determined by the plan administrator may apply to stock options and may include continued service, performance and/or other conditions.
- SARs. SARs entitle their holder, upon exercise, to receive from us an amount equal to the appreciation of the shares subject to the award between the grant date and the exercise date. The exercise price of a SAR may not be less than 100% of the fair market value of the underlying share on the date of grant (except with respect to certain substitute SARs granted in connection with a corporate transaction) and the term of a SAR may not be longer than ten years. Vesting conditions determined by the plan administrator may apply to SARs and may include continued service, performance and/or other conditions.

- Restricted Stock and RSUs. Restricted stock is an award of nontransferable shares of our common stock that remain forfeitable unless and until specified conditions are met, and which may be subject to a purchase price. RSUs are contractual promises to deliver shares of our common stock in the future, which may also remain forfeitable unless and until specified conditions are met, and may be accompanied by the right to receive the equivalent value of dividends paid on shares of our common stock prior to the delivery of the underlying shares. Delivery of the shares underlying RSUs may be deferred under the terms of the award or at the election of the participant, if the plan administrator permits such a deferral. Conditions applicable to restricted stock and RSUs may be based on continuing service, the attainment of performance goals and/or such other conditions as the plan administrator may determine.
- Other Stock or Cash Based Awards. Other stock or cash based awards of cash, fully vested shares of our common stock and other awards valued wholly or partially by referring to, or otherwise based on, shares of our common stock. Other stock or cash based awards may be granted to participants and may also be available as a payment form in the settlement of other awards, as standalone payments and as payment in lieu of base salary, bonus, fees or other cash compensation otherwise payable to any individual who is eligible to receive awards.
- Dividend Equivalents. Dividend equivalents represent the right to receive the equivalent value of dividends paid on shares of our common stock and may be granted alone or in tandem with awards other than stock options or SARs. Dividend equivalents are credited as of dividend record dates during the period between the date an award is granted and the date such award vests, is exercised, is distributed or expires, as determined by the plan administrator.

*Performance Awards.* Performance awards include any of the foregoing awards that are granted subject to vesting and/or payment based on the attainment of specified performance goals or other criteria the plan administrator may determine, which may or may not be objectively determinable. Performance criteria upon which performance goals are established by the plan administrator may include but are not limited to: net earnings or losses (either before or after one or more of interest, taxes, depreciation, amortization, and non-cash equity-based compensation expense); gross or net sales or revenue or sales or revenue growth; net income (either before or after taxes) or adjusted net income; profits (including but not limited to gross profits, net profits, profit growth, net operation profit or economic profit), profit return ratios or operating margin; budget or operating earnings (either before or after taxes or before or after allocation of corporate overhead and bonus); cash flow (including operating cash flow and free cash flow or cash flow return on capital); return on assets; return on capital or invested capital; cost of capital; return on stockholders' equity; total stockholder return; return on sales; costs, reductions in costs and cost control measures; expenses; working capital; earnings or loss per share; adjusted earnings or loss per share; price per share or dividends per share (or appreciation in or maintenance of such price or dividends); regulatory achievements or compliance; implementation, completion or attainment of objectives relating to research, development, regulatory, commercial, or strategic milestones or developments; market share; economic value or economic value added models; division, group or corporate financial goals; customer satisfaction/growth; customer service; employee satisfaction; recruitment and maintenance of personnel; human resources management; supervision of litigation and other legal matters; strategic partnerships and transactions; financial ratios (including those measuring liquidity, activity, profitability or leverage); debt levels or reductions; sales-related goals; financing and other capital raising transactions; cash on hand; acquisition activity; investment sourcing activity; and marketing initiatives, any of which may be measured either in absolute terms for us or any operating unit of our company or as compared to any incremental increase or decrease or as compared to results of a peer group or to market performance indicators or indices.

*Certain Transactions.* The plan administrator has broad discretion to take action under the 2026 Plan, as well as make adjustments to the terms and conditions of existing and future awards, to prevent the dilution or enlargement of intended benefits and facilitate necessary or desirable changes in the event of certain transactions

and events affecting our common stock, such as stock dividends, stock splits, mergers, acquisitions, consolidations and other corporate transactions. In addition, in the event of certain non-reciprocal transactions with our stockholders known as “equity restructurings,” the plan administrator will make equitable adjustments to the 2026 Plan and outstanding awards. In the event of a change in control of our company (as defined in the 2026 Plan), to the extent that the surviving entity declines to continue, convert, assume or replace outstanding awards, then all such awards (other than any award that is regularly scheduled to vest based on attainment of performance-based vesting conditions) will become fully vested and exercisable in connection with the transaction. Upon or in anticipation of a change of control, the plan administrator may cause any outstanding awards to terminate at a specified time in the future and give the participant the right to exercise such awards during a period of time determined by the plan administrator in its sole discretion. Individual award agreements may provide for additional accelerated vesting and payment provisions.

*Foreign Participants, Claw-Back Provisions, Transferability, and Participant Payments.* The plan administrator may modify award terms, establish subplans and/or adjust other terms and conditions of awards, subject to the share limits described above, in order to facilitate grants of awards subject to the laws and/or stock exchange rules of countries outside of the United States. All awards will be subject to the provisions of any claw-back policy implemented by our company, including any claw-back policy adopted to comply with applicable laws, including, without limitation, Rule 10D-1 of the Exchange Act and any rules or regulations promulgated thereunder, as set forth in such claw-back policy and/or the award agreement. With limited exceptions for estate planning, domestic relations orders, certain beneficiary designations and the laws of descent and distribution, awards under the 2026 Plan are generally non-transferable prior to vesting, and are exercisable only by the participant. With regard to tax withholding, exercise price and purchase price obligations arising in connection with awards under the 2026 Plan, the plan administrator may, in its discretion, accept cash or check, shares of our common stock that meet specified conditions, a “market sell order” or such other consideration as set forth in the 2026 Plan.

*Plan Amendment and Termination.* Our board of directors may amend or terminate the 2026 Plan at any time; however, except in connection with certain changes in our capital structure, stockholder approval will be required for any amendment that increases the number of shares available under the 2026 Plan. Stockholder approval is not required for any amendment that “reprices” any stock option or SAR, or cancels any stock option or SAR in exchange for cash or another award when the option or SAR price per share exceeds the fair market value of the underlying shares. No award may be granted pursuant to the 2026 Plan after the tenth anniversary of the earlier of the date on which our stockholders approved the 2026 Plan or the date on which our board of directors adopted the 2026 Plan.

***2026 employee stock purchase plan***

In connection with the offering, we adopted, and our stockholders approved, the ESPP. The material terms of the ESPP are summarized below.

The ESPP is comprised of two distinct components in order to provide increased flexibility to grant options to purchase shares under the ESPP to U.S. and to non-U.S. employees. Specifically, the ESPP authorizes (1) the grant of options to U.S. employees that are intended to qualify for favorable U.S. federal tax treatment under Section 423 of the Code, or the Section 423 Component, and (2) the grant of options that are not intended to be tax-qualified under Section 423 of the Code to facilitate participation for employees located outside of the U.S. who do not benefit from favorable U.S. federal tax treatment and to provide flexibility to comply with non-U.S. law and other considerations, or the Non-Section 423 Component. Where permitted under local law and custom, we expect that the Non-Section 423 Component will generally be operated and administered on terms and conditions similar to the Section 423 Component.

*Shares Available; Administration*. The number of shares initially available for issuance pursuant to the ESPP will be 1,295,482 shares. In addition, we expect that the number of shares available for issuance under the ESPP will be increased on January 1 of each calendar year beginning on and including January 1, 2027 and ending on and including January 1, 2036, by an amount equal to the lesser of: (i) 1% of the aggregate number of shares of common stock outstanding on the final day of the immediately preceding calendar year, and (ii) such smaller number of shares as is determined by our board of directors; provided that no more than 15,000,000 shares of our common stock may be issued under the Section 423 Component.

Our board of directors or a committee designated by our board of directors will have authority to interpret the terms of the ESPP and determine eligibility of participants. We expect that the compensation and talent committee will be the administrator of the ESPP.

*Eligibility*. The plan administrator may designate certain of our subsidiaries as participating "designated subsidiaries" in the ESPP and may change these designations from time to time. Employees of our company and our designated subsidiaries are eligible to participate in the ESPP if they meet the eligibility requirements under the ESPP established from time to time by the plan administrator. However, an employee may not be granted rights to purchase stock under the ESPP if such employee, immediately after the grant, would own (directly or through attribution) stock possessing 5% or more of the total combined voting power or value of all classes of our common or other class of stock.

Eligible employees become participants in the ESPP by enrolling and authorizing payroll deductions by the deadline established by the plan administrator prior to the relevant offering date. Directors who are not employees, as well as consultants, are not eligible to participate. Employees who choose not to participate, or are not eligible to participate at the start of an offering period but who become eligible thereafter, may enroll in any subsequent offering period.

*Participation in an Offering*. Stock will be offered under the ESPP during offering periods. The length of offering periods under the ESPP will be determined by the plan administrator and may be up to 27 months long. Employee payroll deductions will be used to purchase shares on each purchase date during an offering period. The number of purchase periods within, and purchase dates during, each offering period will be established by the plan administrator. Offering periods under the ESPP will commence when determined by the plan administrator. The plan administrator may, in its discretion, modify the terms of future offering periods.

The ESPP will permit participants to purchase our common stock through payroll deductions of up to a specified percentage of their eligible compensation. The plan administrator will establish a maximum number of shares that may be purchased by a participant during any offering period or purchase period, which, in the absence of a contrary designation, will be 25,000 shares for an offering period and/or a purchase period. In addition, no employee will be permitted to accrue the right to purchase stock under the Section 423 Component of the ESPP at a rate in excess of $25,000 worth of shares during any calendar year during which such a purchase right is outstanding (based on the fair market value per share of our common stock as of the first day of the offering period).

On the first trading day of each offering period, each participant automatically will be granted an option to purchase shares of our common stock. The option will be exercised on the applicable purchase date(s) during the offering period, to the extent of the payroll deductions accumulated during the applicable purchase period. We expect that the purchase price of the shares, in the absence of a contrary determination by the plan administrator, will be 85% of the lower of the fair market value of our common stock on the first trading day of the offering period or on the applicable purchase date, which will be the final trading day of the applicable purchase period.

Participants may voluntarily end their participation in the ESPP at any time during a time period specified by the plan administrator, and will be paid their accrued payroll deductions that have not yet been used to

purchase shares of common stock. Participation ends automatically upon a participant's termination of employment.

*Transferability*. A participant may not transfer rights granted under the ESPP other than by will, the laws of descent and distribution or as otherwise provided in the ESPP.

*Certain Transactions*. In the event of certain transactions or events affecting our common stock, such as any stock dividend or other distribution, change in control, reorganization, merger, consolidation or other corporate transaction, the plan administrator will make equitable adjustments to the ESPP and outstanding rights. In addition, in the event of the foregoing transactions or events or certain significant transactions, including a change in control, the plan administrator may provide for (i) either the replacement of outstanding rights with other rights or property or termination of outstanding rights in exchange for cash, (ii) the assumption or substitution of outstanding rights by the successor or survivor corporation or parent or subsidiary thereof, (iii) the adjustment in the number and type of shares of stock subject to outstanding rights, (iv) the use of participants' accumulated payroll deductions to purchase stock on a new purchase date prior to the next scheduled purchase date and termination of any rights under ongoing offering periods or (v) the termination of all outstanding rights.

*Plan Amendment; Termination*. The plan administrator may amend, suspend or terminate the ESPP at any time. However, stockholder approval of any amendment to the ESPP must be obtained for any amendment which increases the aggregate number or changes the type of shares that may be sold pursuant to rights under the ESPP or changes the corporations or classes of corporations whose employees are eligible to participate in the ESPP.

***2024 plan***

We currently maintain the Kailera Therapeutics, Inc. 2024 Equity Incentive Plan, or the 2024 Plan, which was adopted by our board of directors in May 2024. We have previously granted stock options under the 2024 Plan. The principal purpose of the 2024 Plan is to enhance our ability to attract, retain and motivate persons who make (or are expected to make) important contributions to us by providing them with equity ownership opportunities.

Following the completion of this offering, we will not make any further grants under the 2024 Plan. However, the 2024 Plan will continue to govern the terms and conditions of the outstanding awards granted under the 2024 Plan.

*Eligibility*. The 2024 Plan provides for the grant of stock options, stock appreciation rights, restricted stock, unrestricted stock, stock units, including restricted stock units, or other stock-based awards, or any combination thereof, to employees, members of the board of directors and individual consultants and advisors to the Company. The 2024 Plan provides for the grant of ISOs to employees.

*Share reserve*. We have reserved an aggregate of 15,517,688 shares of our common stock for issuance under the 2024 Plan. As of December 31, 2025, options to purchase a total of 13,470,409 shares of our common stock were issued and outstanding, a total of 19,047 shares of common stock had been issued upon the exercise of options granted under the 2024 Plan, and 2,028,232 shares remained available for future grants.

*Administration*. Our board of directors or a committee appointed by our board of directors administers the 2024 Plan. The administrator has the authority to select the service providers to whom equity awards will be granted under the 2024 Plan, the number of shares to be subject to those awards under the 2024 Plan, and the terms and conditions of the awards granted. In addition, the administrator has the authority to construe and

interpret the 2024 Plan and to adopt rules for the administration, interpretation and application of the 2024 Plan that are consistent with the terms of the 2024 Plan.

*Awards*. The 2024 Plan provides that the administrator may grant or issue stock options, stock appreciation rights, restricted stock, unrestricted stock, stock units, including restricted stock units, or other stock-based awards, or any combination thereof. Each award is set forth in a separate agreement with the person receiving the award and indicates the type, terms and conditions of the award. As of the date of this prospectus, only stock options are outstanding under the 2024 Plan.

- NSOs provide for the right to purchase shares of our common stock at a specified price which shall be not less than fair market value on the date of grant, and usually will become exercisable (at the discretion of the administrator) in one or more installments after the grant date, subject to the participant's continued employment or service with us. NSOs may be granted for any term specified by the administrator, but in no event more than 10 years after they are granted.
- ISOs are designed in a manner intended to comply with the provisions of Section 422 of the Code, and will be subject to specified restrictions contained in the Code. Among such restrictions, ISOs must have an exercise price of not less than the fair market value of a share of common stock on the date of grant (or 110% for an individual who owns (or is deemed to own) more than 10% of the total combined voting power of all classes of our capital stock), may only be granted to employees, and must not be exercisable after a period of ten years measured from the date of grant (or five years for an individual who owns (or is deemed to own) more than 10% of the total combined voting power of all classes of our capital stock).

*Transfer*. A participant may not transfer stock awards under our 2024 Plan other than by will, the laws of descent and distribution, or as otherwise provided under our 2024 Plan.

*Certain events*. In the event of any change in our capital structure or our business by reason of any stock dividend, stock split, reverse stock split, recapitalization, reorganization, merger, consolidation, combination, exchange of shares, liquidation, spin-off, split-up or other similar change in the Company's capital structure, the administrator will make appropriate adjustments to: (i) the aggregate number and kind of shares with respect to which awards may be granted or awarded under the 2024 Plan, (ii) the number and kind of shares subject to outstanding awards and terms and conditions of outstanding awards (including, without limitation, any applicable performance targets or criteria with respect to such awards), and (iii) the grant or exercise price per share of any outstanding awards under the 2024 Plan.

In the event of any "covered transaction" under the 2024 Plan, which includes a consolidation, merger or similar transaction or series of transactions (including a change in control), a sale or transfer of all or substantially all of the company's assets, a sale of the company, a dissolution or liquidation of the company, or such other transaction or event as the administrator determines, the administrator is authorized to provide for the acceleration, cash-out, termination, assumption, substitution or conversion of such awards.

*Amendment and termination*. The administrator may amend or terminate the 2024 Plan or any portion thereof at any time; an amendment of the 2024 Plan shall be subject to the approval of our stockholders only to the extent required by applicable laws. As described above, we will cease making awards under the 2024 Plan when the 2026 Plan becomes effective. However, the 2024 Plan will continue to govern the terms and conditions of the outstanding awards granted under it.

The administrator may amend outstanding awards under the 2024 Plan at any time. A participant's consent generally will not be required to amend an outstanding award unless the amendment materially and adversely affects the participant's rights under the award.

## Emerging growth company status

We are an “emerging growth company,” as defined in the JOBS Act. As an emerging growth company we will be exempt from certain requirements related to the disclosure of executive compensation, including the requirements to hold a nonbinding advisory vote on executive compensation and to provide information relating to the ratio of total compensation of our chief executive officer to the median of the annual total compensation of all of our employees, each as required by the Investor Protection and Securities Reform Act of 2010, which is part of the Dodd-Frank Wall Street Reform and Consumer Protection Act.

## Compensation recovery policy

In connection with this offering, we adopted a compensation recovery policy as required by Rule 10D-1 under the Exchange Act and the corresponding Nasdaq listing standards. This policy provides for the mandatory recovery (subject to limited exceptions) from current and former executive officers of incentive-based compensation that was erroneously received during the three years preceding the date that we are required to prepare an accounting restatement. Covered restatements include both a restatement to correct an error that is material to previously issued financial statements or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period. The amount required to be recovered is the excess of the amount of incentive-based compensation received over the amount that otherwise would have been received had it been determined based on the restated financial statements.

# Certain relationships and related party transactions

The following includes a summary of transactions since May 8, 2024, the date of our formation, to which we have been a party in which the amount involved exceeded or will exceed the lesser of $120,000 or one percent of the average of our total assets at year-end for the last two completed fiscal years, and in which any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our capital stock or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest, other than equity and other compensation, termination, change in control and other arrangements, which are described under "Executive and director compensation." We also describe below certain other transactions with our directors, executive officers and stockholders.

## Convertible promissory notes

In May 2025, we issued $100.0 million aggregate principal amount of convertible promissory notes to investors in private placements. The convertible promissory notes were subsequently settled for shares of our Series B convertible preferred stock, as described below.

## Preferred stock financings

*Series A-1 Preferred Stock Financing*. In May 2024 and December 2024, we issued and sold to investors in private placements an aggregate of 30,000,000 shares of Series A-1 convertible preferred stock at a purchase price of $10.00 per share, for aggregate consideration of $300.0 million in cash. The conversion price of the Series A-1 convertible preferred stock is $10.00 per share.

*Series A-2 Preferred Stock Financing*. In May 2024, we issued and sold to Jiangsu Hengrui Pharmaceuticals Co., Ltd., or Hengrui, in a private placement an aggregate of 4,968,789 shares of our Series A-2 convertible preferred stock and an aggregate of 708,814 shares of our Series A-2 non-voting convertible preferred stock as partial consideration for the receipt of certain intellectual property rights. As of December 31, 2024, the conversion price of the Series A-2 convertible preferred stock was $6.6667 per share, and the conversion price of the Series A-2 non-voting convertible preferred stock was $3.4846 per share. In connection with the issuance of Series B convertible preferred stock in October 2025, the conversion price of the Series A-2 convertible preferred stock was set at $5.2426.

*Series B Preferred Stock Financing*. In October 2025, we issued and sold to investors in private placements an aggregate of 35,714,285 shares of Series B convertible preferred stock at a purchase price of $14.00 per share, for aggregate consideration of approximately $500.0 million in cash, and 7,370,254 shares of Series B convertible preferred stock through the settlement of the convertible promissory notes described above. The conversion price of the Series B convertible preferred stock is $14.00 per share.

The following table sets forth the aggregate number of shares of our capital stock acquired by beneficial owners of more than 5% of our capital stock in the financing transactions described above. Each share of our Series A-1 convertible preferred stock and Series B convertible preferred stock will convert into one share of common stock upon the closing of this offering, each share of our Series A-2 convertible preferred stock will convert into 1.9075 shares of common stock and each share of our Series A-2 non-voting convertible preferred stock will convert into 2.8698 shares of common stock upon the closing of this offering.

| Participants(1) | Series A-1 convertible preferred stock | Series A-2 convertible preferred stock | Series A-2 non-voting convertible preferred stock | Series B convertible preferred stock |
|---|---|---|---|---|
| BCLS Fund IV Investments, L.P. | 16,875,000 | — | — | 4,145,768 |
| BCPE Perseus Investor, LP | — | — | — | 17,857,143 |
| Jiangsu Hengrui Pharmaceuticals Co., Ltd. | — | 4,968,789 | 708,814 | — |
| RTW Master Fund, Ltd., RTW Innovation Master Fund, Ltd. And RTW Biotech Opportunities Operating Ltd. | 8,250,000 | — | — | 2,026,820 |
| CPP Investment Board Private Holdings (4) Inc. | — | — | — | 5,000,000 |
| Atlas Venture Fund XIII, L.P. and Atlas Venture Opportunity Fund II, L.P. (the “Atlas Funds”) | 3,750,000 | — | — | 921,282 |

(1) Additional details regarding these stockholders and their equity holdings are provided in this prospectus under the caption “Principal Stockholders.”

Certain of our directors are affiliated with our principal stockholders as indicated in the table below:

| Director | Principal stockholder |
|---|---|
| Adam Koppel, M.D., Ph.D. | BCLS Fund IV Investments, L.P. |
| Amir Zamani, M.D. | BCLS Fund IV Investments, L.P. |
| Andrew Kaplan | BCPE Perseus Investor, LP |
| Michael Gladstone | The Atlas Funds |
| Yuting (Shelley) Liu | Jiangsu Hengrui Pharmaceuticals Co., Ltd. |

## Amended and restated investor rights agreement

In connection with the Series B preferred stock financing, we entered into an Amended and Restated Investors’ Rights Agreement in October 2025 with the holders of our preferred stock, including entities with which certain of our directors are related. The agreement provides, among other things, for certain rights relating to the registration of such holders’ common stock, including shares issuable upon conversion of preferred stock. See “Description of Capital Stock—Registration Rights” for additional information.

## Amended and restated voting agreement

In connection with the Series B preferred stock financing, we entered into an Amended and Restated Voting Agreement in October 2025, pursuant to which the following directors were elected to serve as members on our board of directors and, as of the date of this prospectus, continue to so serve: Adam Koppel, M.D., Ph.D., Amir Zamani, M.D., Michael Gladstone, Andrew Kaplan, Ronald C. Renaud, Jr., Frank Clyburn, Jr., John F. Milligan, Ph.D. and Christopher Hite. Adam Koppel, M.D., Ph.D. and Amir Zamani, M.D. were initially selected to serve on

our board of directors, as designated by BCLS Fund IV Investments, L.P. Andrew Kaplan was initially selected to serve on our board of directors, as designated by Bain Capital Fund XIV, L.P. Michael Gladstone was initially selected to serve on our board of directors, as designated by the Atlas Funds. Christopher Hite, Frank Clyburn, Jr. and John F. Milligan, Ph.D. were initially selected to serve on our board of directors by the affirmative consent of the seated directors selected by the holders of our preferred stock, and Ronald C. Renaud, Jr. is our CEO director. In February 2026 and March 2026, the amended and restated voting agreement was amended and each of Yuting (Shelley) Liu, Ph.D. and Martin Mackay, Ph.D. were selected to serve on our board of directors by the affirmative consent of the seated directors selected by the holders of our preferred stock. Mr. Gladstone and Dr. Zamani resigned from our board of directors immediately prior to the effectiveness of the registration statement of which this prospectus forms a part.

The amended and restated voting agreement, as amended, will terminate upon the closing of this offering, and members previously elected to our board of directors pursuant to this agreement will continue to serve as directors until they resign, are removed or their successors are duly elected by the holders of our common stock. The composition of our board of directors after this offering is described in more detail under “Management—Board Composition and Election of Directors.”

## Hengrui agreements

On May 15, 2024, we entered into the Hengrui License Agreement with Hengrui, a holder of 5% or more of our capital stock, pursuant to which we were granted (a) an exclusive, royalty-bearing, sublicensable license under certain intellectual property rights controlled by Hengrui to develop, manufacture and commercialize the Licensed Products, for the treatment, prevention, or diagnosis of any and all indications, diseases, or conditions worldwide, excluding China, Hong Kong, Macau, and Taiwan, or the Territory, and (b) a non-exclusive right to pre-clinically develop and manufacture the Licensed Products outside of the Territory solely for the development or commercialization of such Licensed Products in the Territory, subject to certain restrictions. We granted Hengrui a non-exclusive, sublicensable license under certain intellectual property rights controlled by us solely to the extent necessary to develop, manufacture and commercialize Licensed Products outside of the Territory, to conduct Hengrui’s obligations under the Hengrui License Agreement, and to pre-clinically develop and manufacture Licensed Products in the Territory solely for development or commercialization of such compounds or products outside of the Territory. See the section entitled “Business—Hengrui license and collaboration agreement” in this prospectus for additional details on the Hengrui License Agreement.

As consideration for the license granted to us by Hengrui, we paid Hengrui an upfront payment of $100.0 million and a technology transfer payment of $10.0 million, and we issued to Hengrui 4,968,789 shares of Series A-2 convertible preferred stock and 708,814 shares of Series A-2 non-voting convertible preferred stock, which collectively represented 19.9% of the outstanding capital stock of the Company at issuance, on a fully-diluted basis.

In January 2025, as part of the agreement with Hengrui, we entered into a supply agreement with Hengrui, pursuant to which Hengrui has agreed to manufacture and supply drug substance and drug product for use in technology transfer and clinical trials in the Territory. In February 2025, we entered into a quality agreement with Hengrui, which sets forth the responsibilities of each party with respect to quality assurance and quality control of the products supplied under the supply agreement. We recognized $0.1 million and $0.8 million of research and development expense under the supply agreement in our consolidated statements of operations and comprehensive loss for the period from May 8, 2024 (inception) to December 31, 2024 and for the year ended December 31, 2025, respectively.

## Employment agreements

We have entered into employment agreements with our named executive officers, as more fully described in the section titled “Executive and director compensation.”

## Director and officer indemnification agreements

We intend to enter into indemnification agreements with each of our directors and executive officers. These agreements, among other things, require us or will require us to indemnify each director (and in certain cases their related venture capital funds) and executive officer to the fullest extent permitted by Delaware law, including indemnification of expenses such as attorneys’ fees, judgments, fines and settlement amounts incurred by the director or executive officer in any action or proceeding, including any action or proceeding by or in right of us, arising out of the person’s services as a director or executive officer. For further information, see the section titled “Description of capital stock—Limitations on liability and indemnification of officers and directors.”

## Policies and procedures for related person transactions

Our board of directors will adopt a written related person transaction policy, to be effective upon the closing of this offering, setting forth the policies and procedures for the review and approval or ratification of related person transactions. This policy will cover, with certain exceptions set forth in Item 404 of Regulation S-K under the Securities Act, any transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we were or are to be a participant, where the amount involved exceeds $120,000 in any fiscal year, or, for so long as we qualify as a smaller reporting company, the lesser of $120,000 or one percent of the average of our total assets at year-end for the last two completed fiscal years, and a related person had, has or will have a direct or indirect material interest, including without limitation, purchases of goods or services by or from the related person or entities in which the related person has a material interest, indebtedness, guarantees of indebtedness and employment by us of a related person. In reviewing and approving any such transactions, our audit committee will be tasked to consider all relevant facts and circumstances, including, but not limited to, whether the transaction is on terms comparable to those that could be obtained in an arm’s length transaction and the extent of the related person’s interest in the transaction. All of the transactions described in this section will have occurred prior to the adoption of this policy.

# Principal stockholders

The following table sets forth information with respect to the beneficial ownership of our common stock, as of March 31, 2026 by:

- each person or group of affiliated persons known by us to beneficially own more than 5% of our common stock;
- each of our named executive officers;
- each of our directors; and
- all of our executive officers and directors as a group.

The number of shares beneficially owned by each stockholder is determined under rules issued by the Securities and Exchange Commission. Under these rules, beneficial ownership includes any shares as to which the individual or entity has sole or shared voting power or investment power. Applicable percentage ownership is based on 84,626,344 shares of common stock outstanding as of March 31, 2026, giving effect to the conversion of all outstanding shares of our preferred stock into shares of our common stock. In computing the number of shares beneficially owned by an individual or entity and the percentage ownership of that person, shares of common stock subject to options, warrants or other rights held by such person that are currently exercisable or will become exercisable within 60 days of March 31, 2026 are considered outstanding, although these shares are not considered outstanding for purposes of computing the percentage ownership of any other person.

We have received non-binding indications of interest from certain of our existing stockholders, including entities affiliated with Bain Capital Private Equity, Bain Capital Life Sciences and Qatar Investment Authority, to purchase up to an aggregate of approximately $225 million in shares of our common stock in this offering at the initial public offering price per share, on the same terms as the other purchasers in this offering. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters could determine to sell more, fewer or no shares to our existing stockholders, and our existing stockholders could determine to purchase more, fewer or no shares in this offering. The following table does not reflect any potential purchases by our existing stockholders.

Unless noted otherwise, the address of all listed stockholders is 180 Third Avenue, 4th Floor, Waltham, Massachusetts 02451. Each of the stockholders listed has sole voting and investment power with respect to the shares beneficially owned by the stockholder unless noted otherwise, subject to community property laws where applicable.

| Name of beneficial owner | Shares of common stock beneficially owned | Percentage of common stock beneficially owned | |
|---|---|---|---|
| | | Before this offering | After this offering |
| ***5% or Greater Stockholders*** | | | |
| BCLS Fund IV Investments, L.P.(1) | 21,020,768 | 24.8% | 17.0% |
| BCPE Perseus Investor, LP(2) | 17,857,143 | 21.1 | 14.4 |
| Jiangsu Hengrui Pharmaceuticals Co., Ltd.(3) | 11,511,853 | 13.6 | 9.3 |
| Entities affiliated with RTW Investments, LP(4) | 10,276,820 | 12.1 | 8.3 |
| CPP Investment Board Private Holdings (4) Inc.(5) | 5,000,000 | 5.9 | 4.0 |
| Entities affiliated with Atlas Venture Fund(6) | 4,671,282 | 5.5 | 3.8 |
| ***Named Executive Officers and Directors*** | | | |
| Ronald C. Renaud, Jr.(7) | 1,609,139 | 1.9 | 1.3 |
| Paul Burgess(7) | 186,681 | * | * |
| Jamie Coleman(7) | 119,187 | * | * |
| Douglas Pagán | — | * | * |

| Name of beneficial owner | Shares of common stock beneficially owned | Percentage of common stock beneficially owned | |
|---|---|---|---|
| | | Before this offering | After this offering |
| Laurie Stelzer[7] | 143,742 | * | * |
| Frank Clyburn, Jr. | — | * | * |
| Michael Gladstone[6] | 4,671,282 | 5.5 | 3.8 |
| Christopher Hite | — | * | * |
| Andrew Kaplan[8] | — | * | * |
| Adam Koppel, M.D., Ph.D.[9] | — | * | * |
| Yuting (Shelley) Liu, Ph.D. | — | * | * |
| Martin Mackay, Ph.D. | — | * | * |
| John F. Milligan, Ph.D.[7] | 118,878 | * | * |
| Amir Zamani, M.D.[10] | — | * | * |
| All current executive officers and directors (16 persons)[11] | 7,229,192 | 8.3% | 5.7% |

* Less than 1%.

(1) Consists of (i) 16,875,000 shares of common stock issuable upon conversion of Series A-1 preferred stock held by BCLS Fund IV Investments, L.P. and (ii) 4,145,768 shares of common stock issuable upon conversion of Series B preferred stock held by BCLS Fund IV Investments, L.P. Bain Capital Life Sciences Investors, LLC ("BCLSI") is the manager of Bain Capital Life Sciences IV General Partner, LLC, which is the general partner of Bain Capital Life Sciences Fund IV, L.P., which is the sole member of BCLS Fund IV Investments GP, LLC, which is the general partner of BCLS Fund IV Investments, L.P. As a result, BCLSI may be deemed to share voting and dispositive power with respect to shares held by BCLS Fund IV Investments, L.P. Voting and investment decisions with respect to the securities held by BCLS Fund IV Investments, L.P. are made by the partners of BCLSI, of whom there are three or more and none of whom individually has the power to direct such decisions. The principal address for BCLS Fund IV Investments, L.P. is 200 Clarendon Street, Boston, MA 02116.

(2) Consists of 17,857,143 shares of common stock issuable upon conversion of Series B preferred stock held by BCPE Perseus Investor, LP. Bain Capital Investors, LLC ("BCI") is the manager of Bain Capital XIV General Partner, LLC, which is the general partner of Bain Capital Fund XIV, L.P., which is the managing member of BCPE Perseus Investor GP, LLC, which is the general partner of BCPE Perseus Investor, LP. As a result, BCI may be deemed to share voting and dispositive power with respect to shares held by BCPE Perseus Investor, LP. Voting and investment decisions with respect to the securities held by BCPE Perseus Investor, LP are made by the partners of BCI, of whom there are three or more and none of whom individually has the power to direct such decisions. The principal address for BCPE Perseus Investor, LP is 200 Clarendon Street, Boston, MA 02116.

(3) Consists of (i) 9,477,719 shares of common stock issuable upon conversion of Series A-2 preferred stock held by Jiangsu Hengrui Pharmaceuticals Co., Ltd., (ii) 2,034,133 shares of common stock issuable upon conversion of Series A-2 non-voting preferred stock held by Jiangsu Hengrui Pharmaceuticals Co., Ltd. and (iii) 1 share of common stock held by Hengrui (USA) Ltd. Hengrui (USA) Ltd. is a wholly-owned subsidiary of Jiangsu Hengrui Pharmaceuticals Co., Ltd. Voting and investment decisions with respect to the securities held by Jiangsu Hengrui Pharmaceuticals Co., Ltd. are made by the board of directors of Jiangsu Hengrui Pharmaceuticals Co., Ltd., of whom there are three or more and none of whom individually has the power to direct such decisions. Voting and investment decisions with respect to the securities held by Hengrui (USA) Ltd. are made by the board of directors of Hengrui (USA) Ltd., of whom there are three or more and none of whom individually has the power to direct such decisions. The principal address of Jiangsu Hengrui Pharmaceuticals Co., Ltd. is 1288 Haike Road, Pudong New District, Shanghai, China. The principal address of Hengrui (USA) Ltd. is 506 Carnegie Center, Suite 102, Princeton, NJ 08540.

(4) Consists of (i) 3,256,175 shares of common stock issuable upon conversion of Series A-1 preferred stock held by RTW Master Fund, Ltd., (ii) 832,839 shares of common stock issuable upon conversion of Series B preferred stock held by RTW Master Fund, Ltd., (iii) 2,827,055 shares of common stock issuable upon conversion of Series A-1 preferred stock held by RTW Innovation Master Fund, Ltd., (iv) 649,319 shares of common stock issuable upon conversion of Series B preferred stock held by RTW Innovation Master Fund, Ltd., (v) 2,166,770 shares of common stock issuable upon conversion of Series A-1 preferred stock held by RTW Biotech Opportunities Operating Ltd., and (vi) 544,662 shares of common stock issuable upon conversion of Series B preferred stock held by RTW Biotech Opportunities Operating Ltd. RTW Investments, LP ("RTW"), in its capacity as the investment manager of RTW Master Fund, Ltd., RTW Innovation Master Fund, Ltd. and RTW Biotech Opportunities Operating Ltd. (each an "RTW Fund" and together, the "RTW Funds") has the power to vote and the power to direct the disposition of the shares held by the RTW Funds. Accordingly, RTW may be deemed to be the beneficial owner of such shares. Roderick Wong, M.D., as the Managing Partner of RTW, has the power to direct the vote and disposition of the securities held by RTW. Dr. Wong disclaims beneficial ownership of the shares held by the RTW Funds, except to the extent of his pecuniary interest therein. The address and principal office of RTW Investments, LP is 40 10th Avenue, Floor 7, New York, NY 10014, and the address of Dr. Wong and each of the RTW Funds is c/o RTW Investments, LP, 40 10th Avenue, Floor 7, New York, NY 10014.

(5) Consists of 5,000,000 shares of common stock issuable upon conversion of Series B preferred stock held by CPP Investment Board Private Holdings (4) Inc. CPP Investment Board Private Holdings (4) Inc. is a wholly-owned subsidiary of Canada Pension Plan Investment Board ("CPPIB"). Investment and voting power with regard to shares held by CPP Investment Board Private Holdings (4) Inc. rests with CPPIB. John Graham is the President and Chief Executive Officer of CPPIB and, in such capacity, may be deemed to have voting and dispositive power with respect to the shares of common stock beneficially owned by CPPIB. Mr. Graham disclaims beneficial ownership over any such shares. The principal address for CPPIB and CPP Investment Board Private Holdings (4) Inc. is One Queen Street East, Suite 2500, Toronto, Ontario, M5C 2W5, Canada.

(6) Consists of (i) 2,250,000 shares of common stock issuable upon conversion of Series A-1 preferred stock held by Atlas Venture Fund XIII, L.P. (“Fund XIII”), (ii) 552,769 shares of common stock issuable upon conversion of Series B preferred stock held by Fund XIII, (iii) 1,500,000 shares of common stock issuable upon conversion of Series A-1 preferred stock held by Atlas Venture Opportunity Fund II, L.P. (“AVOF II”) and (iv) 368,513 shares of common stock issuable upon conversion of Series B preferred stock held by AVOF II. Atlas Venture Associates XIII, L.P. (“XIII LP”) is the general partner of Fund XIII, and Atlas Venture Associates XIII, LLC (“XIII LLC”) is the general partner of XIII LP. Atlas Venture Associates Opportunity II, L.P. (“AVAO II LP”) is the general partner of AVOF II, and Atlas Venture Associates Opportunity II, LLC (“AVAO II LLC”) is the general partner of AVAO II LP. Michael Gladstone, Kevin Bitterman, Bruce Booth, Jason Rhodes, Jean-Francois Formela, and David Grayzel are members of XIII LLC and AVAO II LLC and have shared power to vote and shared power to dispose, acting by majority. Michael Gladstone was a member of our board of directors, but resigned from our board of directors immediately prior to the effectiveness of the registration statement of which this prospectus forms a part. The principal address for Fund XIII and AVOF II is 300 Technology Square, 8th Floor, Cambridge, MA 02139.

(7) Consists solely of options exercisable within 60 days of March 31, 2026.

(8) Does not include shares of common stock held by BCPE Perseus Investor, LP, which is reflected elsewhere in the table. Andrew Kaplan, who is a member of our board of directors, is a partner at Bain Capital Investors, LLC, the ultimate general partner of BCPE Perseus Investor, LP, and as a result, and by virtue of the relationships described in footnote 2 above, may be deemed to share beneficial ownership of the shares held by BCPE Perseus Investor, LP. The address for Mr. Kaplan is c/o Bain Capital Private Equity, LP, 200 Clarendon Street, Boston, MA 02116.

(9) Does not include shares of common stock held by BCLS Fund IV Investments, L.P., which is reflected elsewhere in the table. Adam Koppel, M.D., Ph.D., who is a member of our board of directors, is a partner at Bain Capital Life Sciences Investors, LLC, the ultimate general partner of BCLS Fund IV Investments, L.P., and as a result, and by virtue of the relationships described in footnote 1 above, may be deemed to share beneficial ownership of the shares held by BCLS Fund IV Investments, L.P. The address for Dr. Koppel is c/o Bain Capital Life Sciences, LP, 200 Clarendon Street, Boston, MA 02116.

(10) Does not include shares of common stock held by BCLS Fund IV Investments, L.P., which is reflected elsewhere in the table. Amir Zamani, M.D., who was a member of our board of directors, but resigned from our board of directors immediately prior to the effectiveness of the registration statement of which this prospectus forms a part, is a partner at Bain Capital Life Sciences Investors, LLC, the ultimate general partner of BCLS Fund IV Investments, L.P., and as a result, and by virtue of the relationships described in footnote 1 above, may be deemed to share beneficial ownership of the shares held by BCLS Fund IV Investments, L.P. The address for Dr. Zamani is c/o Bain Capital Life Sciences, LP, 200 Clarendon Street, Boston, MA 02116.

(11) Consists of 4,671,282 shares of common stock issuable upon conversion of preferred stock and 2,557,910 shares of common stock issuable upon the exercise of options within 60 days of March 31, 2026.

# Description of capital stock

## General

The following description summarizes some of the terms of our amended and restated certificate of incorporation and amended and restated bylaws that will become effective upon the closing of this offering, our outstanding warrant, the investors' rights agreement and of the General Corporation Law of the State of Delaware. Because it is only a summary, it does not contain all the information that may be important to you. For a complete description, you should refer to our amended and restated certificate of incorporation, amended and restated bylaws, warrant and investors' rights agreement, copies of which have been or will be filed as exhibits to the registration statement of which this prospectus is a part, as well as the relevant provisions of the General Corporation Law of the State of Delaware. The description of our common stock and preferred stock reflects changes to our capital structure that will occur upon the closing of this offering.

Following the closing of this offering, our authorized capital stock will consist of 800,000,000 shares of common stock, par value $0.00001 per share, and 10,000,000 shares of preferred stock, par value $0.00001 per share.

As of December 31, 2025, there were 19,048 shares of our common stock outstanding and 84,596,391 shares of our common stock issuable upon the automatic conversion of all outstanding shares of our preferred stock in connection with this offering, held of record by 26 stockholders.

## Common stock

Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders and do not have cumulative voting rights. An election of directors by our stockholders shall be determined by a plurality of the votes cast by the stockholders entitled to vote on the election. Subject to the supermajority votes for some matters, other matters shall be decided by the affirmative vote of our stockholders having a majority in voting power of the votes cast by the stockholders present or represented and voting on such matter. Our amended and restated certificate of incorporation and amended and restated bylaws also provide that our directors may be removed only for cause and only by the affirmative vote of the holders of at least two-thirds in voting power of the outstanding shares of capital stock entitled to vote thereon. In addition, the affirmative vote of the holders of at least two-thirds in voting power of the outstanding shares of capital stock entitled to vote thereon is required to amend or repeal, or to adopt any provision inconsistent with, several of the provisions of our amended and restated certificate of incorporation. See below under "—Anti-Takeover Effects of Delaware Law and Our Certificate of Incorporation and Bylaws—Amendment of Charter Provisions." Holders of common stock are entitled to receive proportionately any dividends as may be declared by our board of directors, subject to any preferential dividend rights of any series of preferred stock that we may designate and issue in the future.

In the event of our liquidation or dissolution, the holders of common stock are entitled to receive proportionately our net assets available for distribution to stockholders after the payment of all debts and other liabilities and subject to the prior rights of any outstanding preferred stock. Holders of common stock have no preemptive, subscription, redemption or conversion rights. Our outstanding shares of common stock are, and the shares offered by us in this offering will be, when issued and paid for, validly issued, fully paid and nonassessable. The rights, preferences and privileges of holders of common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

## Preferred stock

Under the terms of our amended and restated certificate of incorporation that will become effective upon the closing of this offering, our board of directors is authorized to direct us to issue shares of preferred stock in one or more series without stockholder approval. Our board of directors has the discretion to determine the rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, of each series of preferred stock.

The purpose of authorizing our board of directors to issue preferred stock and determine its rights and preferences is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions, future financings and other corporate purposes, could have the effect of making it more difficult for a third party to acquire, or could discourage a third party from seeking to acquire, a majority of our outstanding voting stock. Upon the closing of this offering, there will be no shares of preferred stock outstanding, and we have no present plans to issue any shares of preferred stock.

## Options

As of December 31, 2025, options to purchase 13,470,409 shares of our common stock were outstanding under our 2024 Plan, of which 2,520,139 were exercisable and of which 10,950,270 were unvested as of that date.

## Registration rights

Holders of 84,596,391 shares of our common stock are entitled to certain rights with respect to the registration of such shares for public resale under the Securities Act, pursuant to an amended and restated investors' rights agreement by and among us and certain of our stockholders, until the rights otherwise terminate pursuant to the terms of the investors' rights agreement. The registration of shares of common stock as a result of the following rights being exercised would enable holders to trade these shares without restriction under the Securities Act when the applicable registration statement is declared effective.

*Form S-1 registration rights*

If at any time beginning 180 days after the closing date of this offering the holders of the majority of the registrable securities request in writing that we effect a registration with respect to all or part of such registrable securities then outstanding and having an anticipated aggregate offering price that would exceed $25,000,000, net of expenses, we may be required to register their shares. We are obligated to effect at most two registrations in response to these demand registration rights. If the holders requesting registration intend to distribute their shares by means of an underwriting, the managing underwriter of such offering will have the right to limit the numbers of shares to be underwritten for reasons related to the marketing of the shares.

*Piggyback registration rights*

If at any time after this offering we propose to register any shares of our common stock under the Securities Act, subject to certain exceptions, the holders of registrable securities will be entitled to notice of the registration and to include their shares of registrable securities in the registration. If our proposed registration involves an underwriting, the managing underwriter of such offering will have the right to limit the number of shares to be underwritten for reasons related to the marketing of the shares.

*Form S-3 registration rights*

If, at any time after we become entitled under the Securities Act to register our shares on a registration statement on Form S-3, the holders of at least 25% of the registrable securities request in writing that we effect

a registration with respect to registrable securities at an aggregate price to the public in the offering of at least $10,000,000, we will be required to effect such registration; provided, however, that we will not be required to effect such a registration if, within any twelve month period, we have already effected two registrations on Form S-3 for the holders of registrable securities.

*Expenses and indemnification*

Ordinarily, other than underwriting discounts and commissions, we will be required to pay all expenses incurred by us related to any registration effected pursuant to the exercise of these registration rights. These expenses may include all registration and filing fees, printing expenses, fees and disbursements of our counsel, reasonable fees and disbursements of a counsel for the selling securityholders and blue sky fees and expenses. Additionally, we have agreed to indemnify selling stockholders for damages, and any legal or other expenses reasonably incurred, arising from or based upon any untrue statement of a material fact contained in any registration statement, an omission or alleged omission to state a material fact in any registration statement or necessary to make the statements therein not misleading, or any violation or alleged violation by the indemnifying party of securities laws, subject to certain exceptions.

*Termination of registration rights*

The registration rights terminate upon the earlier of four years after the effective date of the registration statement relating to our IPO, the closing of a deemed liquidation event, as defined in our current certificate of incorporation, or as to any holder at such time as Rule 144 or another similar exemption under the Securities Act is available for the sale of all of such holders' shares without limitation during a three-month period without registration.

## Anti-takeover effects of Delaware law and our amended and restated certificate of incorporation and amended and restated bylaws

Some provisions of Delaware law, our amended and restated certificate of incorporation and our amended and restated bylaws could make the following transactions more difficult: an acquisition of us by means of a tender offer; an acquisition of us by means of a proxy contest or otherwise; or the removal of our incumbent officers and directors. It is possible that these provisions could make it more difficult to accomplish or could deter transactions that stockholders may otherwise consider to be in their best interest or in our best interests, including transactions which provide for payment of a premium over the market price for our shares.

These provisions, summarized below, are intended to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors. We believe that the benefits of the increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging these proposals because negotiation of these proposals could result in an improvement of their terms.

***Undesignated preferred stock***

The ability of our board of directors, without action by the stockholders, to issue up to 10,000,000 shares of undesignated preferred stock with voting or other rights or preferences as designated by our board of directors could impede the success of any attempt to change control of us. These and other provisions may have the effect of deferring hostile takeovers or delaying changes in control or management of our company.

***Stockholder meetings***

Our amended and restated bylaws provide that a special meeting of stockholders may be called only by our chair of the board, chief executive officer or president (in the absence of a chief executive officer), or by a resolution adopted by a majority of our board of directors.

***Requirements for advance notification of stockholder nominations and proposals***

Our amended and restated bylaws establish advance notice procedures with respect to stockholder proposals to be brought before a stockholder meeting and the nomination of candidates for election as directors, other than nominations made by or at the direction of the board of directors or a committee of the board of directors.

***Elimination of stockholder action by written consent***

Our amended and restated certificate of incorporation eliminates the right of stockholders to act by written consent without a meeting.

***Staggered board***

Our board of directors is divided into three classes. The directors in each class will serve for a three-year term, one class being elected each year by our stockholders. For more information on the classified board, see the section titled “Management—Board composition and election of directors.” This system of electing and removing directors may tend to discourage a third-party from making a tender offer or otherwise attempting to obtain control of us, because it generally makes it more difficult for stockholders to replace a majority of the directors.

***Removal of directors***

Our amended and restated certificate of incorporation provides that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of the holders of at least two-thirds in voting power of the outstanding shares of stock entitled to vote in the election of directors.

***Stockholders not entitled to cumulative voting***

Our amended and restated certificate of incorporation does not permit stockholders to cumulate their votes in the election of directors. Accordingly, the holders of a majority of the outstanding shares of our common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they choose, other than any directors that holders of our preferred stock may be entitled to elect.

***Delaware anti-takeover statute***

We are subject to Section 203 of the General Corporation Law of the State of Delaware, which prohibits persons deemed to be “interested stockholders” from engaging in a “business combination” with a publicly held Delaware corporation for three years following the date these persons become interested stockholders unless the business combination is, or the transaction in which the person became an interested stockholder was, approved in a prescribed manner or another prescribed exception applies. Generally, 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 voting stock. Generally,

a “business combination” includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. The existence of this provision may have an anti-takeover effect with respect to transactions not approved in advance by the board of directors.

***Choice of forum***

Our amended and restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for: (1) any derivative action, suit or proceeding brought on our behalf; (2) any action, suit or proceeding asserting a claim of breach of a fiduciary duty by any of our directors, officers, or our stockholders; (3) any action, suit or proceeding asserting a claim against us arising pursuant to any provision of the General Corporation Law of the State of Delaware or our certificate of incorporation or bylaws; or (4) any action, suit or proceeding asserting a claim governed by the internal affairs doctrine; provided that the exclusive forum provision will not apply to suits brought to enforce any liability or duty created by the Securities Act or the Exchange Act, or to any claim for which the federal courts have exclusive jurisdiction, including all causes of action asserted against any defendant to such complaint. For instance, the provision would not apply to actions arising under federal securities laws, including suits brought to enforce any liability or duty created by the Securities Act, Exchange Act, or the rules and regulations thereunder. Our amended and restated certificate of incorporation further provides that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America shall, to the fullest extent permitted by law, be the sole and exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. Our amended and restated certificate of incorporation also provides that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock will be deemed to have notice of and to have consented to this choice of forum provision. It is possible that a court of law could rule that the choice of forum provision contained in our amended and restated certificate of incorporation is inapplicable or unenforceable if it is challenged in a proceeding or otherwise.

***Amendment of charter provisions***

The amendment of any of the above provisions, except for the provision making it possible for our board of directors to issue preferred stock and the provision prohibiting cumulative voting, would require approval by holders of at least two-thirds in voting power of the outstanding shares of stock entitled to vote thereon.

The provisions of Delaware law, our amended and restated certificate of incorporation and our amended and restated bylaws could have the effect of discouraging others from attempting hostile takeovers and, as a consequence, they may also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions may also have the effect of preventing changes in the composition of our board and management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders may otherwise deem to be in their best interests.

## Limitations on liability and indemnification of officers and directors

Our amended and restated certificate of incorporation provides that no director or officer will be personally liable to us or our stockholders for monetary damages for breach of fiduciary duty as a director or officer, except as required by applicable law, as in effect from time to time. Section 102(b)(7) of the DGCL permits a corporation to provide in its certificate of incorporation that a director or officer of the corporation shall not be personally liable to the corporation or its stockholders for monetary damages for breach of fiduciary duty as a director or officer, except for liability for:

- any breach of the director’s or officer’s duty of loyalty to our company or our stockholders;

- any act or omission not in good faith or which involved intentional misconduct or a knowing violation of law;
- unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the DGCL;
- any transaction from which the director or officer derived an improper personal benefit.

As a result, neither we nor our stockholders have the right, through stockholders' derivative suits on our behalf, to recover monetary damages against a director or officer for breach of fiduciary duty as a director, including breaches resulting from grossly negligent behavior, except in the situations described above.

Our amended and restated certificate of incorporation also provides that, to the fullest extent permitted by law, we will indemnify any director or officer of our company against all damages, claims and liabilities arising out of the fact that the person is or was our director or officer, or served any other enterprise at our request as a director or officer. Amending this provision will not reduce our indemnification obligations relating to actions taken before an amendment.

## Transfer agent and registrar

The transfer agent and registrar for our common stock will be Fidelity Stock Transfer Solutions LLC. The transfer agent and registrar's address is 245 Summer Street, Boston, Massachusetts 02210, and its telephone number is (617) 563-5800.

## Stock exchange listing

Our common stock has been approved for listing on the Nasdaq Global Select Market under the symbol "KLRA."

# Shares eligible for future sale

Immediately prior to this offering, there was no public market for our common stock. Future sales of substantial amounts of our common stock in the public market, or the perception that such sales may occur, could adversely affect the market price of our common stock.

Upon the closing of this offering, we will have outstanding an aggregate of 123,677,939 shares of common stock, assuming the issuance of 39,062,500 shares of common stock offered by us in this offering, the automatic conversion of all outstanding shares of our preferred stock into 84,596,391 shares of our common stock and no exercise of options or warrants after December 31, 2025. Of these shares, all shares sold in this offering will be freely tradable without restriction or further registration under the Securities Act, except for any shares purchased by our "affiliates," as that term is defined in Rule 144 under the Securities Act, whose sales will be subject to the Rule 144 resale restrictions described below, other than the holding period requirement.

The remaining 84,615,439 shares of common stock will be "restricted securities," as that term is defined in Rule 144 under the Securities Act. These restricted securities are eligible for public sale only if they are registered under the Securities Act or if they qualify for an exemption from registration under Rules 144 or 701 under the Securities Act, which are summarized below. We expect that substantially all of these shares will be subject to the 180-day lock-up period under the lock-up agreements described below. Upon expiration of the lock-up period, substantially all of the shares subject to such lock up restrictions will be available for sale in the public market, subject in some cases to applicable volume limitations under Rule 144.

In addition, of the 13,470,409 shares of our common stock that were subject to stock options outstanding as of December 31, 2025, options to purchase 2,520,139 shares of common stock were vested as of December 31, 2025 and, upon exercise, these shares will be eligible for sale subject to the lock–up agreements described below and Rules 144 and 701 under the Securities Act, as applicable.

## Lock-up agreements

We and each of our directors and executive officers and holders of substantially all of our outstanding capital stock, have agreed that, without the prior written consent of two of the representatives of the underwriters, one of whom must be J.P. Morgan Securities LLC and the other of whom shall be selected by us in our sole discretion, we and they will not, subject to certain exceptions, during the period ending 180 days after the date of this prospectus, 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 purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any shares of our common stock or any securities convertible into or exercisable or exchangeable for common stock; or enter into any hedging, swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of our common stock, whether any transaction described above is to be settled by delivery of our common stock or such other securities, in cash or otherwise.

Upon the expiration of the applicable lock-up periods, substantially all of the shares subject to such lock-up restrictions will become eligible for sale, subject to the limitations discussed above. For a further description of these lock-up agreements, see the section titled "Underwriting."

## Rule 144

***Affiliate resales of restricted securities***

In general, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is an affiliate of ours, or who was an affiliate at any time during the 90 days before a sale,

who has beneficially owned shares of our common stock for at least six months would be entitled to sell in "broker's transactions" or certain "riskless principal transactions" or to market makers, a number of shares within any three-month period that does not exceed the greater of:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately 1,236,779 shares immediately after this offering; or
- the average weekly trading volume in our common stock on The Nasdaq Global Select Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Affiliate resales under Rule 144 are also subject to the availability of current public information about us. In addition, if the number of shares being sold under Rule 144 by an affiliate during any three-month period exceeds 5,000 shares or has an aggregate sale price in excess of $50,000, the seller must file a notice on Form 144 with the Securities and Exchange Commission and Nasdaq concurrently with either the placing of a sale order with the broker or the execution directly with a market maker.

***Non-affiliate resales of restricted securities***

In general, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is not an affiliate of ours at the time of sale, and has not been an affiliate at any time during the three months preceding a sale, and who has beneficially owned shares of our common stock for at least six months but less than a year, is entitled to sell such shares subject only to the availability of current public information about us. If such person has held our shares for at least one year, such person can resell under Rule 144(b)(1) without regard to any Rule 144 restrictions, including the 90-day public company requirement and the current public information requirement.

Non-affiliate resales are not subject to the manner of sale, volume limitation or notice filing provisions of Rule 144.

## Rule 701

In general, under Rule 701, any of an issuer's employees, directors, officers, consultants or advisors who purchases shares from the issuer in connection with a compensatory stock or option plan or other written agreement before the effective date of a registration statement under the Securities Act is entitled to sell such shares 90 days after such effective date in reliance on Rule 144. An affiliate of the issuer can resell shares in reliance on Rule 144 without having to comply with the holding period requirement, and non-affiliates of the issuer can resell shares in reliance on Rule 144 without having to comply with the current public information and holding period requirements.

The Securities and Exchange Commission has indicated that Rule 701 will apply to typical stock options granted by an issuer before it becomes subject to the reporting requirements of the Exchange Act, along with the shares acquired upon exercise of such options, including exercises after an issuer becomes subject to the reporting requirements of the Exchange Act.

## Equity plans

We intend to file one or more registration statements on Form S-8 under the Securities Act to register all shares of common stock subject to outstanding stock options and common stock issued or issuable under our stock plans. We expect to file the registration statement covering shares offered pursuant to our stock plans shortly after the date of this prospectus, permitting the resale of such shares by non-affiliates in the public market without restriction under the Securities Act and the sale by affiliates in the public market, subject to compliance with the resale provisions of Rule 144.

## Registration rights

Upon the closing of this offering, the holders of 84,596,391 shares of common stock, which includes all of the shares of common stock issuable upon the automatic conversion of our preferred stock upon the closing of this offering, or their transferees will be entitled to various rights with respect to the registration of these shares under the Securities Act. Registration of these shares under the Securities Act would result in these shares becoming fully 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. Shares covered by a registration statement will be eligible for sale in the public market upon the expiration or release from the terms of the lock-up agreement described above.

# Material U.S. federal income tax consequences to Non-U.S. Holders

The following discussion is a summary of the material U.S. federal income tax consequences to Non-U.S. Holders (as defined below) of the purchase, ownership and disposition of our common stock issued pursuant to this offering, but does not purport to be a complete analysis of all potential tax effects. The effects of other U.S. federal tax laws, such as estate and gift tax laws, and any applicable state, local or non-U.S. tax laws are not discussed. This discussion is based on the U.S. Internal Revenue Code of 1986, as amended, or the Code, Treasury Regulations promulgated thereunder, judicial decisions and published rulings and administrative pronouncements of the U.S. Internal Revenue Service, or the IRS, in each case in effect as of the date hereof. These authorities may change or be subject to differing interpretations. Any such change or differing interpretation may be applied retroactively in a manner that could adversely affect a Non-U.S. Holder. We have not sought and will not seek any rulings from the IRS regarding the matters discussed below. There can be no assurance the IRS or a court will not take a contrary position to that discussed below regarding the tax consequences of the purchase, ownership and disposition of our common stock.

This discussion is limited to Non-U.S. Holders that hold our common stock as a "capital asset" within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all U.S. federal income tax consequences relevant to a Non-U.S. Holder's particular circumstances, including the impact of the Medicare contribution tax on net investment income and the alternative minimum tax. In addition, it does not address consequences relevant to Non-U.S. Holders subject to special rules, including, without limitation:

- U.S. expatriates and former citizens or long-term residents of the United States;
- persons holding our common stock as part of a hedge, straddle or other risk reduction strategy or as part of a conversion transaction or other integrated investment;
- banks, insurance companies and other financial institutions;
- brokers, dealers or traders in securities;
- "foreign controlled foreign corporations," "controlled foreign corporations," "passive foreign investment companies" and corporations that accumulate earnings to avoid U.S. federal income tax;
- partnerships or other entities or arrangements treated as partnerships for U.S. federal income tax purposes (and investors therein);
- tax-exempt organizations or governmental organizations;
- persons deemed to sell our common stock under the constructive sale provisions of the Code;
- persons who hold or receive our common stock pursuant to the exercise of any employee stock option or otherwise as compensation;
- tax-qualified retirement plans;
- "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; and
- persons subject to special tax accounting rules as a result of any item of gross income with respect to the stock being taken into account in an applicable financial statement.

If an entity treated as a partnership for U.S. federal income tax purposes holds our common stock, the tax treatment of a partner in the partnership will depend on the status of the partner, the activities of the

partnership and certain determinations made at the partner level. Accordingly, partnerships holding our common stock and the partners in such partnerships should consult their tax advisors regarding the U.S. federal income tax consequences to them.

**THIS DISCUSSION IS FOR INFORMATIONAL PURPOSES ONLY AND IS NOT TAX ADVICE. INVESTORS SHOULD CONSULT THEIR TAX ADVISORS WITH RESPECT TO THE APPLICATION OF THE U.S. FEDERAL INCOME TAX LAWS TO THEIR PARTICULAR SITUATIONS AS WELL AS ANY TAX CONSEQUENCES OF THE PURCHASE, OWNERSHIP AND DISPOSITION OF OUR COMMON STOCK ARISING UNDER THE U.S. FEDERAL ESTATE OR GIFT TAX LAWS OR UNDER THE LAWS OF ANY STATE, LOCAL OR NON-U.S. TAXING JURISDICTION OR UNDER ANY APPLICABLE INCOME TAX TREATY**.

## Definition of a non-U.S. holder

For purposes of this discussion, a “Non-U.S. Holder” is any beneficial owner of our common stock that is neither a “U.S. person” nor an entity treated as a partnership for U.S. federal income tax purposes. A “U.S. person” is any person that, for U.S. federal income tax purposes, is or is treated as any of the following:

- an individual who is a citizen or resident of the United States;
- a corporation created or organized under the laws of the United States, any state thereof or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust that (i) is subject to the primary supervision of a U.S. court and the control of one or more “United States persons” (within the meaning of Section 7701(a)(30) of the Code), or (ii) has a valid election in effect to be treated as a “United States person” for U.S. federal income tax purposes.

## Distributions

As described in the section titled “Dividend policy,” we do not anticipate declaring or paying any dividends to holders of our common stock in the foreseeable future. However, if we do make distributions of cash or property on our common stock, such distributions will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Amounts not treated as dividends for U.S. federal income tax purposes will constitute a return of capital and first be applied against and reduce a Non-U.S. Holder’s adjusted tax basis in its common stock, but not below zero. Any excess will be treated as capital gain and will be treated as described below under “—Sale or Other Taxable Disposition.”

Subject to the discussion below regarding effectively connected income, dividends paid to a Non-U.S. Holder will be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends (or such lower rate specified by an applicable income tax treaty, provided the Non-U.S. Holder furnishes a valid IRS Form W-8BEN or W-8BEN-E (or other applicable documentation) certifying qualification for the lower treaty rate). A Non-U.S. Holder that does not timely furnish the required documentation, but that qualifies for a reduced treaty rate, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS. Non-U.S. Holders should consult their tax advisors regarding their entitlement to benefits under any applicable income tax treaties.

If dividends paid to a Non-U.S. Holder are effectively connected with the Non-U.S. Holder’s conduct of a trade or business within the United States for U.S. federal income tax purposes (and, if required by an applicable income tax treaty, the Non-U.S. Holder maintains a permanent establishment in the United States to which such

dividends are attributable), the Non-U.S. Holder will be exempt from the U.S. federal withholding tax described above. To claim the exemption, the Non-U.S. Holder must furnish to the applicable withholding agent a valid IRS Form W-8ECI (or other applicable documentation) certifying that the dividends are effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States for U.S. federal income tax purposes.

Any such effectively connected dividends will be subject to U.S. federal income tax on a net income basis at the regular rates applicable to U.S. persons. A Non-U.S. Holder that is a corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on such effectively connected dividends, as adjusted for certain items. Non-U.S. Holders should consult their tax advisors regarding any applicable tax treaties that may provide for different rules.

### Sale or other taxable disposition

A Non-U.S. Holder will not be subject to U.S. federal income tax on any gain realized upon the sale or other taxable disposition of our common stock unless:

- the gain is effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States for U.S. federal income tax purposes (and, if required by an applicable income tax treaty, the Non-U.S. Holder maintains a permanent establishment in the United States to which such gain is attributable);
- the Non-U.S. Holder is a nonresident alien individual present in the United States for 183 days or more during the taxable year of the sale or other taxable disposition and certain other requirements are met; or
- our common stock constitutes a U.S. real property interest, or the USRPI, by reason of our status as a U.S. real property holding corporation, or the USRPHC, for U.S. federal income tax purposes.

Gain described in the first bullet point above generally will be subject to U.S. federal income tax on a net income basis at the regular rates applicable to U.S. persons. A Non-U.S. Holder that is a corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on such effectively connected gain, as adjusted for certain items.

A Non-U.S. Holder described in the second bullet point above will be subject to U.S. federal income tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on gain realized upon the sale or other taxable disposition of our common stock, which may be offset by U.S. source capital losses of the Non-U.S. Holder (even though the individual is not considered a resident of the United States), provided the Non-U.S. Holder has timely filed U.S. federal income tax returns with respect to such losses.

With respect to the third bullet point above, we believe we currently are not, and do not anticipate becoming, a USRPHC. Because the determination of whether we are a USRPHC depends, however, on the fair market value of our USRPIs relative to the fair market value of our non-U.S. real property interests and our other business assets, there can be no assurance we currently are not a USRPHC or will not become one in the future. Even if we are or were to become a USRPHC, gain arising from the sale or other taxable disposition of our common stock by a Non-U.S. Holder will not be subject to U.S. federal income tax if our common stock is "regularly traded" on an "established securities market" (in each case, as defined by applicable Treasury Regulations), and such Non-U.S. Holder owned, actually and constructively, 5% or less of our common stock throughout the shorter of the five-year period ending on the date of the sale or other taxable disposition or the Non-U.S. Holder's holding period.

Non-U.S. Holders should consult their tax advisors regarding potentially applicable income tax treaties that may provide for different rules.

## Information reporting and backup withholding

Payments of dividends on our common stock will not be subject to backup withholding, provided the applicable withholding agent does not have actual knowledge or reason to know the holder is a U.S. person and the Non-U.S. Holder either certifies its non-U.S. status, such as by furnishing a valid IRS Form W-8BEN, W-8BEN-E or W-8ECI (or other applicable documentation), or otherwise establishes an exemption. However, information returns are required to be filed with the IRS in connection with any distributions on our common stock paid to the Non-U.S. Holder, regardless of whether such distributions constitute dividends or whether any tax was actually withheld. In addition, proceeds from the sale or other taxable disposition of our common stock within the United States or conducted through certain U.S.-related brokers generally will not be subject to backup withholding or information reporting if the applicable withholding agent receives the certification described above and does not have actual knowledge or reason to know that such holder is a U.S. person or the Non-U.S. Holder otherwise establishes an exemption. Proceeds of a sale or other taxable disposition of our common stock conducted through a non-U.S. office of a non-U.S. broker generally will not be subject to backup withholding or information reporting. Copies of information returns that are filed with the IRS may also be made available under the provisions of an applicable treaty or agreement to the tax authorities of the country in which the Non-U.S. Holder resides or is established.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a refund or a credit against a Non-U.S. Holder's U.S. federal income tax liability, provided the required information is timely furnished to the IRS.

## Additional withholding tax on payments made to foreign accounts

Withholding taxes may be imposed under Sections 1471 to 1474 of the Code (such Sections commonly referred to as the Foreign Account Tax Compliance Act, or FATCA) on certain types of payments made to non-U.S. financial institutions and certain other non-U.S. entities. Specifically, a 30% withholding tax may be imposed on dividends on, or, subject to the proposed Treasury Regulations discussed below, gross proceeds from the sale or other disposition of, our common stock paid to a "foreign financial institution" or a "non-financial foreign entity" (each as defined in the Code), unless (i) the foreign financial institution undertakes certain diligence and reporting obligations, (ii) 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 (iii) the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from these rules. If the payee is a foreign financial institution and is subject to the diligence and reporting requirements in (i) 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 applies to payments of dividends on our common stock. While withholding under FATCA would have applied also to payments of gross proceeds from the sale or other disposition of stock beginning on or after January 1, 2019, proposed Treasury Regulations eliminate FATCA withholding on payments of gross proceeds entirely. Taxpayers generally may rely on these proposed Treasury Regulations until final Treasury Regulations are issued.

Prospective investors should consult their tax advisors regarding the potential application of withholding under FATCA to their investment in our common stock.

# Underwriting

We are offering the shares of common stock described in this prospectus through a number of underwriters. J.P. Morgan Securities LLC, Jefferies LLC, Leerink Partners LLC, TD Securities (USA) LLC and Evercore Group L.L.C. are acting as joint book-running managers of the offering and as representatives of the underwriters. We have entered into an underwriting agreement with the underwriters. Subject to the terms and conditions of the underwriting agreement, we have agreed to sell to the underwriters, and each underwriter has severally agreed to purchase, at the public offering price less the underwriting discounts and commissions set forth on the cover page of this prospectus, the number of shares of common stock listed next to its name in the following table:

| Name | Number of shares |
|---|---|
| J.P. Morgan Securities LLC | 10,937,500 |
| Jefferies LLC | 6,250,000 |
| Leerink Partners LLC | 6,250,000 |
| TD Securities (USA) LLC | 6,250,000 |
| Evercore Group L.L.C. | 6,250,000 |
| William Blair & Company, L.L.C. | 3,125,000 |
| Total | 39,062,500 |

The underwriters are committed to purchase all the shares of common stock offered by us if they purchase any shares. The underwriting agreement also provides that if an underwriter defaults, the purchase commitments of non-defaulting underwriters may also be increased or the offering may be terminated.

The underwriters propose to offer the shares of common stock directly to the public at the initial public offering price set forth on the cover page of this prospectus and to certain dealers at that price less a concession not in excess of $0.672 per share. After the initial offering of the shares to the public, if all of the shares of common stock are not sold at the initial public offering price, the underwriters may change the offering price and the other selling terms. Sales of any shares of common stock made outside of the United States may be made by affiliates of the underwriters.

The underwriters have an option to purchase up to 5,859,375 additional shares of common stock from us to cover sales of shares by the underwriters which exceed the number of shares specified in the table above. The underwriters have 30 days from the date of this prospectus to exercise this option to purchase additional shares. If any shares are purchased with this option to purchase additional shares, the underwriters will purchase shares in approximately the same proportion as shown in the table above. If any additional shares of common stock are purchased, the underwriters will offer the additional shares on the same terms as those on which the shares are being offered.

We have received non-binding indications of interest from certain of our existing stockholders, including entities affiliated with Bain Capital Private Equity, Bain Capital Life Sciences and Qatar Investment Authority, to purchase up to an aggregate of approximately $225 million in shares of our common stock in this offering at the initial public offering price per share, on the same terms as the other purchasers in this offering. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters could determine to sell more, fewer or no shares to our existing stockholders, and our existing stockholders could determine to purchase more, fewer or no shares in this offering. The underwriters will receive the same underwriting discount and commissions on these shares as they will on any other shares sold to the public in this offering. The number of shares of common stock available for sale to the general public will be reduced to the extent that our existing stockholders purchase shares of common stock in the offering.

The underwriting fee is equal to the public offering price per share of common stock less the amount paid by the underwriters to us per share of common stock. The underwriting fee is $1.12 per share. The following table shows the per share and total underwriting discounts and commissions to be paid to the underwriters assuming both no exercise and full exercise of the underwriters' option to purchase additional shares.

| | Without option to purchase additional shares exercise | With full option to purchase additional shares exercise |
|---|---|---|
| Per share | $ 1.12 | $ 1.12 |
| Total | $ 43,750,000 | $ 50,312,500 |

We estimate that the total expenses of this offering, including registration, filing and listing fees, printing fees and legal and accounting expenses, but excluding the underwriting discounts and commissions, will be approximately $6.3 million. We have agreed to reimburse the underwriters for expenses of up to $50,000 relating to the clearance of this offering with the Financial Industry Regulatory Authority.

A prospectus in electronic format may be made available on the web sites maintained by one or more underwriters, or selling group members, if any, participating in the offering. The underwriters may agree to allocate a number of shares to underwriters and selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the representatives to underwriters and selling group members that may make Internet distributions on the same basis as other allocations.

We have agreed that we will not (i) 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 purchase, lend or otherwise transfer or dispose of, directly or indirectly, or submit to, or file with, the Securities and Exchange Commission a registration statement under the Securities Act relating to, any shares of our common stock or securities convertible into or exercisable or exchangeable for any shares of our common stock, provided that we may undertake preparations related thereto, or publicly disclose the intention to make any offer, sale, pledge, loan, disposition or filing, or (ii) enter into any hedging, swap or other arrangement that transfers all or a portion of the economic consequences associated with the ownership of any shares of common stock or any such other securities (regardless of whether any of these transactions are to be settled by the delivery of shares of common stock or such other securities, in cash or otherwise), in each case without the prior written consent of two of the representatives of the underwriters, one of whom must be J.P. Morgan Securities LLC and the other of whom shall be selected by us in our sole discretion, for a period of 180 days after the date of this prospectus, other than the shares of our common stock to be sold in this offering.

The restrictions on our actions, as described above, do not apply to: (i) the issuance of shares of common stock or securities convertible into or exercisable for shares of our common stock pursuant to the conversion or exchange of convertible or exchangeable securities or the exercise of warrants or options (including net exercise) or the settlement of RSUs (including net settlement), in each case outstanding on the date of the underwriting agreement and described in this prospectus; (ii) grants of stock options, stock awards, restricted stock, RSUs, or other equity awards and the issuance of shares of our common stock or securities convertible into or exercisable or exchangeable for shares of our common stock (whether upon the exercise of stock options or otherwise) to our employees, officers, directors, advisors, or consultants pursuant to the terms of an equity compensation plan in effect as of the closing of this offering; (iii) the sale or issuance of or entry into an agreement to sell or issue up to 10% of the outstanding shares of our common stock, or securities convertible into, exercisable for, or which are otherwise exchangeable for, our common stock, immediately following the closing of this offering, in connection with any merger, acquisition of securities, businesses, property or other assets, joint ventures, strategic alliances, or commercial, lending or other collaborative or other strategic transactions or the assumption of an employee

benefit plan in connection with a merger or acquisition; (iv) our filing of any registration statement on Form S-8 relating to securities granted or to be granted pursuant to any plan in effect on the date of the underwriting agreement or any assumed benefit plan pursuant to an acquisition or similar strategic transaction; or (v) facilitating the establishment of a trading plan on behalf of our stockholder, officer or director pursuant to Rule 10b5-1 under the Exchange Act for the transfer of shares of common stock, provided that (i) such plan does not provide for the transfer of common stock during the lock-up period and (ii) to the extent a public announcement or filing under the Exchange Act, if any, is required of or voluntarily made by us regarding the establishment of such plan, such announcement or filing shall include a statement to the effect that no transfer of common stock may be made under such plan during the lock-up period.

Our directors and executive officers, and substantially all of our shareholders (such persons, the “lock-up parties”) have entered into lock-up agreements with the underwriters prior to the commencement of this offering pursuant to which each lock-up party, with limited exceptions, for a period of 180 days after the date of this prospectus (such period, the “restricted period”), may not, without the prior written consent of two of the representatives of the underwriters, one of whom must be J.P. Morgan Securities LLC and the other of whom shall be selected by us in our sole discretion, (1) 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 purchase, lend or otherwise transfer or dispose of, directly or indirectly, any shares of our common stock or any securities convertible into or exercisable or exchangeable for our common stock (including, without limitation, common stock or such other securities which may be deemed to be beneficially owned by such lock-up parties as of the date of the underwriting agreement in accordance with the rules and regulations of the SEC and securities which may be issued upon exercise of a stock option or warrant (collectively with the common stock, the “lock-up securities”)), (2) enter into any hedging, swap or other agreement or transaction that transfers, in whole or in part, any of the economic consequences of ownership of the lock-up securities, whether any such transaction described in clause (1) or (2) above is to be settled by delivery of lock-up securities, in cash or otherwise, (3) make any demand for, or exercise any right with respect to, the registration of any lock-up securities, or (4) publicly disclose the intention to do any of the foregoing. Such persons or entities have further acknowledged that these undertakings preclude them from engaging during the restricted period in any hedging or other transactions or arrangements (including, without limitation, any short sale or the purchase or sale of, or entry into, any put or call option, or combination thereof, forward, swap or any other derivative transaction or instrument, however described or defined) designed or intended, or which could reasonably be expected to lead to or result in, a sale or disposition or transfer (by any person or entity, whether or not a signatory to such agreement) of any economic consequences of ownership, in whole or in part, directly or indirectly, of any lock-up securities, whether any such transaction or arrangement (or instrument provided for thereunder) would be settled by delivery of lock-up securities, in cash or otherwise.

The restrictions described in the immediately preceding paragraph and contained in the lock-up agreements between the underwriters and the lock-up parties do not apply, subject in certain cases to various conditions, to certain transactions, including (a) sales, transfers or other disposals of, or entry into any transaction relating to the lock-up securities: (i) as a bona fide gift or gifts, or for bona fide estate planning purposes; (ii) by will, other testamentary document or intestacy; (iii) to any immediate family member of the lock-up party or any trust or other legal entity for the direct or indirect benefit of the lock-up party or any immediate family member, or if the lock-up party is a trust, to a trustor, trustee (or co-trustee) or beneficiary of the trust or to the estate of a beneficiary of the trust; (iv) to a corporation, partnership, limited liability company or other entity of which the lock-up party and/or its immediate family members are, directly or indirectly, the legal and beneficial owners of all of the outstanding equity securities or similar interests; (v) in the case of a corporation, partnership, limited liability company, trust or other business entity, (A) to another corporation, partnership, limited liability company, trust or other business entity that is a direct or indirect affiliate of the lock-up party, or to any investment fund or other, directly or indirectly, entity controlling, controlled by, managing, managed by, or

under common control or common investment management with the lock-up party or its affiliates (including, for the avoidance of doubt, where the lock-up party is a partnership, to its general partner or a successor partnership or fund, or any other funds managed by such partnership) or (B) as part of a distribution, transfer or disposition to limited partners, general partners, members, beneficiaries, stockholders, affiliates, or holders of similar equity interests of the lock-up party or its affiliates (including a fund managed by the same manager or managing member or general partner or management company or by an entity controlling, controlled by, or under common control with such manager or managing member or general partner or management company as the lock-up party or who shares a common investment advisor with the lock-up party); (vi) to a nominee or custodian of a person or entity to whom a disposition or transfer would be permissible under clauses (i) through (v); (vii) by operation of law, such as pursuant to a qualified domestic order, divorce settlement, divorce decree or separation agreement, or pursuant to a final order of a court or regulatory agency; (viii) to us from an employee or consultant of ours upon death, disability or termination of employment, in each case, of such employee or consultant; (ix) as part of a sale (including any swap, hedge, derivate or other synthetic arrangement) of lock-up securities (A) purchased by the lock-up party in this offering or (B) acquired in open market or other transactions after this offering or that otherwise do not involve or relate to shares of our capital stock owned by the lock-up party prior to this offering, provided, however, that the carveout specified in clause (ix) shall not be available to our directors and executive officers; (x) to us in connection with the vesting, settlement or exercise of restricted stock units, options, warrants or other rights to purchase shares of our common stock (including, in each case, by way of “net” or “cashless” exercise), including for the payment of exercise price and tax withholdings or remittance payments due as a result of the vesting, settlement, or exercise of such restricted stock units, options, warrants or rights; (xi) in connection with open market transactions to generate such amount of net proceeds to the lock-up parties from such sales (after deducting commissions) in an aggregate amount up to the total amount of taxes or estimated taxes (as applicable) that become due as a result of the vesting, exercise and/or settlement of our equity awards held by the lock-up parties and issued pursuant to a plan or arrangement described in this prospectus that vest, are exercised and/or settle during the restricted period, and provided further, that the carveout specified in clause (xi) shall not be available to our directors and executive officers, or (xii) pursuant to a bona fide third-party tender offer, merger, consolidation or other similar transaction made to all shareholders involving a change in control, provided that if such transaction is not completed, all such lock-up securities would remain subject to the restrictions in the immediately preceding paragraph; (b) exercise of outstanding options, settlement of restricted stock units or other equity awards, or exercise of warrants pursuant to plans or other equity compensation arrangements described in this prospectus, provided that any lock-up securities received upon such exercise, vesting or settlement would be subject to restrictions similar to those in the immediately preceding paragraph; (c) conversion of outstanding preferred stock, warrants to acquire preferred stock, or convertible securities into shares of our common stock or warrants to acquire shares of our common stock, provided that any common stock or warrants received upon such conversion would be subject to restrictions similar to those in the immediately preceding paragraph; (d) any demand or requests for, any right with respect to, or any action in preparation of the registration by us under the Securities Act of the lock-up party’s lock-up securities or other securities; provided that (1) no public filing with the SEC or any other public announcement may be made during the restricted period in relation to such registration, (2) the representatives of the underwriters must have received prior written notice from us and/or the lock-up parties of a confidential submission of a registration statement with the SEC during the restricted period at least seven business days prior to such submission, and (3) no lock-up securities or other securities of ours may be sold, distributed or exchanged prior to the expiration of the restricted period; and (e) the establishment of trading plans under Rule 10b5-1 under the Exchange Act for the transfer of lock-up securities, provided that (1) such plans do not provide for the transfer of lock-up securities during the restricted period and (2) any public announcement or filing under the Exchange Act regarding such plan includes a statement to the effect that no transfer of stock may be made under such plan during the restricted period.

The securities subject to any of the lock-up agreements with the underwriters may be released from the restrictions described above, in whole or in part at any time, with the consent of two of the representatives of the underwriters, one of whom must be J.P. Morgan Securities LLC and the other of whom shall be selected by us in our sole discretion.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act.

Our common stock has been approved for listing on the Nasdaq Global Select Market under the symbol “KLRA”.

In connection with this offering, the underwriters may engage in stabilizing transactions, which involves making bids for, purchasing and selling shares of common stock in the open market for the purpose of preventing or retarding a decline in the market price of the common stock while this offering is in progress. These stabilizing transactions may include making short sales of common stock, which involves the sale by the underwriters of a greater number of shares of common stock than they are required to purchase in this offering, and purchasing shares of common stock on the open market to cover positions created by short sales. Short sales may be “covered” shorts, which are short positions in an amount not greater than the underwriters’ option to purchase additional shares referred to above, or may be “naked” shorts, which are short positions in excess of that amount. The underwriters may close out any covered short position either by exercising their option to purchase additional shares, in whole or in part, or by purchasing shares in the open market. In making this determination, the underwriters will consider, among other things, the price of shares available for purchase in the open market compared to the price at which the underwriters may purchase shares through the option to purchase additional shares. 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 that could adversely affect investors who purchase in this offering. To the extent that the underwriters create a naked short position, they will purchase shares in the open market to cover the position.

The underwriters have advised us that, pursuant to Regulation M of the Securities Act, they may also engage in other activities that stabilize, maintain or otherwise affect the price of the common stock, including the imposition of penalty bids. This means that if the representatives of the underwriters purchase common stock in the open market in stabilizing transactions or to cover short sales, the representatives can require the underwriters that sold those shares as part of this offering to repay the underwriting discount received by them.

These activities may have the effect of raising or maintaining the market price of the common stock or preventing or retarding a decline in the market price of the common stock, and, as a result, the price of the common stock may be higher than the price that otherwise might exist in the open market. If the underwriters commence these activities, they may discontinue them at any time. The underwriters may carry out these transactions on the Nasdaq Global Select Market, in the over-the-counter market or otherwise.

Prior to this offering, there has been no public market for our common stock. The initial public offering price was determined by negotiations between us and the representatives of the underwriters. In determining the initial public offering price, we and the representatives of the underwriters considered a number of factors including:

- the information set forth in this prospectus and otherwise available to the representatives;
- our prospects and the history and prospects for the industry in which we compete;
- an assessment of our management;
- our prospects for future earnings;

- the general condition of the securities markets at the time of this offering;
- the recent market prices of, and demand for, publicly traded common stock of generally comparable companies; and
- other factors deemed relevant by the underwriters and us.

Neither we nor the underwriters can assure investors that an active trading market will develop for our shares of common stock, or that the shares will trade in the public market at or above the initial public offering price.

Other than in the United States, no action has been taken by us or the underwriters that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

## Notice to prospective investors in the European Economic Area

In relation to each Member State of the European Economic Area, each a Relevant State, no shares of our common stock have been offered or will be offered pursuant to the offering to the public in that Relevant State prior to the publication of a prospectus in relation to the shares of our common stock which has been approved by the competent authority in that Relevant State or, where appropriate, approved in another Relevant State and notified to the competent authority in that Relevant State, all in accordance with the Prospectus Regulation, except that offers of Shares may be made to the public in that Relevant State other than at any time under the following exemptions under the Prospectus Regulation:

(a) to any legal entity which is a qualified investor as defined under the Prospectus Regulation;

(b) to fewer than 150 natural or legal persons (other than qualified investors as defined under the Prospectus Regulation), subject to obtaining the prior consent of the underwriters 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 shares of common stock shall require us or any underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation and each person who initially acquires any shares of common stock or to whom any offer is made will be deemed to have represented, acknowledged and agreed to and with each of the underwriters and us that it is a “qualified investor” within the meaning of Article 2(e) of the Prospectus Regulation.

In the case of any shares of common stock being offered to a financial intermediary as that term is used in the Prospectus Regulation, each such financial intermediary will be deemed to have represented, acknowledged and agreed that the shares of common stock acquired by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer of any shares of common stock to the public other than their offer or resale in a Relevant State to qualified investors as so defined or in circumstances in which the prior consent of the underwriters has been obtained to each such proposed offer or resale.

For the purposes of this provision, the expression an “offer to the public” in relation to any shares of common stock in any Relevant State 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.

## Notice to prospective investors in the United Kingdom

No shares of common stock 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 of our common stock which either (i) has been approved by the Financial Conduct Authority or (ii) is to be treated as if it had been approved by the Financial Conduct Authority in accordance with the transitional provisions in Article 74 (transitional provisions) of the Prospectus (Amendment etc.) (EU Exit) Regulations 2019/1234, except that the shares of our common stock 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 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 share of our common stock shall require us or any representative 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 of our common stock 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 of our common stock to be offered so as to enable an investor to decide to purchase or subscribe for any shares of our common stock 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.

In addition, in the United Kingdom, this document is being distributed only to, and is directed only at, and any offer subsequently made may only be directed at persons who are “qualified investors” (as defined in the Prospectus Regulation) (i) who have professional experience in matters relating to investments falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended, or the Order, and/or (ii) who are high net worth companies (or persons to whom it may otherwise be lawfully communicated) falling within Article 49(2)(a) to (d) of the Order (all such persons together being referred to as “relevant persons”) or otherwise in circumstances which have not resulted and will not result in an offer to the public of the Shares in the United Kingdom within the meaning of the Financial Services and Markets Act 2000.

Any person in the United Kingdom that is not a relevant person should not act or rely on the information included in this document or use it as basis for taking any action. In the United Kingdom, any investment or investment activity that this document relates to may be made or taken exclusively by relevant persons.

## Notice to prospective investors in Canada

The shares of common stock may be sold 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 shares of common stock must be made in accordance with an exemption from, 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 for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 of National Instrument 33-105 Underwriting Conflicts, or 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.

## Notice to prospective investors in Switzerland

This prospectus does not constitute an offer to the public or a solicitation to purchase or invest in any shares. No shares have been offered or will be offered to the public in Switzerland, except that offers of shares may be made to the public in Switzerland at any time under the following exemptions under the Swiss Financial Services Act ("FinSA"):

(a) to any person which is a professional client as defined under the FinSA;

(b) to fewer than 500 persons (other than professional clients as defined under the FinSA), subject to obtaining the prior consent of the representatives of the underwriters for any such offer; or

(c) in any other circumstances falling within Article 36 FinSA in connection with Article 44 of the Swiss Financial Services Ordinance,

provided that no such offer of shares shall require the Company or any investment bank to publish a prospectus pursuant to Article 35 FinSA.

The shares have not been and will not be listed or admitted to trading on a trading venue in Switzerland.

Neither this document nor any other offering or marketing material relating to the shares constitutes a prospectus as such term is understood pursuant to the FinSA and neither this document nor any other offering or marketing material relating to the shares may be publicly distributed or otherwise made publicly.

## Notice to prospective investors in Hong Kong

The shares of common stock have not been offered or sold, and will not be offered or sold, in Hong Kong, by means of any document, other than (a) to "professional investors" as defined in the Securities and Futures Ordinance (Cap. 571 of the laws of Hong Kong), or the SFO, and any rules made thereunder; or (b) in other circumstances which do not result in the document being a "prospectus" as defined in the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32) of Hong Kong, or the CO, or which do not constitute an offer to the public within the meaning of the CO. No advertisement, invitation or document relating to the shares of common stock has been or may be issued or has been or may be in the possession of any person for the purposes of issue, 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 of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to shares of common stock which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" as defined in the SFO and any rules made thereunder.

## Notice to prospective investors in Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, no shares of common stock have been or will be offered or sold and no shares of common stock have been or will be made the subject of an invitation for subscription or purchase, and no prospectus or any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares, has been or will be circulated or distributed, whether directly or indirectly, to any person in Singapore other than (i) to an institutional investor (as defined in Section 4A of the Securities and Futures Act 2001 of Singapore, as modified or amended from time to time (the "SFA")) pursuant to 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.

Singapore SFA Product Classification—in connection with Section 309B of the SFA and the CMP Regulations 2018, unless otherwise specified before an offer of shares of our common stock, we have determined, and hereby notify all relevant persons (as defined in Section 309A(1) of the SFA), that the shares of common stock 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)

## Notice to prospective investors in Japan

The shares of common stock have not been and will not be registered pursuant to Article 4, Paragraph 1 of the Financial Instruments and Exchange Act. Accordingly, none of the shares of common stock nor any interest therein may be offered or sold, directly or indirectly, in Japan or to, or for the benefit of, any "resident" of Japan (which term as used herein means any person resident in Japan, including any corporation or other entity organized under the laws of Japan), or to others for re-offering or resale, directly or indirectly, in Japan or to or for the benefit of a resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the Financial Instruments and Exchange Act and any other applicable laws, regulations and ministerial guidelines of Japan in effect at the relevant time.

## Notice to prospective investors in the United Arab Emirates

The shares of common stock have not been, and are not being, publicly offered, sold, promoted or advertised in the United Arab Emirates (including the Dubai International Financial Centre, or the DIFC) other than in compliance with the laws of the United Arab Emirates (and the DIFC) governing the issue, offering and sale of securities. Further, this prospectus does not constitute a public offer of securities in the United Arab Emirates (including the DIFC) and is not intended to be a public offer. This prospectus has not been approved by or filed with the Central Bank of the United Arab Emirates, the Securities and Commodities Authority or the Dubai Financial Services Authority, or the DFSA.

## Notice to prospective investors in Israel

This prospectus does not constitute a prospectus under the Israeli Securities Law, 5728—1968, or the Israeli Securities Law, and has not been filed with or approved by the Israel Securities Authority. In Israel, this prospectus is being distributed only to, and is directed only at, and any offer of the shares of common stock is directed only at, (i) a limited number of persons in accordance with the Israeli Securities Law and (ii) investors listed in the first addendum, or the Addendum, to the Israeli Securities Law, consisting primarily of joint investment in trust funds, provident funds, insurance companies, banks, portfolio managers, investment

advisors, members of the Tel Aviv Stock Exchange, underwriters, venture capital funds, entities with equity in excess of NIS 50 million and "qualified individuals," each as defined in the Addendum (as it may be amended from time to time), or, collectively referred to as qualified investors (in each case, purchasing for their own account or, where permitted under the Addendum, for the accounts of their clients who are investors listed in the Addendum). Qualified investors are required to submit written confirmation that they fall within the scope of the Addendum, are aware of the meaning of same and agree to it.

## Notice to prospective investors in Australia

This prospectus:

(a) does not constitute a disclosure document or a prospectus under Chapter 6D.2 of the Corporations Act 2001 (Cth), or the Corporations Act;

(b) has not been, and will not be, lodged with the Australian Securities and Investments Commission, or ASIC, as a disclosure document for the purposes of the Corporations Act and does not purport to include the information required of a disclosure document for the purposes of the Corporations Act; and

(c) may only be provided in Australia to select investors who are able to demonstrate that they fall within one or more of the categories of investors, or Exempt Investors, available under section 708 of the Corporations Act.

The shares of common stock may not be directly or indirectly offered for subscription or purchased or sold, and no invitations to subscribe for or buy the shares of common stock may be issued, and no draft or definitive offering memorandum, advertisement or other offering material relating to any shares of common stock may be distributed in Australia, except where disclosure to investors is not required under Chapter 6D of the Corporations Act or is otherwise in compliance with all applicable Australian laws and regulations. By submitting an application for the shares of common stock, you represent and warrant to us that you are an Exempt Investor.

As any offer of shares of common stock under this document will be made without disclosure in Australia under Chapter 6D.2 of the Corporations Act, the offer of those securities for resale in Australia within 12 months may, under section 707 of the Corporations Act, require disclosure to investors under Chapter 6D.2 if none of the exemptions in section 708 applies to that resale. By applying for the shares of common stock you undertake to us that you will not, for a period of 12 months from the date of issue of the shares of common stock, offer, transfer, assign or otherwise alienate those shares of common stock to investors in Australia except in circumstances where disclosure to investors is not required under Chapter 6D.2 of the Corporations Act or where a compliant disclosure document is prepared and lodged with ASIC.

## Notice to prospective investors in China

This prospectus will not be circulated or distributed in the PRC and the shares of common stock will not be offered or sold, and will not be offered or sold to any person for re-offering or resale directly or indirectly to any residents of the PRC except pursuant to any applicable laws and regulations of the PRC. Neither this prospectus nor any advertisement or other offering material may be distributed or published in the PRC, except under circumstances that will result in compliance with applicable laws and regulations.

## Notice to prospective investors in Korea

The shares of common stock have not been and will not be registered under the Financial Investments Services and Capital Markets Act of Korea and the decrees and regulations thereunder, or the FSCMA, and the shares of

common stock have been and will be offered in Korea as a private placement under the FSCMA. None of the shares of common stock may be offered, sold or delivered directly or indirectly, or offered or sold to any person for re-offering or resale, directly or indirectly, in Korea or to any resident of Korea except pursuant to the applicable laws and regulations of Korea, including the FSCMA and the Foreign Exchange Transaction Law of Korea and the decrees and regulations thereunder, or FETL. Furthermore, the purchaser of the shares of common stock shall comply with all applicable regulatory requirements (including but not limited to requirements under the FETL) in connection with the purchase of the shares of common stock. By the purchase of the shares of common stock, the relevant holder thereof will be deemed to represent and warrant that if it is in Korea or is a resident of Korea, it purchased the shares of common stock pursuant to the applicable laws and regulations of Korea.

## Notice to prospective investors in Saudi Arabia

This document may not be distributed in the Kingdom of Saudi Arabia except to such persons as are permitted under the Offers of Securities Regulations as issued by the board of the Saudi Arabian Capital Market Authority, or CMA, pursuant to resolution number 2-11-2004 dated 4 October 2004 as amended by resolution number 1-28-2008, as amended, or the CMA Regulations. The CMA does not make any representation as to the accuracy or completeness of this document and expressly disclaims any liability whatsoever for any loss arising from, or incurred in reliance upon, any part of this document. Prospective purchasers of the securities offered hereby should conduct their own due diligence on the accuracy of the information relating to the securities. If you do not understand the contents of this document, you should consult an authorized financial adviser.

## Notice to prospective investors in the Dubai International Financial Centre

This document relates to an Exempt Offer in accordance with the Markets Rules 2012 of the DFSA. This document is intended for distribution only to persons of a type specified in the Markets Rules 2012 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 supplement nor taken steps to verify the information set forth herein and has no responsibility for this document. The securities to which this 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 document, you should consult an authorized financial advisor.

In relation to its use in the DIFC, this document is strictly private and confidential and is being distributed to a limited number of investors and must not be provided to any person other than the original recipient, and may not be reproduced or used for any other purpose. The interests in the securities may not be offered or sold directly or indirectly to the public in the DIFC.

## Notice to prospective investors in Bermuda

Shares of common stock may be offered or sold in Bermuda only in compliance with the provisions of the Investment Business Act of 2003 of Bermuda which regulates the sale of securities in Bermuda. Additionally, non-Bermudian persons (including companies) may not carry on or engage in any trade or business in Bermuda unless such persons are permitted to do so under applicable Bermuda legislation.

## Notice to prospective investors in the British Virgin Islands

The shares of common stock are not being, and may not be offered, to the public or to any person in the British Virgin Islands for purchase or subscription by or on behalf of the Company. The shares of common stock may be

offered to companies incorporated under the BVI Business Companies Act, 2004 (British Virgin Islands), or the BVI Companies, but only where the offer will be made to, and received by, the relevant BVI Company entirely outside of the British Virgin Islands.

## Notice to prospective investors in Malaysia

No prospectus or other offering material or document in connection with the offer and sale of the shares of common stock has been or will be registered with the Securities Commission of Malaysia, or the Commission, for the Commission's approval pursuant to the Capital Markets and Services Act 2007. 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 of common stock may not be circulated or distributed, nor may the shares of common stock be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Malaysia other than (i) a closed end fund approved by the Commission, (ii) a holder of a Capital Markets Services License, (iii) a person who acquires the shares of common stock, as principal, if the offer is on terms that the shares of common stock may only be acquired at a consideration of not less than RM250,000 (or its equivalent in foreign currencies) for each transaction, (iv) an individual whose total net personal assets or total net joint assets with his or her spouse exceeds RM3 million (or its equivalent in foreign currencies), excluding the value of the primary residence of the individual, (v) an individual who has a gross annual income exceeding RM300,000 (or its equivalent in foreign currencies) per annum in the preceding twelve months, (vi) an individual who, jointly with his or her spouse, has a gross annual income of RM400,000 (or its equivalent in foreign currencies), per annum in the preceding twelve months, (vii) a corporation with total net assets exceeding RM10 million (or its equivalent in a foreign currencies) based on the last audited accounts, (viii) a partnership with total net assets exceeding RM10 million (or its equivalent in foreign currencies), (ix) a bank licensee or insurance licensee as defined in the Labuan Financial Services and Securities Act 2010, (x) an Islamic bank licensee or takaful licensee as defined in the Labuan Financial Services and Securities Act 2010, and (xi) any other person as may be specified by the Commission; provided that, in the each of the preceding categories (i) to (xi), the distribution of the shares of common stock is made by a holder of a Capital Markets Services License who carries on the business of dealing in securities. The distribution in Malaysia of this prospectus is subject to Malaysian laws. This prospectus does not constitute and may not be used for the purpose of public offering or an issue, offer for subscription or purchase, invitation to subscribe for or purchase any securities requiring the registration of a prospectus with the Commission under the Capital Markets and Services Act 2007.

## Notice to prospective investors in Taiwan

The shares of common stock have not been and will not be registered with the Financial Supervisory Commission of Taiwan pursuant to relevant securities laws and regulations and may not be sold, issued or offered within Taiwan through a public offering or in circumstances which constitutes an offer within the meaning of the Securities and Exchange Act of Taiwan that requires a registration or approval of the Financial Supervisory Commission of Taiwan. No person or entity in Taiwan has been authorized to offer, sell, give advice regarding or otherwise intermediate the offering and sale of the shares of common stock in Taiwan.

## Notice to prospective investors in South Africa

Due to restrictions under the securities laws of South Africa, the shares of common stock are not offered, and the offer shall not be transferred, sold, renounced or delivered, in South Africa or to a person with an address in South Africa, unless one or other of the following exemptions applies:

Section 96(1)(a): the offer, transfer, sale, renunciation or delivery is to:

(a) persons whose ordinary business, or part of whose ordinary business, is to deal in securities, as principal or agent;

(b) the South African Public Investment Corporation;

(c) persons or entities regulated by the Reserve Bank of South Africa;

(d) authorised financial service providers under South African law;

(e) financial institutions recognised as such under South African law;

(f) a wholly-owned subsidiary of any person or entity contemplated in (iii), (iv) or (v), acting as agent in the capacity of an authorized portfolio manager for a pension fund, or as manager for a collective investment scheme (in each case duly registered as such under South African law); or

(g) any combination of the persons in (i) to (vi); or

Section 96(1)(b): the total contemplated acquisition cost of the securities, for a single addressee acting as principal is equal to or greater than ZAR1,000,000 or such higher amount as may be promulgated by notice in the Government Gazette of South Africa pursuant to section 96(2)(a) of the South African Companies Act.

Information made available in this prospectus should not be considered as “advice” as defined in the South African Financial Advisory and Intermediary Services Act, 2002.

## Other relationships

Certain of the underwriters and their affiliates have provided in the past to us and our affiliates and may provide from time to time in the future certain commercial banking, financial advisory, investment banking and other services for us and such affiliates in the ordinary course of their business, for which they have received and may continue to receive customary fees and commissions. In addition, from time to time, certain of the underwriters and their affiliates may effect transactions for their own account or the account of customers, and hold on behalf of themselves or their customers, long or short positions in our debt or equity securities or loans, and may do so in the future.

# Legal matters

The validity of the shares of common stock offered hereby will be passed upon for us by Latham & Watkins LLP. Certain legal matters will be passed upon for the underwriters by Paul Hastings LLP.

# Experts

The consolidated financial statements of Kailera Therapeutics, Inc. at December 31, 2024 and 2025, and for the period from May 8, 2024 (inception) to December 31, 2024 and for the year ended December 31, 2025, appearing in this Prospectus and Registration Statement have been audited by Ernst & Young LLP, independent registered public accounting firm, as set forth in their report thereon appearing elsewhere herein, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

# Where you can find more information

We have filed with the Securities and Exchange Commission a registration statement on Form S-1 under the Securities Act with respect to the shares of 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 and schedules filed therewith. For further information about us and the common stock offered hereby, we refer you to the registration statement and the exhibits and schedules filed thereto. Statements contained in this prospectus regarding the contents of any contract or any other document that is filed as an exhibit to the registration statement are not necessarily complete, and each such statement is qualified in all respects by reference to the full text of such contract or other document filed as an exhibit to the registration statement.

You may read our SEC filings, including this registration statement, over the Internet at the SEC's website at www.sec.gov. Upon the completion of this offering, we will be subject to the information reporting requirements of the Exchange Act and we will file reports, proxy statements and other information with the SEC. These reports, proxy statements and other information will be available for review at the SEC's website referred to above. We also maintain a website at www.kailera.com, at which, following the completion of this offering, you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. Information contained on or accessible through our website is not a part of this prospectus or the registration statement of which it forms a part, and the inclusion of our website address in this prospectus is an inactive textual reference only. You should not consider the contents of our website in making an investment decision with respect to our common stock.

# Kailera Therapeutics, Inc.
# Index to consolidated financial statements

**Index to consolidated financial statements as of December 31, 2024 and 2025 and for the period from May 8, 2024 (inception) to December 31, 2024 and for the year ended December 31, 2025**

# Report of independent registered public accounting firm

To the Stockholders and the Board of Directors of Kailera Therapeutics, Inc.

## Opinion on the financial statements

We have audited the accompanying consolidated balance sheets of Kailera Therapeutics, Inc. (the Company) as of December 31, 2024 and 2025, the related consolidated statements of operations and comprehensive loss, convertible preferred stock and stockholders' deficit and cash flows for the period from May 8, 2024 (inception) to December 31, 2024 and for the year ended December 31, 2025 and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2024 and 2025, and the results of its operations and its cash flows for the period from May 8, 2024 (inception) to December 31, 2024 and for the year ended December 31, 2025, in conformity with U.S. generally accepted accounting principles.

## Basis for opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the 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. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2024.

Boston, Massachusetts
February 11, 2026

# Kailera Therapeutics, Inc.
# Consolidated balance sheets

| (amounts in thousands, except share data) | 2024 | December 31, 2025 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 175,178 | $ 160,267 |
| Marketable securities | — | 385,789 |
| Prepaid expenses and other current assets | 2,433 | 11,481 |
| Total current assets | 177,611 | 557,537 |
| Property and equipment, net | 209 | 1,955 |
| Restricted cash | — | 761 |
| Long-term marketable securities | — | 106,672 |
| Non-current clinical deposits | — | 12,185 |
| Operating lease right-of-use assets | 471 | 10,463 |
| Other non-current assets | 154 | 2,721 |
| Total assets | $ 178,445 | $ 692,294 |
| **Liabilities, convertible preferred stock and stockholders' deficit** | | |
| Current liabilities: | | |
| Accounts payable | $ 2,008 | $ 7,529 |
| Accrued expenses and other current liabilities | 2,994 | 37,836 |
| Preferred stock tranche right liability | 1,400 | — |
| Operating lease liabilities, current | 509 | 1,040 |
| Total current liabilities | 6,911 | 46,405 |
| Operating lease liabilities, non-current | — | 9,713 |
| Other non-current liabilities | — | 270 |
| Total liabilities | 6,911 | 56,388 |
| Commitments and contingencies (Note 14) | | |
| Convertible preferred stock: | | |
| Series A convertible preferred stock: $0.00001 par value; 45,677,603 and 35,677,603 shares authorized at December 31, 2024 and 2025, respectively; 35,677,603 shares issued and outstanding at December 31, 2024 and 2025; liquidation value of $356.8 million at December 31, 2024 and 2025 | 390,306 | 390,306 |
| Series B convertible preferred stock: $0.00001 par value; no shares and 43,084,539 shares authorized at December 31, 2024 and 2025, respectively; no shares and 43,084,539 shares issued and outstanding at December 31, 2024 and 2025, respectively; liquidation value of $603.2 million at December 31, 2025 | — | 602,058 |
| Stockholders' deficit: | | |
| Common stock, $0.00001 par value; 60,000,000 and 105,384,000 shares authorized at December 31, 2024 and 2025, respectively; 1 and 19,048 shares issued and outstanding at December 31, 2024 and 2025, respectively | — | — |
| Additional paid-in capital | 941 | 11,981 |
| Accumulated other comprehensive income | — | 229 |
| Accumulated deficit | (219,713) | (368,668) |
| Total stockholders' deficit | (218,772) | (356,458) |
| Total liabilities, convertible preferred stock and stockholders' deficit | $ 178,445 | $ 692,294 |

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

# Kailera Therapeutics, Inc.
# Consolidated statements of operations and comprehensive loss

| (amounts in thousands, except share data) | Period from May 8, 2024 (inception) to December 31, 2024 | Year Ended December 31, 2025 |
|---|---|---|
| **Operating expenses** | | |
| Research and development | $ 6,975 | $ 109,113 |
| Acquired in-process research and development as part of the acquisition of the Hengrui License | 214,070 | — |
| General and administrative | 9,371 | 49,227 |
| Total operating expenses | 230,416 | 158,340 |
| **Loss from operations** | (230,416) | (158,340) |
| **Other income (expense)** | | |
| Interest income | 2,508 | 11,048 |
| Other income (expense), net | 8,195 | (1,663) |
| Total other income | 10,703 | 9,385 |
| Net loss | $ (219,713) | $ (148,955) |
| Other comprehensive income | | |
| Unrealized gain | — | 229 |
| Comprehensive loss | (219,713) | (148,726) |
| Net loss per share attributable to common stockholders—basic and diluted | $ (219,713) | $ (949) |
| Weighted-average common stock outstanding—basic and diluted | 1 | 157 |

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

# Kailera Therapeutics, Inc.
# Consolidated statements of convertible preferred stock and stockholders' deficit

| | Series A-1 convertible preferred stock | | Series A-2 convertible preferred stock | | Series A-2 (NV) convertible preferred stock | | Series B convertible preferred stock | | Common stock | | Additional paid-in capital | Accumulated other comprehensive income | Accumulated deficit | stockh |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Amount | Shares | Amount | Shares | Amount | Shares | Amount | | | | |
| May 8, 2024 (Inception) | — | $ — | — | $ — | — | $ — | — | $ — | — | $ — | $ — | $ — | $ — | $ |
| Issuance of common stock | — | — | — | — | — | — | — | — | 1 | — | — | — | — | |
| Issuance of preferred stock, net of issuance costs of $1,258 | 20,000,000 | 194,358 | 4,968,789 | 84,501 | 708,814 | 11,447 | — | — | — | — | — | — | — | |
| Issuance of preferred stock upon tranche closing | 10,000,000 | 100,000 | — | — | — | — | — | — | — | — | — | — | — | |
| Stock-based compensation expense | — | — | — | — | — | — | — | — | — | — | 941 | — | — | |
| Net loss | — | — | — | — | — | — | — | — | — | — | — | — | (219,713) | (2 |
| December 31, 2024 | 30,000,000 | $294,358 | 4,968,789 | $ 84,501 | 708,814 | $ 11,447 | — | $ — | 1 | $ — | $ 941 | $ — | $ (219,713) | $ (2 |
| Issuance of preferred stock, net of issuance costs of $626 | — | — | — | — | — | — | 43,084,539 | 602,058 | — | — | — | — | — | |
| Exercise of stock options | — | — | — | — | — | — | — | — | 19,047 | — | 100 | — | — | |
| Stock-based compensation expense | — | — | — | — | — | — | — | — | — | — | 10,940 | — | — | |
| Unrealized gain on marketable securities | — | — | — | — | — | — | — | — | — | — | — | 229 | — | |
| Net loss | — | — | — | — | — | — | — | — | — | — | — | — | (148,955) | (1 |
| December 31, 2025 | 30,000,000 | $294,358 | 4,968,789 | $ 84,501 | 708,814 | $ 11,447 | 43,084,539 | $602,058 | 19,048 | $ — | $ 11,981 | $ 229 | $ (368,668) | $ (3 |

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

# Kailera Therapeutics, Inc.
# Consolidated statements of cash flows

| (amounts in thousands) | Period from May 8, 2024 (inception) to December 31, 2024 | Year Ended December 31, 2025 |
|---|---|---|
| **Cash flows from operating activities:** | | |
| Net loss | $ (219,713) | $ (148,955) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization expense | 53 | 310 |
| Stock-based compensation expense | 941 | 10,940 |
| Non-cash issuance of equity in exchange for the acquisition of the Hengrui License | 96,364 | — |
| Non-cash issuance of derivative instrument for the acquisition of the Hengrui License | 4,800 | — |
| Change in fair value of preferred stock tranche right liability | (3,400) | (1,400) |
| Change in fair value of derivative instrument | (4,800) | — |
| Change in fair value of convertible promissory notes | — | 3,184 |
| Non-cash lease expense | 37 | 651 |
| Accretion of discounts on investments, net | — | (1,730) |
| Other | — | 9 |
| Changes in operating assets and liabilities: | | |
| Prepaid expenses and other current assets | (2,432) | (8,751) |
| Non-current clinical deposits | — | (12,185) |
| Other non-current assets | (154) | (143) |
| Accounts payable | 2,008 | 4,690 |
| Accrued expenses and other current liabilities | 2,994 | 33,300 |
| Operating lease liabilities | — | (400) |
| Other non-current liabilities | — | 270 |
| Net cash used in operating activities | (123,302) | (120,210) |
| **Cash flows from investing activities:** | | |
| Purchases of property and equipment | (262) | (2,088) |
| Purchases of marketable securities | — | (632,158) |
| Maturities of marketable securities | — | 141,647 |
| Net cash used in investing activities | (262) | (492,599) |
| **Cash flows from financing activities:** | | |
| Proceeds from issuance of Series A convertible preferred stock, net of issuance costs | 298,742 | — |
| Proceeds from issuance of Series B convertible preferred stock, net of issuance costs | — | 498,874 |
| Proceeds from issuance of convertible promissory notes | — | 100,000 |
| Proceeds from the exercise of stock options | — | 100 |
| Payments of deferred offering costs related to initial public offering | — | (315) |
| Net cash provided by financing activities | 298,742 | 598,659 |

| (amounts in thousands) | Period from May 8, 2024 (inception) to December 31, 2024 | Year Ended December 31, 2025 |
|---|---|---|
| **Net increase (decrease) in cash, cash equivalents and restricted cash** | **175,178** | **(14,150)** |
| Cash and cash equivalents at beginning of period | — | 175,178 |
| Cash, cash equivalents and restricted cash at end of period | $ 175,178 | $ 161,028 |
| **Reconciliation of cash, cash equivalents and restricted cash** | | |
| Cash and cash equivalents | $ 175,178 | $ 160,267 |
| Restricted cash | — | 761 |
| Total cash, cash equivalents and restricted cash | $ 175,178 | $ 161,028 |
| **Supplemental disclosure of non-cash investing and financing activities:** | | |
| Right-of-use asset obtained in exchange for lease obligation | $ 612 | $ 10,611 |
| Increase in right-of-use assets and operating lease liabilities from operating lease modifications | $ — | $ 32 |
| Deferred offering costs included in accounts payable and accrued expenses | $ — | $ 2,263 |

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

# Kailera Therapeutics, Inc.
# Notes to consolidated financial statements

## 1. Nature of the business

Kailera Therapeutics, Inc. (the “Company” or “Kailera”) is an advanced clinical-stage biotechnology company focused on elevating the next era of obesity care by advancing a diversified pipeline to provide options for people living with obesity no matter where they are in their treatment journey.

The Company was incorporated in May 2024 and is subject to risks and uncertainties common to early-stage companies in the biopharmaceutical industry, including but not limited to, new technological innovations, protection of proprietary technology, dependence on key personnel, compliance with government regulations, reliance on third-party organizations for the discovery, manufacturing, clinical support of its product candidates, and the need to obtain additional financing. Product candidates currently under development will require significant additional research and development efforts, including extensive nonclinical and clinical testing and regulatory approval, prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel and infrastructure and extensive compliance-reporting capabilities.

There can be no assurance that the Company’s research and development efforts will be successfully completed, that adequate protection for the Company’s intellectual property will be obtained, that any products developed will obtain necessary government regulatory approval or that any approved products will be commercially viable. Even if the Company’s product development efforts are successful, it is uncertain when, if ever, the Company will generate significant revenue from product sales. The Company operates in an environment of rapid change in technology and substantial competition from pharmaceutical and biotechnology companies. In addition, the Company is dependent upon the services of its employees and consultants.

Through December 31, 2025, the Company has funded its operations primarily with proceeds from the sale and issuance of shares of convertible preferred stock and the issuance of convertible promissory notes, which converted into shares of convertible preferred stock. The Company has incurred losses since its inception, including a net loss of $219.7 million and $149.0 million for the period from May 8, 2024 (inception) to December 31, 2024 and for the year ended December 31, 2025, respectively. In addition, as of December 31, 2025, the Company had an accumulated deficit of $368.7 million. The Company expects to continue to generate operating losses for the near future. The future viability of the Company is dependent on its ability to raise additional capital to finance its operations. The Company’s inability to raise capital as and when needed could have a negative impact on its financial condition and ability to pursue its business strategies, and could require it to significantly delay, scale back or discontinue the development and commercialization of one or more of its product candidates. There can be no assurance that the current operating plan will be achieved or that additional funding will be available on terms acceptable to the Company, or at all.

The Company believes the cash, cash equivalents and marketable securities on hand of $652.7 million as of December 31, 2025, will be sufficient to fund its operations and capital expenditure requirements for at least twelve months from the date these consolidated financial statements are issued.

## 2. Summary of significant accounting policies

***Basis of Presentation***

The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America (“GAAP”). Any reference in these notes to

applicable guidance is meant to refer to the authoritative United States generally accepted accounting principles as found in the Accounting Standards Codification ("ASC") and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB").

***Principles of consolidation***

The accompanying consolidated financial statements include the accounts of Kailera Therapeutics, Inc. and its wholly owned subsidiaries. All intercompany transactions and balances have been eliminated in consolidation.

***Reclassifications***

Certain reclassifications have been made in prior periods to conform to the current year presentation.

***Use of estimates***

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting periods. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, the accrual of research and development expenses and the valuation of equity, including stock-based compensation expense, derivative instruments and convertible promissory notes. Additionally, in calculating the right-of-use assets and lease liabilities, estimates and assumptions were used to determine the incremental borrowing rates and expected lease terms. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known. Actual results could differ materially from those estimates.

***Concentrations of credit risk and off-balance sheet risk***

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash, cash equivalents, restricted cash, short-term investments and long-term investments. Periodically, the Company maintains deposits in accredited financial institutions in excess of federally insured limits. The Company deposits its cash, cash equivalents, restricted cash, short-term investments and long-term investments in financial institutions that it believes have high credit quality, has not experienced any losses on such accounts, and does not believe it is exposed to any unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

The Company is dependent on the third-party contract research organizations ("CROs") and contract manufacturing organizations ("CMOs") with whom they do business. In particular, the Company relies and expects to continue to rely on a small number of CMOs to supply it with its requirements of active pharmaceutical ingredients and formulated drugs in order to perform research and development activities on its programs. The Company also relies on a limited number of CROs to perform research and development activities on its behalf. The Company's clinical development programs could be adversely affected by significant interruption from these providers.

***Cash and cash equivalents***

The Company considers all highly liquid investments purchased with original maturities of 90 days or less at acquisition to be cash equivalents. Cash and cash equivalents include cash held in banks and amounts held in interest-bearing money market accounts. Cash equivalents are carried at cost, which approximates their fair market value.

***Restricted Cash***

Cash accounts with any type of restriction are classified as restricted cash. There was no restricted cash as of December 31, 2024.

In connection with the Company's lease agreement entered into in March 2025 (see Note 7), the Company maintained a letter of credit of $0.8 million, which is refundable at the end of the lease term. As of December 31, 2025, the underlying cash balance collateralizing this letter of credit was classified as restricted cash (non-current) on its consolidated balance sheet based on the release date of the restrictions of this cash.

***Investments***

The Company's investments consist of marketable debt securities. Marketable debt securities with contractual maturities less than 12 months at the balance sheet date are considered short-term marketable securities. Marketable debt securities with contractual maturities 12 months or greater at the balance sheet date are considered long-term marketable securities. The Company classifies all investments held as available-for-sale. Available-for-sale securities are recorded at fair value based upon market prices at period end, with the unrealized gains and losses reported in other comprehensive loss. The amortized cost of debt securities in this category is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization is included in interest income in the consolidated statements of operations and comprehensive loss. Realized gains and losses and declines in value due to credit-related factors on available-for-sale securities are included in other income (expense), net in the consolidated statements of operations and comprehensive loss. The cost of securities sold is based on the specific identification method. Interest on securities classified as available-for-sale is included in interest income in the consolidated statements of operations and comprehensive loss.

At each balance sheet date, the Company assesses available-for-sale debt securities in an unrealized loss position to determine whether the unrealized loss or any potential credit losses should be recognized in other income (expense), net in the consolidated statements of operations and comprehensive loss. The Company evaluates whether it intends to sell, or it is more likely than not that it will be required to sell, the security before recovery of its amortized cost basis. The Company also evaluates whether the decline in fair value has resulted from credit losses or other factors. In making this assessment, the Company considers the severity of the impairment, any changes in interest rates, changes to the underlying credit ratings and forecasted recovery, among other factors. The credit-related portion of unrealized losses, and any subsequent improvements, are recorded in other income (expense), net in the consolidated statements of operations and comprehensive loss. No impairment or credit losses were recognized during any of the periods presented.

***Deferred offering costs***

The Company capitalizes certain legal, professional, accounting and other third-party fees that are directly associated with in-process equity financings as deferred offering costs until such financings are consummated. After consummation of the equity financing, these costs are recorded as a reduction of the proceeds generated as a result of the offering. Should the planned equity financing be abandoned, the deferred offering costs will be expensed immediately as a charge to operating expenses in the consolidated statements of operations and comprehensive loss. The Company recorded deferred offering costs of $0.2 million and $2.6 million in other non-current assets on the consolidated balance sheets as of December 31, 2024 and 2025, respectively.

***Property and equipment***

Property and equipment are recorded at cost. Depreciation and amortization is calculated using the straight-line method over the following estimated useful lives of the assets:

| | Estimated useful life |
|---|---|
| Laboratory equipment | 5 years |
| Furniture and fixtures | 5 years |
| Computer equipment | 3 years |
| Office equipment | 5 years |
| Leasehold improvements | Lesser of estimated useful life or lease term |

Upon disposal, retirement or sale, the cost of assets disposed of and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is included in the results of operations. Expenditures for repairs and maintenance that do not improve or extend the lives of the respective assets are charged to expense as incurred.

***Impairment of long-lived assets***

Long-lived assets consist of property and equipment and right-of-use ("ROU") assets. Long-lived assets to be held and used are tested for recoverability whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative industry or economic trends and significant changes or planned changes in the use of the assets. If an impairment review is performed to evaluate a long-lived asset group for recoverability, the Company compares forecasts of undiscounted cash flows expected to result from the use and eventual disposition of the long-lived asset group to its carrying value. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of an asset group are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired asset group over its fair value, determined based on discounted cash flows.

***Convertible Promissory Notes***

The Company has elected to account for convertible promissory notes utilizing the fair value option in accordance with ASC 825, *Financial Instruments* ("ASC 825"). The convertible notes are initially measured based on the amount of allocated proceeds from the transaction and are remeasured at fair value on each reporting date, with changes in fair value recognized as a gain or loss as a component of other income (expense), net in the consolidated statements of operations and comprehensive loss. The portion of any change in fair value resulting from a change in the instrument-specific credit risk is presented separately.

The fair value option may be applied instrument by instrument but is irrevocable. As a result of applying the fair value option, direct costs and fees related to the convertible notes were recognized in general and administrative expense. Accrued interest for the convertible notes is not recognized separately, but is considered in determining the fair value of the convertible notes on each reporting date.

***Convertible preferred stock***

The Company classifies convertible preferred stock as temporary equity in the accompanying consolidated balance sheets due to terms that allow for redemption of the shares upon certain events that are outside of the Company's control. The Company does not accrete the carrying values of the preferred stock to the redemption values unless the occurrence of these events is considered probable. Subsequent adjustments of the carrying values to the ultimate redemption values will be made only when it becomes probable that these events will occur.

Obligations for holders of convertible preferred stock to purchase additional shares are assessed as either embedded features within the shares or as freestanding instruments. Freestanding obligations are recorded at fair value, with subsequent changes in fair value recognized in other income (expense), net in the consolidated statements of operations and comprehensive loss.

***Research and development costs***

Research and development costs are expensed as incurred. Research and development expenses consist of costs incurred in performing research and development activities, including salaries, stock-based compensation

and benefits, facilities costs, depreciation, third-party license fees, and external costs to outside vendors engaged to conduct nonclinical development activities and clinical trials as well as to manufacture research and development materials. Non-refundable prepayments for goods or services that will be used or rendered for future research and development activities are deferred and capitalized. Such amounts are recognized as an expense as the goods are delivered or the related services are performed or until it is no longer expected that the goods will be delivered or the services rendered.

***Accrued research and development costs***

The Company has entered into various research and development contracts. The costs under these contracts are recorded as research and development expenses as incurred. The Company records accrued expenses for estimated ongoing research and development costs. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of its open contracts, including the phase or completion of events, invoices received and contracted costs. Judgments and estimates are made in determining the accrued balances at the end of any reporting period. Actual results could differ from the Company's estimates. The Company's historical accrual estimates have not been materially different from the actual costs.

***Asset acquisitions and acquired in-process research and development expenses***

The Company measures and recognizes asset acquisitions that are not deemed to be business combinations based on the cost to acquire the asset or group of assets, which includes transaction costs. Goodwill is not recognized in asset acquisitions. In an asset acquisition, the cost allocated to acquire in-process research and development ("IPR&D") with no alternative future use is recognized as expense on the acquisition date.

Contingent consideration in asset acquisitions is recognized in the period the triggering event is determined to be probable of occurrence and the related amount is reasonably estimable. Such amounts are expensed or capitalized based on the nature of the associated asset at the date the related contingency is resolved.

***Patent and trademark costs***

All patent- and trademark-related costs incurred in connection with filing and prosecuting patent applications such as direct application fees, and legal and consulting expenses are expensed as incurred due to the uncertainty about the recovery of the expenditure. Patent- and trademark-related costs are classified as general and administrative expenses within the Company's consolidated statements of operations and comprehensive loss.

***Embedded derivatives***

Features embedded into contracts are assessed to determine if they represent embedded derivatives which require bifurcation and separate recognition. Embedded derivatives requiring bifurcation are accounted for at fair value, with subsequent changes in fair value recognized as a component of other income (expense), net in the consolidated statements of operations and comprehensive loss.

***Stock-based compensation***

For stock-based awards issued to employees, non-employees, and members of the Company's board of directors (the "Board") for their services on the Board, the Company measures the estimated fair value of the stock-based award on the date of grant and recognizes compensation expense for those awards over the requisite service period, which is generally the vesting period of the respective award. The Company issues stock-based awards with service-based vesting conditions and records the expense for these awards using the straight-line method. The Company issues performance-based awards and records the expense for these awards over the expected vesting term and recognizes expense only if it is probable the performance-based conditions will be achieved. The Company has not issued any stock-based awards with market-based vesting conditions. The Company accounts for forfeitures as they occur.

The Company classifies stock-based compensation expense in its consolidated statements of operations and comprehensive loss in the same manner in which the award recipient's cash compensation costs are classified.

Given the absence of an active market for the Company's common stock, the Board, the members of which the Company believes have extensive business, finance, and venture capital experience, were required to estimate the fair value of the Company's common stock at the time of each grant of a stock-based award. The Company and the Board determined the estimated fair value of the Company's equity instruments based on a number of factors, including external market conditions affecting the biopharmaceutical industry. The Company and the Board utilized various valuation methodologies in accordance with the framework of the American Institute of Certified Public Accountants' Technical Practice Aid, *Valuation of Privately-Held Company Equity Securities Issued as Compensation*, to estimate the fair value of its common stock. Each valuation methodology includes estimates and assumptions that require the Company's judgment. These estimates and assumptions include a number of objective and subjective factors in determining the value of the Company's common stock at each grant date, including: (1) prices paid for the Company's convertible preferred stock, which the Company had sold to outside investors in arm's-length transactions, and the rights, preferences, and privileges of the Company's convertible preferred stock and common stock; (2) the Company's stage of development; (3) the fact that the grants of stock-based awards involved illiquid securities in a private company; and (4) the likelihood of achieving a liquidity event for the common stock underlying the stock-based awards, such as an initial public offering or sale of the Company, given prevailing market conditions.

The fair value of each stock option award is estimated on the date of grant using the Black-Scholes option pricing model. As there is no public market for its common stock, the Company determined the volatility for awards granted based on an analysis of reported data for a group of guideline companies that issued options with substantially similar terms. The expected volatility has been determined using a weighted average of the historical volatility measures of this group of guideline companies. The Company expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded stock price. The expected term of the Company's stock options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. The Company has not paid, and does not anticipate paying, cash dividends on its common stock; therefore, the expected dividend yield is assumed to be zero.

***Income taxes***

The Company accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the consolidated financial statements. Under this method, the Company determines deferred tax assets and liabilities on the basis of the differences between the financial statement and tax bases of assets and liabilities by using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date.

The Company recognizes deferred tax assets to the extent that it believes that these assets are more likely than not to be realized. In making such a determination, the Company considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies, and results of recent operations. If the Company determines that it would be able to realize its deferred tax assets in the future in excess of their net recorded amount, the Company would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes.

The Company records uncertain tax positions in accordance with ASC 740 on the basis of a two-step process in which (1) it determines whether it is more likely than not that the tax positions will be sustained on the basis of

the technical merits of the position and (2) for those tax positions that meet the more-likely-than-not recognition threshold, the Company recognizes the largest amount of tax benefit that is more than 50 percent likely to be realized upon ultimate settlement with the related tax authority.

The Company recognizes interest and penalties related to unrecognized tax benefits on the income tax expense line in the accompanying consolidated statements of operations and comprehensive loss.

***Comprehensive loss***

Comprehensive loss is defined as the change in stockholders' equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. Comprehensive loss includes net loss as well as other changes in stockholders' deficit which includes changes in unrealized gains (losses) on marketable securities.

***Net income (loss) per share attributable to common stockholders***

Net income (loss) per share attributable to common stockholders is determined using the two-class method, which includes the weighted-average number of shares of common stock outstanding during the period and other securities that participate in dividends (a participating security). In periods of income, the convertible preferred stock would be considered participating securities because the shares include rights to participate in dividends with the common stock; however, the convertible preferred stock is not considered a participating security in periods of loss as they do not have an obligation to share in the Company's net losses.

Under the two-class method, basic net income (loss) per share attributable to common stockholders is computed by dividing the net income (loss) attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period. Diluted net income (loss) per share attributable to common stockholders is computed using the more dilutive of (1) the two-class method or (2) the if-converted method.

***Fair value measurements***

Certain assets and liabilities of the Company are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1—Quoted prices in active markets for identical assets or liabilities.
- Level 2—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3—Unobservable inputs that are supported by little or no market activity that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

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

***Leases***

The Company accounts for leases in accordance with ASC Topic 842, *Leases* ("ASC 842"). The Company has elected to combine lease and non-lease components together for its real estate operating leases. As a result, for these applicable classes of underlying assets, the Company accounted for each separate lease component and the non-lease components associated with that lease component as a single lease component.

In accordance with ASC 842, the Company determines whether an arrangement is or contains a lease at inception. A contract is or contains a lease if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration. The Company records leases at the lease commencement date, when control of the underlying asset is transferred from the lessor to the lessee, as operating or finance leases and records a right-of-use ("ROU") asset and a lease liability on the consolidated balance sheets for all leases with a lease term of greater than twelve months. The Company has elected to not recognize leases with a lease term of twelve months or less on the balance sheet and will recognize lease payments for such short-term leases as an expense on a straight-line basis.

The Company enters into contracts that contain both lease and non-lease components. Non-lease components may include items such as maintenance, utilities, or other operating costs. For leases of real estate, the Company combines the lease and associated non-lease components in its lease arrangements as a single lease component. Variable costs, such as utilities or maintenance costs, are not included in the measurement of right-of-use assets and lease liabilities, but rather are expensed when the event determining the amount of variable consideration to be paid occurs.

Operating lease assets and liabilities are recognized at the lease commencement date based on the present value of the lease payments over the lease term using the discount rate implicit in the lease if readily determinable. If the rate implicit is not readily determinable, the Company utilizes its incremental borrowing rate based upon the available information at the lease commencement date. ROU assets are further adjusted for items such as initial direct costs, prepaid rent, or lease incentives. Operating lease payments are expensed using the straight-line method as an operating expense over the lease term. The Company's lease terms may include options to extend the lease when it is reasonably certain that the Company will exercise that option.

***Subsequent event considerations***

The Company considers events or transactions that occur after the balance sheet date but prior to the issuance of the consolidated financial statements to provide additional evidence for certain estimates or to identify matters that require additional disclosure. Subsequent events have been evaluated as required.

***Emerging growth company status and smaller reporting company status***

The Company is an "emerging growth company," as defined in the Jumpstart Our Business Startups Act, or JOBS Act, and may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies. The Company may take advantage of these exemptions until the Company is no longer an "emerging growth company." Section 107 of the JOBS Act provides that an "emerging growth company" can take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards. The Company has elected to use the extended transition period for complying with new or revised accounting standards and as a result of this election, its financial statements may not be comparable to companies that comply with public company effective dates. The Company may take advantage of these exemptions up until the last day of the fiscal year following the fifth anniversary of an offering or such earlier time that it is no longer an "emerging growth company". As of the date of the issuance of these financial statements, the Company is also a "smaller reporting company". If the Company is a smaller reporting company at the time it ceases to be an emerging growth company, the Company may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies.

***Recently issued and adopted accounting pronouncements***

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies and adopted by the Company as of the specified effective date. Unless otherwise discussed, the Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on its financial statements and disclosures.

In December 2023, the FASB issued ASU 2023-09, "*Income Taxes (Topic 740)—Improvements to Income Tax Disclosures* ("ASU 2023-09"). ASU 2023-09 enhances the transparency and decision usefulness of income tax disclosures by requiring consistent categories and greater disaggregation of information in the rate reconciliation and income taxes paid disaggregated by jurisdiction. The amendments in ASU 2023-09 are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2024, and is applicable to the Company in fiscal 2025. The Company adopted this standard retrospectively and included the required disclosures in Note 12 "Income Taxes."

In November 2024, the FASB issued ASU 2024-03, *Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses* ("ASU 2024-03"). The amendments in ASU 2024-03 require public entities to disclose specified information about certain costs and expenses. ASU 2024-03 is effective for fiscal years beginning after December 15, 2026, and for interim periods within those fiscal years beginning after December 15, 2027. The Company is currently evaluating the impact of this standard on its consolidated financial statements.

In September 2025, the FASB issued ASU 2025-06, *Intangibles—Goodwill and Other—Internal-Use Software* ("ASU 2025-06"). The amendments change (i) the criteria regarding the timing of the capitalization of costs for internal-use software and (ii) the accounting for website development costs. The amendments are effective for annual periods beginning after December 15, 2027. The Company is currently evaluating the impact of the amendments on its consolidated financial statements.

In December 2025, the FASB issued ASU 2025-12, *Codification Improvements* ("ASU 2025-12"). ASU 2025-12 addresses suggestions received from stakeholders on the ASC and to make other incremental improvements to U.S. GAAP. The update represents changes to the ASC that (1) clarify, (2) correct errors, or (3) make minor improvements. The amendments make the ASC easier to understand and apply. The guidance is effective for fiscal years beginning after December 15, 2026, including interim periods within those fiscal years. The Company is currently evaluating the impact of this standard on its consolidated financial statements.

## 3. Marketable securities

The following table summarizes the amortized cost and estimated fair value of the Company's investments, which are considered to be available-for-sale investments, and were included in short-term marketable securities and long-term marketable securities as of December 31, 2025:

| | December 31, 2025 | | | |
|---|---|---|---|---|
| | Amortized Cost | Gross Unrealized Gains | Gross Unrealized Losses | Fair Value |
| Marketable securities: | | | | |
| U.S. government agency debt securities | $ 169,690 | $ 108 | $ — | $ 169,798 |
| Corporate debt securities | 122,737 | 23 | (47) | 122,713 |
| Commercial paper | 93,241 | 37 | — | 93,278 |
| | $ 385,668 | $ 168 | $ (47) | $ 385,789 |

| | December 31, 2025 | | | |
|---|---|---|---|---|
| | Amortized Cost | Gross Unrealized Gains | Gross Unrealized Losses | Fair Value |
| Long-term marketable securities: | | | | |
| U.S. government agency debt securities | $ 62,038 | $ 80 | $ — | $ 62,118 |
| Corporate debt securities | 44,537 | 18 | (1) | 44,554 |
| | $ 106,575 | $ 98 | $ (1) | $ 106,672 |

Certain short-term marketable securities with original maturities of less than 90 days are included in cash and cash equivalents on the consolidated balance sheets and are not included in the tables above. As of December 31, 2025, all short-term marketable securities had contractual maturities within one year and all long-term marketable securities had contractual maturities between one to two years. The Company held no marketable securities during the year ended December 31, 2024.

The aggregate fair value of available-for-sale securities held by the Company in an unrealized loss position for less than 12 months as of December 31, 2025 was $79.0 million. There were no available-for-sale securities in a continuous unrealized loss position for greater than 12 months. The Company evaluated its securities for potential impairment and considered the decline in market value to be primarily attributable to current economic and market conditions. Additionally, the Company does not intend to sell the investments in an unrealized loss position and does not expect it will be required to sell the investments before recovery of their amortized cost bases, which may be maturity. Given the Company's intent and ability to hold such investments until recovery, and the lack of a significant change in credit risk for these investments, the Company does not consider these investments to be impaired and there are no allowances for credit losses as of December 31, 2025.

## 4. Fair value of financial assets and liabilities

The following tables present information about the Company's financial assets and liabilities measured at fair value on a recurring basis and indicate the level of the fair value hierarchy utilized to determine such fair values (in thousands):

| | Fair value measurements as of December 31, 2025 | | | |
|---|---|---|---|---|
| | Level 1 | Level 2 | Level 3 | Total |
| Cash equivalents: | | | | |
| Money market funds | $ 104,212 | $ — | $ — | $ 104,212 |
| Corporate debt securities | — | 27,353 | — | 27,353 |
| Commercial paper | — | 25,922 | — | 25,922 |
| Marketable securities: | | | | |
| U.S. government agency debt securities | $ — | $ 231,915 | $ — | $ 231,915 |
| Corporate debt securities | — | 167,268 | — | 167,268 |
| Commercial paper | — | 93,278 | — | 93,278 |
| Total assets | $ 104,212 | $ 545,736 | $ — | $ 649,948 |

| | Fair value measurements as of December 31, 2024 | | | |
|---|---|---|---|---|
| | Level 1 | Level 2 | Level 3 | Total |
| Cash equivalents: | | | | |
| Money market funds | $ 173,678 | $ — | $ — | $ 173,678 |
| Total assets | $ 173,678 | $ — | $ — | $ 173,678 |
| Liabilities: | | | | |
| Preferred stock tranche right liability | $ — | $ — | $ 1,400 | $ 1,400 |
| Total liabilities | $ — | $ — | $ 1,400 | $ 1,400 |

For the period from May 8, 2024 (inception) to December 31, 2024 and for the year ended December 31, 2025, there were no transfers between Level 1, Level 2 and Level 3.

The purchasers of Series A-1 convertible preferred stock received an obligation to purchase additional shares in the future, which was considered to be a freestanding instrument. Consideration was allocated to this instrument at fair value upon issuance. This instrument was adjusted to fair value on each reporting date, with changes in fair value reported within other income (expense), net in the consolidated statements of operations and comprehensive loss. A portion of this instrument was settled during the period from May 8, 2024 (inception) to December 31, 2024. The portion of the instrument that was settled was determined to not have any fair value as the underlying shares were purchased at fair value. On May 8, 2025, the Company issued convertible promissory notes (the “Notes”), for an aggregate purchase price of $100.0 million, and as a result, their outstanding obligations under the preferred stock tranche obligation were satisfied. The fair value of the preferred stock tranche obligation at settlement was recorded as proceeds received for the Notes. At settlement, there was no value associated with the preferred stock tranche obligation as the convertible promissory notes were purchased for fair value. The Company elected to account for the Notes using the fair value option, with changes in fair value recognized as a component of other income (expense), net in the consolidated statements of operations and comprehensive loss. The Notes were settled on October 31, 2025, in connection with the issuance of Series B convertible preferred stock.

In May 2024, the Company entered into a license and collaboration agreement with Jiangsu Hengrui Pharmaceuticals Co., Ltd. (“Hengrui”) which contained a payment obligation upon the Company’s receipt of certain partnership payments, as defined in the agreement, that may occur prior to November 15, 2025. This feature was determined to represent an embedded derivative instrument, which was recorded at fair value upon issuance and recognized as acquired in-process research and development expense. The feature is adjusted to fair value on each reporting date, with changes in fair value reported within other income (expense), net in the consolidated statements of operations and comprehensive loss. The feature was concluded to have a de minimis value as of December 31, 2024 due to the anticipated expiration of the feature. The feature ultimately expired with no related payments during the year ended December 31, 2025.

The following table sets forth a summary of changes in the fair value of the partnership payments derivative, the preferred stock tranche right liability and the Notes for the period from May 8, 2024 (inception) to December 31, 2024 and the year ended December 31, 2025, for which fair value is determined by a Level 3 input (in thousands):

| | Partnership payments derivative | Preferred stock tranche right liability | Convertible promissory notes |
|---|---|---|---|
| Balance as of May 8, 2024 (Inception) | $ — | $ — | $ — |
| Issuance of instrument | 4,800 | 4,800 | — |
| Change in fair value of instrument | (4,800) | (3,400) | — |
| Balance as of December 31, 2024 | — | 1,400 | — |
| Issuance of notes | — | — | 100,000 |
| Change in fair value of instrument | — | (1,400) | 3,200 |
| Conversion of notes | — | — | (103,200) |
| Balance as of December 31, 2025 | $ — | $ — | $ — |

There were no changes in instrument-specific credit risk for the period from May 8, 2024 (inception) to December 31, 2024 or for the year ended December 31, 2025.

In order to determine the fair value of the preferred stock tranche obligation, the Company utilized a hybrid method. The Company prepared valuations with two scenarios, an initial public offering scenario and a trade sale scenario to allocate the equity value to the respective share classes and a forward contract model to estimate the value associated with the remaining preferred stock tranche. The two scenarios were weighted based on management's assessment of the probability of each event occurring. The most significant estimate utilized in the valuation models was the estimated time to the closing of the Series A-1 convertible preferred stock second tranche in the potential change of control event timeline. The potential change of control event scenario timelines considered as of May 15, 2024 were less than six months, between six and twelve months, and at twelve months from the initial closing date of the Series A-1 convertible preferred stock financing. The potential change of control event scenario timelines considered as of December 31, 2024 were between six and twelve months and at twelve months from the initial closing date of the Series A-1 convertible preferred stock financing. The following summarizes certain key assumptions utilized in determining the fair value of the preferred stock tranche right liability:

| | May 15, 2024 | December 31, 2024 |
|---|---|---|
| Time to the Series A-1 Convertible Preferred Second Tranche Closing | 1 year | 0.3 years |

The fair value of the preferred stock tranche obligation at settlement was considered to be equal to the fair value of the Notes that were issued in settlement of the provision. As the Notes were issued at fair value, the fair value of the preferred stock tranche obligation was considered to be zero at settlement. The fair value of the Notes at settlement were considered to be equal to the fair value of the preferred stock issued at settlement.

In order to determine the fair value of the derivative instrument, the Company utilized available facts and circumstances to make estimates utilized in the valuation model. The valuation models utilized a Monte Carlo simulation model to estimate the enterprise value of the business to estimate the partnership payments that would be subject to the derivative instrument. The most significant estimates utilized in the valuation models were the total value of the Company's equity, the expected volatility of future equity, risk-free rate based on the U.S. Treasury yield terms commensurate with the simulation term, and the potential change of control event

timeline. The potential change of control event scenario timelines considered as of May 15, 2024 were less than six months, between six and twelve months, and between twelve and eighteen months from the execution of the license agreement. The potential change of control event scenario timelines considered as of December 31, 2024 were between six and twelve months and between twelve and eighteen months from the execution of the license agreement. The following summarizes certain key assumptions utilized in determining the fair value of the derivative instrument:

| | May 15, 2024 | December 31, 2024 |
|---|---|---|
| Total Equity Value | $ 494.3 million | $ 419.5 million |
| Term | 1.25 years | 0.62 years |
| Volatility | 80.0% | 61.0% |
| Risk-Free Rate | 4.9% | 4.1% |

The derivative instrument expired on November 15, 2025.

## 5. Prepaid expenses and other current assets

Prepaid expenses and other current assets consisted of the following (in thousands):

| | December 31, 2024 | 2025 |
|---|---|---|
| Interest receivable | $ — | $ 2,725 |
| Prepaid expenses | 968 | 2,645 |
| Prepaid clinical | 530 | 2,356 |
| Prepaid manufacturing | — | 1,724 |
| Prepaid other research and development | — | 459 |
| Prepaid bonuses | 592 | 338 |
| Other | 343 | 1,234 |
| | $2,433 | $11,481 |

## 6. Property and equipment, net

Property and equipment, net consisted of the following (in thousands):

| | December 31, 2024 | 2025 |
|---|---|---|
| Furniture and fixtures | $262 | $1,309 |
| Computer equipment | — | 184 |
| Leasehold improvements | — | 562 |
| Less: accumulated depreciation | (53) | (100) |
| | $209 | $1,955 |

Depreciation expense was less than $0.1 million and $0.2 million for the period from May 8, 2024 (inception) to December 31, 2024 and for the year ended December 31, 2025, respectively. Through December 31, 2025, the Company has not recorded any impairment losses on long-lived assets.

## 7. Leases

From May 8, 2024 (inception) to December 31, 2024, the Company entered into lease agreements for office space located in Waltham, Massachusetts and San Diego, California, both of which were scheduled to expire in

2025 and were classified as operating leases. Each lease contained both fixed and variable lease payments. The lease for the premises in Waltham, Massachusetts included an option to extend the lease term for one six-month period. In accordance with the lease agreements, the Company provided security deposits which are refundable at the end of the lease term. The security deposits, for a total of less than $0.1 million, were recorded within prepaids and other current assets as of December 31, 2024. The security deposit, for a total of less than $0.1 million, related to the San Diego, California lease was recorded within prepaids and other current assets as of December 31, 2025.

On March 21, 2025, the Company executed a new, seven-year, non-cancellable operating lease agreement for approximately 39,500 square feet of office space in Waltham, Massachusetts for its corporate headquarters. The lease commenced on October 15, 2025, following completion of construction to prepare the premises for the Company's intended use. The lease provided for base rent of $2.2 million for the first year, which will increase by approximately 2% each year. The Company's lease payments also include real estate taxes and other operating expenses allocable to the leased premises, which exceed base year amounts. The Company has the option to extend the lease for one additional five-year term with base rent calculated on the then-market rate. In accordance with the lease agreement, the Company maintained a letter of credit of $761 thousand, which is refundable at the end of the lease term. As of December 31, 2025, the underlying cash balance collateralizing this letter of credit was classified as restricted cash (non-current) on its consolidated balance sheets based on the release date of the restrictions of this cash. In connection with the new lease agreement, the Company amended its existing lease in Waltham, Massachusetts to extend the lease term to end shortly after the lease commencement date of its new lease agreement, which occurred in the fourth quarter of 2025.

Upon commencement of the lease for its corporate headquarters, the Company recognized operating lease liabilities of $10.6 million, based on an expected contractual obligation of $15.9 million and an incremental borrowing rate of 12.0% and recognized a right-of-use asset of $10.6 million.

The following table summarizes the effect of lease costs in the Company's consolidated statements of operations and comprehensive loss (in thousands):

| | Period from May 8, 2024 (inception) to December 31, 2024 | Year Ended December 31, 2025 |
|---|---|---|
| Operating lease costs | $ 154 | $ 936 |
| Variable lease costs | — | — |
| Total lease costs | $ 154 | $ 936 |

For the period from May 8, 2024 (inception) to December 31, 2024 and for the year ended December 31, 2025, the Company made cash payments for operating leases of less than $0.1 million and $0.7 million, respectively.

The following table summarizes the future minimum lease payments due under operating leases as of December 31, 2025 (in thousands):

| | Total minimum lease payments |
|---|---|
| **Year Ending December 31,** | |
| 2026 | 2,251 |
| 2027 | 2,220 |
| 2028 | 2,259 |
| 2029 | 2,299 |
| 2030 | 2,338 |
| 2031 and thereafter | 4,386 |
| Total lease payments | 15,753 |
| Less: interest | (5,000) |
| Total lease liabilities | $ 10,753 |

The total lease liabilities are presented on the Company's consolidated balance sheets based on maturity dates. As of December 31, 2025, $1.0 million is classified under "operating lease liabilities, current" for the portion due within twelve months, and $9.7 million is classified under "operating lease liabilities, non-current."

As of December 31, 2024, the weighted average remaining lease term was 0.8 years and the weighted average incremental borrowing rate used to determine the operating lease liability was 9.1%. As of December 31, 2025, the weighted average remaining lease term was 6.8 years and the weighted average incremental borrowing rate used to determine the operating lease liability was 12%.

## 8. Accrued expenses and other current liabilities

Accrued expenses and other current liabilities consisted of the following:

| | December 31, | |
|---|---|---|
| | 2024 | 2025 |
| Accrued clinical | $ — | $18,888 |
| Accrued employee compensation and benefits | 1,822 | 9,054 |
| Accrued professional services | — | 3,866 |
| Accrued manufacturing | 396 | 3,812 |
| Accrued other research and development | 16 | 1,300 |
| Other | 760 | 916 |
| | $2,994 | $37,836 |

## 9. Convertible preferred stock

As of December 31, 2025, the authorized capital stock of the Company included 78,762,142 shares of $0.00001 par value preferred stock, of which 30,000,000 shares have been designated as Series A-1 convertible preferred stock, 5,677,603 shares have been designated as Series A-2 convertible preferred stock and 43,084,539 shares have been designated as Series B convertible preferred stock. The Series A-2 convertible preferred stock comprises of 4,968,789 shares of voting stock and 708,814 shares of nonvoting stock.

On May 15, 2024, the Company issued and sold 20,000,000 shares of Series A-1 convertible preferred stock at a price of $10.00 per share. The Company also issued 5,677,603 shares of Series A-2 convertible preferred stock, comprising of 4,968,789 voting shares and 708,814 nonvoting shares, as partial consideration for the receipt of

certain intellectual property rights. In addition, the holders of the Series A-1 convertible preferred stock were required to purchase an additional 20,000,000 shares no later than May 15, 2025 for a purchase price of $10.00 per share, subject to potential adjustment.

On December 9, 2024, the parties modified the initial purchase agreement and the Company issued and sold an additional 10,000,000 shares of Series A-1 convertible preferred stock at a price of $10.00 per share. This issuance of additional shares of Series A-1 convertible preferred stock resulted in a change in the conversion ratio for the outstanding shares of Series A-2 convertible preferred stock from one-for-one to 1.67-for-one. The obligation for the holders of the Series A-1 convertible preferred stock to purchase an additional 10,000,000 shares remained outstanding as of December 31, 2024.

The obligation for the holders of Series A-1 convertible preferred stock to purchase additional shares was considered to be a freestanding instrument. The obligation was accounted for as a liability and was initially recorded at fair value with changes in fair value recognized through earnings as other income (expense), net in the consolidated statements of operations and comprehensive loss. Upon settlement of the obligation, the fair value was reclassified from liabilities to Series A-1 convertible preferred stock.

The Series A-1 convertible preferred stock was recorded based on the allocated consideration, which was the cash consideration less the amounts allocated to the obligation to purchase additional shares. The Series A-2 convertible preferred stock was initially recorded at fair value. The preferred stock is classified within temporary equity as the shares are redeemable upon the occurrence of certain contingent events which are outside of the control of the Company. The occurrence of these events was not considered to be probable as of December 31, 2025. The Company assessed the preferred stock for any embedded derivatives that would require bifurcation on the date of each issuance and concluded that there were no such features.

On May 8, 2025, the Company issued convertible promissory notes (the “Notes”) to the holders of the Series A-1 convertible preferred stock for an aggregate purchase price of $100.0 million, and as a result, their outstanding obligations under the preferred stock tranche obligation were satisfied. The Notes had a contractual interest rate of 7.0% and provided for conversion of all principal and interest into either Series A-1 convertible preferred stock upon maturity on September 30, 2025, at a conversion price of $10.00 per share, or a newly created series of preferred stock upon the occurrence of a qualified financing at a conversion price equal to the cash price paid per share by the investors in such qualified financing. The fair value of the preferred stock tranche obligation at settlement was recorded as proceeds received for the Notes. At settlement, there was no value associated with the preferred stock tranche obligation as the convertible promissory notes were purchased for fair value. The Company elected to account for the Notes using the fair value option, with changes in fair value recognized as a component of other income (expense), net in the consolidated statements of operations and comprehensive loss. As the fair value election was utilized, contractual interest was not separately accounted for. The Notes were amended on September 29, 2025 to extend the maturity date to November 28, 2025 and settled on October 31, 2025 in connection with the issuance of Series B convertible preferred stock described below.

On October 31, 2025, the Company issued and sold 35,714,285 shares of Series B convertible preferred stock at a price of $14.00 per share and issued 7,370,254 shares of Series B convertible preferred stock upon conversion of the Notes in full, representing $100.0 million of principal and $3.2 million of accrued interest. This issuance of Series B convertible preferred stock resulted in a change in the conversion ratio for the outstanding shares of Series A-2 convertible preferred stock from 1.67-for-one as of December 31, 2024 to 2.03-for-one as of December 31, 2025.

The Series B convertible preferred stock was initially recorded at fair value based on the cash consideration, or $500.0 million, and the fair value of the Notes at settlement, or $103.2 million. The preferred stock is classified

within temporary equity as the shares are redeemable upon the occurrence of certain contingent events which are outside of the control of the Company. The occurrence of these events was not considered to be probable upon issuance. The Company assessed the preferred stock for any embedded derivatives that would require bifurcation on the date of issuance and concluded that there were no such features.

In connection with the Series B convertible preferred stock issuance, the Company increased the number of shares of common stock authorized for issuance to 105,384,000 shares at $0.00001 par value per share and increased the number of shares of preferred stock authorized for issuance to 78,762,142 shares at $0.00001 par value per share.

The preferred stock consisted of the following:

| | | | December 31, 2025 | | |
|---|---|---|---|---|---|
| | Preferred shares authorized | Preferred shares issued and outstanding | Carrying value | Liquidation preference | Common stock issuable upon conversion |
| Series A-1 convertible preferred stock | 30,000,000 | 30,000,000 | $ 294,357,583 | $ 300,000,000 | 30,000,000 |
| Series A-2 voting convertible preferred stock * | 4,968,789 | 4,968,789 | 84,500,659 | 49,687,890 | 9,477,719 |
| Series A-2 nonvoting convertible preferred stock * | 708,814 | 708,814 | 11,447,346 | 7,088,140 | 2,034,133 |
| Total Series A-2 convertible preferred stock * | 5,677,603 | 5,677,603 | 95,948,005 | 56,776,030 | 11,511,852 |
| Series B convertible preferred stock | 43,084,539 | 43,084,539 | 602,057,535 | 603,183,546 | 43,084,539 |
| Total | 78,762,142 | 78,762,142 | $ 992,363,123 | $ 959,959,576 | 84,596,391 |

| | | | December 31, 2024 | | |
|---|---|---|---|---|---|
| | Preferred shares authorized | Preferred shares issued and outstanding | Carrying value | Liquidation preference | Common stock issuable upon conversion |
| Series A-1 convertible preferred stock | 40,000,000 | 30,000,000 | $ 294,357,583 | $ 300,000,000 | 30,000,000 |
| Series A-2 voting convertible preferred stock * | 4,968,789 | 4,968,789 | 84,500,659 | 49,687,890 | 7,453,184 |
| Series A-2 nonvoting convertible preferred stock * | 708,814 | 708,814 | 11,447,346 | 7,088,140 | 2,034,154 |
| Total Series A-2 convertible preferred stock * | 5,677,603 | 5,677,603 | 95,948,005 | 56,776,030 | 9,487,338 |
| Total | 45,677,603 | 35,677,603 | $ 390,305,588 | $ 356,776,030 | 39,487,338 |

* No deemed liquidation events occurred prior to November 15, 2025. The liquidation preference presented as of December 31, 2024 assumes there is no deemed liquidation event prior to November 15, 2025.

*Voting rights—*

The holders of the Series A-1 convertible preferred stock, Series A-2 voting convertible preferred stock and Series B convertible preferred stock are entitled to vote as a single class with the holders of the Company's common stock with one vote for each share of common stock that the preferred stock is convertible into. In addition, the holders of preferred stock are entitled to elect five directors of the Company.

The holders of Series A-2 nonvoting convertible preferred stock do not have any voting rights, except for election of the preferred directors and certain protective rights.

*Dividends—*

Prior to the payment of any dividend, except a common stock dividend, to the common stockholders, the holders of preferred stock are entitled to receive an amount at least equal to the amount that would have been received had all shares of preferred stock been converted to common stock immediately prior to issuance of the dividend. As of the date the consolidated financial statements were issued, no cash dividends have been declared or paid.

*Liquidation rights—*

In the event of any voluntary or involuntary liquidation or a deemed liquidation event, the holders of Series B convertible preferred stock are entitled to receive an amount equal to the greater of: (i) purchase price per share plus any dividends declared but unpaid or (ii) an amount per share as would have been payable had all shares of Series B convertible preferred stock been converted into common stock immediately prior to such event.

After payment of such liquidation preferences to the holders of Series B convertible preferred stock, the holders of Series A convertible preferred stock are entitled to receive an amount equal to the greater of: (i) purchase price per share plus any dividends declared but unpaid or (ii) an amount per share as would have been payable had all shares of Series A convertible preferred stock been converted into common stock immediately prior to such event.

After payment of such liquidation preferences, holders of common stock receive the remaining assets of the Company available for distribution to its stockholders.

*Conversion—*

Shares of preferred stock are convertible into common stock based on a defined conversion ratio, which is originally set at one-for one, adjustable for certain dilutive events. As of December 31, 2025, the conversion ratio is 1:1 for Series A-1 convertible preferred stock, 1:2.03 for Series A-2 convertible preferred stock, and 1:1 for Series B convertible preferred stock.

Conversion is at the election of the holders of the preferred stock at any time, or automatically upon a qualified initial public offering or at the election of 60% of the holders of the preferred stock. However, if an automatic conversion would result in the holders of the Series A-2 convertible preferred stock holding greater than 19.9% of the capital stock on a fully-diluted basis, the holders of the Series A-2 convertible preferred stock may elect to not convert.

*Redemption—*

The preferred stock is not redeemable at the election of the holders and is only redeemable upon the occurrence of certain deemed liquidation events, as discussed above.

## 10. Common stock

As of December 31, 2024, the authorized capital stock of the Company included 60,000,000 shares of common stock, $0.00001 par value with one common share issued and outstanding. As of December 31, 2025, the authorized capital stock of the Company included 105,384,000 shares of common stock, $0.00001 par value, with 19,048 shares of common stock issued and outstanding.

The voting, dividend and liquidation rights of the holders of the Company’s common stock are subject to the rights, powers and preferences of the holders of the preferred stock set forth above.

Each share of common stock entitles the holder to one vote, together with the holders of the preferred stock. Common stockholders are entitled to receive dividends, subject to the preferential dividend rights of the preferred stock. Through December 31, 2025, no cash dividends have been declared or paid.

As of December 31, 2024 and 2025, the Company has reserved the following shares of common stock for future issuance:

| | 2024 | December 31, 2025 |
|---|---|---|
| Shares reserved for conversion of Series A-1 preferred stock | 40,000,000 | 30,000,000 |
| Shares reserved for conversion of Series A-2 preferred stock | 11,355,206 | 11,511,852 |
| Shares reserved for conversion of Series B preferred stock | — | 43,084,539 |
| Shares reserved for exercise of outstanding stock options | 5,709,341 | 13,470,409 |
| Shares reserved for issuance under equity compensation plans | 2,478,389 | 2,028,232 |
| Total shares of authorized common stock reserved for future issuance | 59,542,936 | 100,095,032 |

## 11. Stock-based compensation

***2024 Equity incentive plan***

The Company's 2024 Equity Incentive Plan (the "2024 Plan") provides for the Company to sell or issue common stock or restricted stock, or to grant incentive stock options or nonqualified stock options for the purchase of common stock, to employees, directors and consultants of the Company.

The total number of common shares that may be issued under the 2024 Plan was 15,517,688 shares as of December 31, 2025, of which 2,028,232 shares remained available for future grant.

The 2024 Plan is administered by the Board, or its delegee. The exercise prices, vesting and other restrictions are determined at the discretion of the Board, or its delegee, except that the exercise price per share of stock options may not be less than 100% of the fair market value of the common stock on the date of grant and the term of the stock option may not be greater than ten years. For any person who owns stock possessing more than 10% of the total combined voting power of all classes of stock of the Company or any affiliate, the exercise price per share of incentive stock options may not be less than 110% of the fair market value of the share of common stock on the date of grant. The Company generally grants stock-based awards with service conditions only ("service-based" awards) which generally vest over three or four years. The Company also has granted performance-based awards which vest upon the achievement of specified events. Stock options generally expire after ten years.

***Stock option valuation***

The assumptions that the Company used to determine the grant-date fair value of stock options granted were as follows, presented on a weighted-average basis:

| | Period from May 8, 2024 (inception) to December 31, 2024 | Year Ended December 31, 2025 |
|---|---|---|
| Expected option life (years) | 5.97 | 6.03 |
| Risk-free interest rate | 3.9% | 3.9% |
| Expected volatility | 78.2% | 80.8% |
| Expected dividend yield | 0.0% | 0.0% |

***Stock option activity***

The following table summarizes the Company's stock option activity during the year ended December 31, 2025:

| | Number of options | Weighted-average exercise price | Weighted-average remaining contractual term (years) | Aggregate intrinsic value |
|---|---|---|---|---|
| Outstanding as of December 31, 2024 | 5,709,341 | $ 5.25 | 9.86 | $ 856 |
| Granted | 8,375,376 | 6.79 | | |
| Exercised | (19,047) | 5.25 | | |
| Cancelled or forfeited | (595,261) | 5.43 | | |
| Outstanding as of December 31, 2025 | 13,470,409 | $ 6.20 | 9.17 | $ 52,398 |
| Exercisable at December 31, 2025 | 2,520,139 | $ 5.39 | 8.37 | $ 11,837 |

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the underlying stock options and the estimated fair value of the Company's common stock for those stock options that had exercise prices lower than the estimated fair value of the Company's common stock at December 31, 2025.

The weighted-average grant-date fair value of the Company's stock options granted for the period from May 8, 2024 (inception) to December 31, 2024 and for the year ended December 31, 2025 was $3.67 and $4.85, respectively.

***Stock-based compensation***

Stock-based compensation expense was allocated as follows (in thousands):

| | Period from May 8, 2024 (inception) to December 31, 2024 | Year Ended December 31, 2025 |
|---|---|---|
| Research and development | $ 89 | $ 1,472 |
| General and administrative | 852 | 9,468 |
| Total stock-based compensation expense | $ 941 | $ 10,940 |

During the year ended December 31, 2025, the Company recorded $2.6 million in share-based compensation expense related to stock options with performance-based vesting conditions for which the performance criteria was met, which is included in the table above.

As of December 31, 2025, total unrecognized compensation cost related to the unvested stock-based awards with service-based vesting conditions was $47.3 million, which is expected to be recognized over a weighted-average period of 3.3 years.

## 12. Income taxes

For the period from May 8, 2024 (inception) to December 31, 2024 and for the year ended December 31, 2025, the Company did not record a current or deferred income tax expense or (benefit) due to current and historical losses incurred by the Company.

Loss before income taxes for the period from May 8, 2024 (inception) to December 31, 2024 and for the year ended December 31, 2025 were as follows (in thousands):

| | Period from May 8, 2024 (inception) to December 31, 2024 | Year Ended December 31, 2025 |
|---|---|---|
| United States | $ (219,713) | $ (148,955) |
| Non-United States | — | — |
| Total | $ (219,713) | $ (148,955) |

A reconciliation of income tax expense (benefit) computed at the statutory federal income tax rate to income taxes as reflected in the consolidated financial statements is as follows:

| | Period from May 8, 2024 (inception) to December 31, 2024 | | Year Ended December 31, 2025 | |
|---|---|---|---|---|
| | Amount | Percent | Amount | Percent |
| Loss before income taxes | $ (219,713) | | $ (148,955) | |
| Federal income tax expense at statutory rate | (46,140) | 21.0% | (31,281) | 21.0% |
| State and local income taxes, net of federal benefit | — | 0.0% | (48) | 0.0% |
| Tax credits: | | | | |
| Federal R&D credit | — | 0.0% | (1,819) | 1.2% |
| Changes in valuation allowance | 26,534 | (12.1)% | 32,323 | (21.7)% |
| Nontaxable or nondeductible items: | | | | |
| Acquisition of IPR&D | 21,244 | (9.7)% | — | 0.0% |
| Other | (1,638) | 0.7% | 928 | (0.6)% |
| Other adjustments: | | | | |
| Return to provision and other | — | 0.0% | (103) | 0.1% |
| Total | $ — | 0.0% | $ — | 0.0% |

The Company's effective tax rate of zero differs from the U.S. statutory tax rate of 21% primarily as a result of the valuation allowance maintained against the Company's net deferred tax assets.

Deferred taxes are recognized for temporary differences between the basis of assets and liabilities for financial statement and income tax purposes. The significant components of the Company's deferred tax assets and liabilities are comprised of the following (in thousands):

| | December 31, 2024 | 2025 |
|---|---|---|
| Deferred tax assets: | | |
| U.S. and state net operating loss carryforwards | $ 3,054 | $13,981 |
| Research and development credits | — | 1,819 |
| Research and development capitalization | 1,521 | 24,866 |
| Accruals and reserves | 269 | 2,019 |
| Stock-based compensation | 141 | 2,354 |
| Lease liability | 127 | 2,675 |
| License fee amortization | 26,545 | 24,626 |

| | December 31, 2024 | December 31, 2025 |
|---|---|---|
| Other | 11 | 50 |
| Total deferred tax assets | $ 31,668 | $ 72,390 |
| Valuation allowance | (31,550) | (69,787) |
| Net deferred tax assets | $ 118 | $ 2,603 |
| Deferred tax liabilities: | | |
| Right-of-use asset | $ (118) | $ (2,603) |
| Total deferred tax liabilities | $ (118) | $ (2,603) |
| Net deferred tax assets (liabilities) | $ — | $ — |

Future realization of the tax benefits of existing temporary differences and net operating loss carryforwards ultimately depends on the existence of sufficient taxable income within the carryforward period. As of December 31, 2025, the Company performed an evaluation to determine whether a valuation allowance was needed. The Company considered all available evidence, both positive and negative, which included the results of operations for the current year. The Company determined that it was not possible to reasonably quantify future taxable income and determined that it is more likely than not that all of the deferred tax assets will not be realized. Accordingly, the Company maintained a full valuation allowance as of December 31, 2025.

As of December 31, 2024 and 2025, the Company had a federal net operating loss (“NOL”) carryforward of $12.2 million and $54.6 million, respectively, which can be carried forward indefinitely. As of December 31, 2024 and 2025, the Company has state NOL carryforwards of $7.9 million and $40.3 million, respectively, which begin to expire in 2044.

As of December 31, 2025, the Company had $1.8 million of U.S. federal research and development tax credits that begin to expire in 2045.

The Company provides for U.S. federal, state, and applicable foreign income and withholding taxes on the financial reporting basis over the tax basis of its foreign subsidiary investment because the Company does have the intentions and ability to indefinitely reinvest the undistributed earnings of its foreign subsidiaries. As a result, deferred taxes have not been recorded for the outside basis differences in its foreign subsidiary as of December 31, 2025 to the extent such differences are expected to result in future taxable income upon repatriation. The Company reviews its ability and intentions to indefinitely reinvest its foreign earnings at each balance sheet date.

Under Section 382 of the U.S. Internal Revenue Code of 1986, as amended (the “Code”), if a corporation undergoes an “ownership change,” the corporation’s ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income may be limited. The Company has completed a study through December 31, 2025 to assess whether an “ownership change” has occurred or whether there have been multiple ownership changes since it became a “loss corporation” as defined in Section 382. The Company concluded that an ownership change had occurred on October 31, 2025 as a result of the Company’s Series B convertible preferred stock financing; however, it is not expected there will be any tax attributes that expire unused.

On July 4, 2025, for tax years beginning after December 31, 2024, the One Big Beautiful Bill Act (“OBBBA”) enacted a new rule under Section 174A allowing companies to immediately expense any U.S.-based R&D expenditures. For U.S.-based R&D expenditures, companies may either immediately expense or elect to capitalize and amortize over at least 60 months under Section 174A. However, foreign R&D expenditures continue to require capitalization subject to the mandatory 15-year amortization period under Section 174.

The Company has elected to continue amortizing the previously capitalized costs over their remaining life. Beginning in tax year 2025, instead of immediately expensing U.S.-based R&D expenditures under Section 174A, the Company has elected to capitalize and amortize its U.S.-based R&D expenditures under Section 59(e) over a 10-year period. Any foreign R&D expenditures will continue to be capitalized and amortized over 15 years in accordance with the requirements of Section 174.

The calculation of the Company's tax liabilities involves dealing with uncertainties in the application of complex tax laws and regulations for both federal taxes and the many states in which the Company operates or does business. ASC 740 states that a tax benefit from an uncertain tax position may be recognized when it is more likely than not that the position will be sustained upon examination, including resolutions of any related appeals or litigation processes, on the basis of the technical merits.

The Company records uncertain tax positions as liabilities in accordance with ASC 740 and adjusts these liabilities when management's judgment changes as a result of the evaluation of new information not previously available. Because of the complexity of some of these uncertainties, the ultimate resolution may result in a payment that is materially different from its current estimate of the unrecognized tax benefit liabilities. These differences will be reflected as increases or decreases to income tax expense in the period in which new information is available. As of December 31, 2024 and 2025 the Company has not recorded any uncertain tax positions in its consolidated financial statements.

The Company recognizes interest and penalties related to unrecognized tax benefits on the income tax expense line in the accompanying consolidated statements of operations and comprehensive loss. As of December 31, 2024 and 2025, no accrued interest or penalties are included on the related tax liability line in the consolidated balance sheets.

The Company files tax returns as prescribed by the tax laws of the jurisdictions in which it operates. In the normal course of business, the Company is subject to examination by federal and state jurisdictions, where applicable. There are currently no pending tax examinations. The Company's tax year is still open under statute from inception to the present.

## 13. Net loss per share

For purposes of the diluted net loss per share calculation, stock options, unvested restricted stock and convertible preferred stock are considered to be common stock equivalents but have been excluded from the calculation of diluted net loss per share, as their effect would be anti-dilutive for the periods presented. Therefore, the weighted-average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same.

The following potentially dilutive common stock equivalents, presented based on amounts outstanding at the period end, were excluded from the computation of diluted net loss per share attributable to common stockholders for the periods indicated because including them would have had an anti-dilutive effect:

| | December 31, | |
|---|---|---|
| | 2024 | 2025 |
| Options to purchase common stock | 5,709,341 | 13,470,409 |
| Convertible preferred stock (as converted to common stock) | 39,487,338 | 84,596,391 |
| Total | 45,196,679 | 98,066,800 |

## 14. Commitments and contingencies

***Legal proceedings***

The Company, from time to time, may be party to litigation arising in the ordinary course of business. The Company was not subject to any material legal proceedings for the period from May 8, 2024 (inception) to December 31, 2024 or for the year ended December 31, 2025, and, to the best of its knowledge, no material legal proceedings are currently pending or threatened.

***Significant agreements***

*Hengrui license and collaboration agreement*

In May 2024, the Company entered into a license and collaboration agreement (the "Hengrui License Agreement") with Jiangsu Hengrui Pharmaceuticals Co., Ltd. ("Hengrui"). Upon execution of the Hengrui License Agreement, the Company paid $100.0 million in cash as a non-refundable upfront payment and incurred a $10.0 million technology transfer fee, which was paid in December 2024. The Company also issued 5,677,603 shares of Series A-2 convertible preferred stock. The fair value of these shares is accounted for as additional consideration for the acquired license.

Under the terms of the Hengrui License Agreement, the Company obtained the exclusive right to develop, manufacture and commercialize specified programs worldwide, excluding China, Hong Kong, Macau, and Taiwan (the "Territory"). The Company is obligated to use commercially reasonable efforts to advance these programs. The Company may not pursue development of any competitive products, as defined in the Hengrui License Agreement, for a period of two years. The Company also has a right of first refusal on certain programs that are under development by Hengrui as well as options to license specified new form products and combination products developed by Hengrui.

Hengrui must provide certain transition and data sharing services and must also manufacture clinical materials on behalf of the Company upon request. The Company is responsible for all costs of developing and commercializing the programs in the Territory.

The Company is obligated to make clinical and regulatory milestone payments of up to an aggregate of $200.0 million. In addition, the Company is obligated to make commercial milestone payments of up to an aggregate of $5.7 billion. The Company is also obligated to make tiered royalty payments ranging from mid-single digit to low-tens based on a percentage of net sales by the Company. If the Company entered into any partnering relationships prior to November 15, 2025, the Company would have been required to pay Hengrui specified percentages of any consideration received based on the timing of when such an agreement was executed. The Company did not enter into any such partnering relationships prior to November 15, 2025.

If the Company elects to receive rights to the specified new form products or combination products, the Company must make option exercise payments of either a mid-seven figure amount or low-eight figure amount, which may be refundable with respect to combination products in certain circumstances.

The Company accounted for the arrangement as an asset acquisition of in-process research and development technology. As a result, at inception of the arrangement, the Company recognized expense in its consolidated statements of operations and comprehensive loss equal to the $100.0 million upfront cash payment, the $96.4 million fair value of Series A-2 convertible preferred stock issued as partial consideration for the arrangement, the $10.0 million technology transfer payment, and the $4.8 million fair value of the potential partnership payments, which was considered to be a derivative instrument. All other payments will be recognized upon achievement.

## 15. Benefit plan

The Company's employees are eligible to participate in the Company's 401(k) retirement plan (the "401(k) Plan"). Participants may contribute up to 100% of their annual compensation to the 401(k) Plan, subject to statutory limitations. The 401(k) Plan has a safe harbor match. The Company made matching contributions of up to 3.5% of the eligible employee's compensation for the period from May 8, 2024 (inception) to December 31, 2024 and for the year ended December 31, 2025. The Company's contributions for the period from May 8, 2024 (inception) to December 31, 2024 and for the year ended December 31, 2025 were less than $0.1 million and $0.8 million, respectively.

## 16. Related party transactions

In May 2024, the Company entered into the Hengrui License Agreement. As partial consideration for this arrangement, the Company issued shares of Series A-2 convertible preferred stock, which represented 19.9% of the outstanding capital stock of the Company at issuance, on a fully-diluted basis.

In addition, as part of the agreement with Hengrui, Hengrui has agreed to provide the Company with manufacturing services and supplies. In connection with these services, the Company recognized $0.1 million and $0.8 million in research and development expense in its consolidated statements of operations and comprehensive loss from May 8, 2024 (inception) to December 31, 2024 and for the year ended December 31, 2025, respectively. Amounts due to Hengrui by the Company in connection with these services totaled $0.1 million as of both December 31, 2024 and 2025, which amounts were included in accrued expenses on the consolidated balance sheets.

## 17. Segment reporting

The Company operates and manages its business as a single operating segment for the purposes of assessing performance and making operating decisions. The Company's current focus is on the development of a broad, advanced, and differentiated portfolio of clinical-stage injectable and oral therapies for the treatment of obesity. The Company has one reportable segment. The determination of reportable segments is based on the CODM's use of financial information provided for the purpose of assessing performance and making operating decisions. The Company's CODM is its Chief Executive Officer.

The CODM assesses performance for the segment based on net loss. The measure of segment assets is reported on the balance sheet as total assets.

To date, the Company has not generated any product revenue. The Company expects to continue to incur significant expenses and operating losses for the foreseeable future as it advances product candidates through all stages of development and clinical trials and, ultimately, seeks regulatory approval. As such, the CODM uses cash forecast models in deciding how to invest into the segment. Such cash forecast models are reviewed to assess the entity-wide operating results and performance. Net loss is used to monitor budget versus actual results. Monitoring budgeted versus actual results is used in assessing performance of the segment, along with cash forecast models.

The table below summarizes the expense categories reviewed by the CODM for the period from May 8, 2024 (inception) to December 31, 2024 and for the year ended December 31, 2025:

| | Period from May 8, 2024 (inception) to December 31, 2024 | Year Ended December 31, 2025 |
|---|---|---|
| External research and development[1] | | |
| Ribupatide | $ (4,443) | $ (62,606) |
| KAI-7535 | (346) | (8,524) |
| KAI-4729 | (43) | (740) |
| Oral ribupatide | — | (47) |
| Unallocated research and development and other[2] | (482) | (8,592) |
| Acquired in-process research and development as part of the acquisition of the Hengrui License | (214,070) | — |
| General and administrative[3] | (4,414) | (16,360) |
| Personnel related (including stock-based compensation)[4] | (6,618) | (61,471) |
| Interest income | 2,508 | 11,048 |
| Other income (expense), net | 8,195 | (1,663) |
| Net loss | $ (219,713) | $ (148,955) |

1) External research and development is allocated to the Company's programs, and includes nonclinical, clinical trial, contract manufacturing, non-employee consultant and contractor, and other research and development costs.

2) Unallocated research and development includes external costs that are not program specific primarily related to consultant and contractor costs, in addition to research and development allocated rent expense and depreciation.

3) General and administrative includes external costs related to the Company's executive, finance, legal, and other administrative functions, such as professional fees for legal, patent, consulting, accounting, audit and tax services. General and administrative also includes information technology costs and general and administrative allocated rent expense and depreciation.

4) Internal costs includes salaries and related costs, including stock-based compensation, for employees.

## 18. Subsequent events

The Company has completed an evaluation of all subsequent events after December 31, 2025 through February 11, 2026, the date the consolidated financial statements were issued, to ensure that these consolidated financial statements include appropriate disclosure of events both recognized in the consolidated financial statements as of December 31, 2025, and events which occurred subsequently but were not recognized in the consolidated financial statements.

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***39,062,500 Shares***

***Common Stock***

# Prospectus

*Joint Book-Running Managers*

**J.P. Morgan** **Jefferies** **Leerink Partners** **TD Cowen** **Evercore ISI**

*Lead Manager*

**William Blair**

April 16, 2026

**Through and including May 11, 2026 (the 25th day after the date of this prospectus), all dealers effecting transactions in 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 a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.**