UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2025

OR

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

Commission File Number 001-42513

AARDVARK THERAPEUTICS, INC.

(Exact name of Registrant as specified in its Charter)

Delaware	**82-1606367**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
4370 La Jolla Village Drive, Suite 1050 San Diego, CA	**92122**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (858) 225-7696

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.00001 per share	**AARD**	**The Nasdaq Stock Market LLC**

Securities registered pursuant to Section 12(g) of the Act: **None**

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

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

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

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

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

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

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

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

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant was approximately $162.9 million on June 30, 2025, the last business day of the registrant's most recently completed second fiscal quarter based on the closing price of $13.52 per share, which was the closing price of the registrant's common stock as reported on the Nasdaq Global Select Market on such date. Shares of common stock held by each executive officer and director and by each other person who may be deemed to be an affiliate of the registrant on such date have been excluded from this computation. The determination of affiliate status for this purpose is not necessarily a conclusive determination for other purposes.

The number of shares of Registrant's common stock outstanding as of February 28, 2026 was 21,816,041.

DOCUMENTS INCORPORATED BY REFERENCE

None.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (Annual Report) contains forward-looking statements about us and our industry within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act), and Section 27A of the Securities Act of 1933, as amended (the Securities Act), which statements involve substantial risks and uncertainties. Forward-looking statements generally relate to future events or our future financial or operating performance. All statements other than statements of historical facts contained in this Annual Report, including statements regarding our future results of operations and financial position, business strategy, product candidates, planned preclinical studies and clinical trials, results of preclinical studies and clinical trials, research and development plans and costs, plans for manufacturing, regulatory approvals, timing and likelihood of success, as well as plans and objectives of management for future operations, are forward-looking statements. In some cases, you can identify forward-looking statements because they contain words such as "may," "will," "might," "should," "would," "expects," "plans," "anticipates," "could," "intends," "target," "outlook," "projects," "forecast," "contemplates," "believes," "estimates," "predicts," "potential" or "continue" or the negative of these words or other similar terms or expressions that concern our expectations, strategy, plans or intentions, but the absence of these words does not mean that a statement is not forward-looking. Forward-looking statements contained in this Annual Report include, but are not limited to, statements about:

- *the initiation, timing, progress, status and results of our preclinical studies, clinical trials and research and development programs for our product candidates, and our anticipated timeline for providing further guidance on, or results of, our preclinical studies and clinical trials;*
- *our ability to demonstrate, and the timing of, preclinical proof-of-concept in vivo for our product candidates;*
- *our ability to successfully complete our clinical trials;*
- *our ability to quickly leverage our initial product candidates and to progress additional candidates;*
- *the prevalence of certain diseases and conditions we intend to treat and the size of the market opportunity for our product candidates;*
- *estimates of the number of patients with certain diseases and conditions we intend to treat and the number of subjects that we intend to enroll in our clinical trials;*
- *the likelihood of our clinical trials demonstrating safety and efficacy of our product candidates;*
- *the beneficial characteristics, including safety, efficacy and therapeutic effects, and potential advantages of our product candidates;*
- *the timing or likelihood of regulatory filings and approval for our product candidates;*
- *our ability to meet future regulatory standards with respect to our product candidates, if approved;*
- *our plans relating to the further development and manufacturing of our product candidates, including additional indications that we may pursue;*
- *our ability to identify additional product candidates or technologies with significant commercial potential that are consistent with our commercial objectives;*
- *the rate and degree of market acceptance and therapeutic benefits of our product candidates, if approved, and any other product candidates we may develop;*
- *the implementation of our strategic plans for our business, product candidates, research programs and technologies;*
- *the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates;*
- *anticipated developments related to our competitors and our industry;*
- *our competitive position and ability to leverage the clinical, regulatory and manufacturing advancements to accelerate our clinical trials and regulatory approval of product candidates;*
- *the success of competing therapies that are or may become available;*
- *our ability to identify and enter into future license agreements and collaborations;*
- *the expected potential benefits of strategic collaborations with third parties and our ability to attract collaborators with development, regulatory, manufacturing or commercialization expertise;*
- *our ability to efficiently and cost-effectively conduct our current and future clinical trials;*
- *our reliance on third parties to conduct clinical trials of our product candidates;*

- *our reliance on third parties for the manufacture of our product candidates;*
- *our plans relating to sales strategy, manufacturing and commercializing our product candidates, if approved;*
- *our ability to attract and retain sales personnel, or to contract with a sales organization, if our product candidates are approved;*
- *anticipated regulatory and legal developments in the United States and foreign countries in which we may seek regulatory approval for our product candidates in the future;*
- *our ability to expand internationally;*
- *our ability to attract and retain key scientific and management personnel;*
- *our expected or anticipated financial performance;*
- *our ability to obtain funding for our operations necessary to complete further development and commercialization of our product candidates, if approved;*
- *our ability to maintain existing, and establish new, strategic collaborations, licensing, or other arrangements, including our ability to comply with our financial obligations pursuant to the terms of such agreements;*
- *the sufficiency of our existing capital resources to fund our future operating expenses and capital expenditure requirements;*
- *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 anticipated use of our cash, cash equivalents and short-term investments resources, estimates of our expenses, capital requirements and needs for additional financing.*

We caution you that the forward-looking statements highlighted above do not encompass all of the forward-looking statements made in this Annual Report.

We have based the forward-looking statements contained in this Annual Report primarily on our current expectations and projections about future events and trends that we believe may affect our business, financial condition, results of operations or growth prospects. The outcome of the events described in these forward-looking statements is subject to risks, uncertainties and other factors described in Part I, Item 1A, "Risk Factors", of this Annual Report and Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations", of this Annual Report and elsewhere in this Annual Report. Moreover, we operate in a very competitive and challenging environment. New risks and uncertainties emerge from time to time, and it is not possible for us to predict all risks and uncertainties that could have an impact on the forward-looking statements contained in this Annual Report. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. We cannot assure you that the results, events and circumstances reflected in the forward-looking statements will be achieved or occur, and actual results, events or circumstances could differ materially from those described in the forward-looking statements. You should, however, review the factors and risks we describe in the reports we will file from time to time with the Securities and Exchange Commission (SEC) after the date of this Annual Report.

In addition, statements that "we believe" and similarly qualified 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 Annual Report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and you are cautioned not to rely unduly upon them.

The forward-looking statements made in this Annual Report relate only to events as of the date on which the statements are made. We undertake no obligation to update any forward-looking statements made in this Annual Report to reflect events or circumstances after the date of this Annual Report or to reflect new information or the occurrence of unanticipated events, except as required by law. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures, other strategic transactions or investments we may make or enter into.

Throughout this Annual Report, unless the context otherwise requires, the terms "Aardvark," "we," "us" and "our" in this Annual Report refer to Aardvark Therapeutics, Inc. and its subsidiaries.

PART I

Item 1. Business.

Overview

We are a clinical-stage biopharmaceutical company focused on developing novel, small-molecule therapeutics to activate innate homeostatic pathways for the treatment of metabolic diseases. We target biological pathways associated with alleviating hunger that we believe have the potential to deliver transformative outcomes for patients. We have focused our efforts on developing selective compounds, targeting Bitter Taste Receptors (TAS2Rs) for hunger-associated conditions. Our initial compounds target TAS2Rs expressed in the gut lumen, which normally respond to the chemicals in food and participate in the gut-brain axis. Our research has shown that activating these receptors can induce the secretion of endogenous signaling molecules, including cholecystokinin (CCK), peptide YY (PYY) and glucagon-like peptide-1 (GLP-1).

TAS2Rs are a family of 26 different nutrient-sensing G protein-coupled receptors (GPCRs) that are broadly expressed among vertebrates. TAS2Rs are present in the oral cavity to convey bitter taste and are highly expressed in many other tissues throughout the body where they are key in regulating metabolic and inflammatory pathways. CCK has long been recognized as a promising pharmaceutical target because its release is triggered with food and it helps suppress hunger, which is the feeling of discomfort that comes from a perception of not having eaten recently. We believe suppression of hunger could be complementary to the suppression of appetite reported from patients on GLP-1 receptor targeted treatments, which reduce the desirability of food. Previous approaches to directly agonize CCK receptors through exogenous molecules have been limited by safety concerns driven by systemic exposure, resulting in on-target, off-tissue toxicity, and in turn leading to adverse effects, such as pancreatitis. Our wholly-owned lead product candidate, ARD-101, is an oral, largely gut-restricted small-molecule agonist of certain TAS2Rs expressed in the gut lumen. ARD-101, in contrast to previous approaches to directly agonize CCK receptors, elicits the endogenous release of CCK by leveraging the body's natural response to TAS2R agonism. Besides our product candidates, we are not aware of any approved or other clinical-stage candidates targeting certain TAS2Rs.

ARD-101 has limited systemic absorption, which we believe reduces the potential for systemic toxicity and has contributed to ARD-101 being well-tolerated in our Phase 1 and 2 trials. We have completed a Phase 1 clinical trial of ARD-101 in healthy volunteers and a Phase 2 clinical trial in subjects with hyperphagia associated with Prader-Willi Syndrome (PWS). The Phase 2 clinical trial in hyperphagia associated with PWS evaluated two dosing regimens over 28 days followed by a 14-day withdrawal period. In Part 1 of the trial, 12 subjects completed the treatment period at a fixed dose of 200 mg delivered orally twice daily (BID). These 12 subjects that completed treatment had no significant treatment-related adverse events and, of these subjects, eight completed the Hyperphagia for Clinical Trial Questionnaire-9 (HQ-CT 9), with seven having complete post–database lock datasets. In this subgroup of seven, the mean decline at day 28 was approximately 9 points. In Part 2 of the trial, four subjects were dosed under a revised protocol: 400 mg BID for seven days, followed by 600 mg BID for seven days and ending with 800 mg BID for 14 days. The four subjects that completed the trial per protocol had only grade 1 treatment-related adverse events and showed a decrease in HQ-CT 9 of approximately eight points at 28 days. In our completed Phase 2 clinical trial in subjects with hyperphagia associated with PWS, ARD-101 was shown to be well-tolerated and demonstrated clinical activity through a reduction in Hyperphagia Questionnaire for Clinical Trials (HQ-CT) scores.

In the second quarter of 2025, we initiated dosing for a Phase 3 clinical trial for hyperphagia associated with PWS, which we refer to as the HERO (**H**unger **E**limination or **R**eduction **O**bjective) trial. We previously reached alignment with the FDA on a protocol for a Phase 3 clinical trial, which we initiated in December 2024. In August 2025, we submitted a protocol amendment to remove the use of anti-psychotics and insulin-requiring type 2 diabetes as exclusion criteria for the clinical trial. In October 2025, we reached alignment with the FDA on a protocol amendment to lower the minimum age of eligibility to participate in the trial from 13 to 10 years of age. This change broadened the eligible trial population and expanded the potential addressable opportunity within PWS. In December 2025, we submitted an additional protocol amendment seeking to further lower the minimum age of eligibility to participate in the trial to 7 years of age. During the third quarter of 2025, we commenced enrollment for the HERO Open Label Extension (OLE) trial, which was available to patients completing the HERO trial and we initiated our first clinical sites in Australia. In January 2026, we announced over 50% completion of the target enrollment of 90 patients in the HERO trial and within the first quarter of 2026, we initiated clinical sites in the UK, South Korea and Canada.

On February 27, 2026, we voluntarily paused enrollment and dosing in the HERO and OLE trials following reversible cardiac observations in a healthy volunteer study and are currently reviewing the data and collaborating with the FDA to determine next steps. As a result, aspects of the trial design, development timeline and future clinical plans may change. Following the voluntary pause, we are reviewing the trial designs and protocols in collaboration with the FDA and the previously agreed protocol elements may be revisited. For additional detail, please see the subsection titled "—ARD—ARD-101 Overview" below.

Our second TAS2R program, ARD-201, was planned to be a fixed-dose combination of ARD-101 and a dipeptidyl peptidase-4 (DPP-4) inhibitor for the treatment of obesity and obesity-related conditions. We previously initiated a Phase 2 clinical trial, which we referred to as the POWER (Prevention Of WEight Regain) trial, in December 2025, to explore the efficacy of ARD-201 in the prevention of weight regain among patients who have successfully lost over 15% of body weight on GLP-1RA therapy. In addition, we previously planned to initiate a second Phase 2 trial for ARD-201 in the first half of 2026, which we referred to as the STRENGTH (Sitagliptin and TAS2R for weight Reduction with Exercise, Nutrition, and GLP-1RA Trial and Hunger assessment) trial. Because ARD-201 contains ARD-101 as a component of the planned combination therapy, we are assessing the potential implications of the

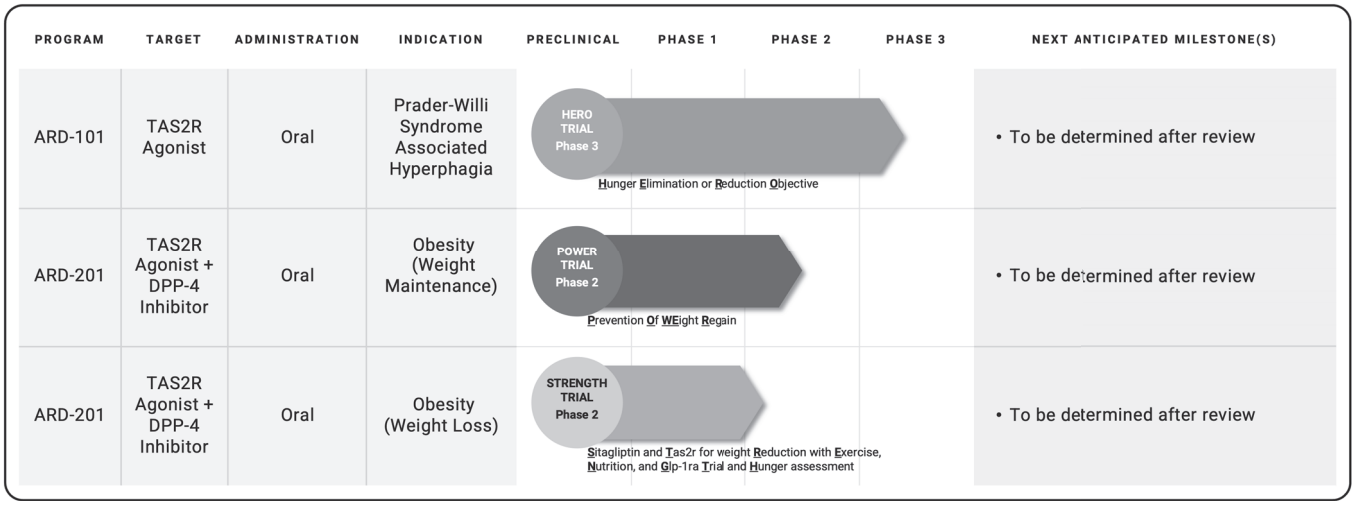
voluntary pause of the HERO trial on the ARD-201 program. Following this assessment, we have voluntarily paused the STRENGTH and POWER clinical trials while we complete our ongoing evaluation of the safety observations identified in the healthy volunteer study of ARD-101 and continue discussions with the FDA regarding next steps for the ARD-101 program. We expect to provide further guidance in the second quarter of 2026.

In preparation for these trials, we expanded our clinical management and regulatory capabilities, including hiring clinical, regulatory and quality personnel, and we expect to continue to need to expand our clinical management and regulatory capabilities and to rely on third parties to conduct our later stage or pivotal clinical trials in the future. However, the timing of additional staffing and operational expansion may be delayed as we evaluate next steps following the voluntary pause of the HERO trial and related clinical programs.

Our Pipeline

We are advancing the below portfolio of wholly-owned novel and proprietary small-molecule programs that we believe can induce satiety in patients with hunger-associated indications, as outlined below. As discussed above, certain clinical programs, including the HERO trial for ARD-101 and the POWER and STRENGTH trials for ARD-201, are currently paused while we evaluate safety observations and continue discussions with the FDA regarding next steps.

Our Hunger Associated TAS2R Pipeline



Our Team and Investors

We have assembled a management team of biopharmaceutical experts with extensive experience in building and operating organizations that develop and deliver innovative medicines to patients. Our Founder, Chairperson of our board of directors and Chief Executive Officer, Dr. Tien Lee, founded our company in 2017. He brings over 20 years of experience as a biotechnology innovator and executive and was integrally involved with the founding or advancement of several biopharmaceutical companies. Before founding our company, Dr. Lee joined NantKwest in 2014 and served as its Chief Strategy Officer until March 2017. Dr. Lee is also an inventor or co-inventor of multiple biomedical and biotechnology innovations. Our Chief Medical Officer, Dr. Manasi Jaiman, Chief Financial Officer and Chief Operating Officer, Nelson Sun, as well as other senior members of our team, collectively bring extensive clinical and business development experience to our company.

Prior to our IPO in February 2025, we had raised $129.1 million supported by a syndicate of leading life sciences and institutional investors, including the completion of our $85.0 million Series C financing led by Decheng Capital in May 2024. In February 2025, we completed our IPO with the sale of 6,120,661 shares of common stock, which included the partial exercise by the underwriters of their option to purchase 232,661 additional shares, at an initial public offering price of $16.00 per share and received net proceeds of approximately $87.5 million.

Our Strategy

Our goal is to become a leader in the treatment of obesity and obesity-related conditions, starting with rare hyperphagias. We intend to leverage the experience and capabilities of our executive management team and our established networks throughout the biopharmaceutical industry to identify, develop and commercialize product candidates that are designed to offer enhanced efficacy, tolerability and convenience, thereby providing benefits to patients and their treating clinicians. We intend to achieve our goals by implementing the following strategies:

- **Advance the clinical development of ARD-101 for the treatment of hyperphagia associated with PWS.** Our lead product candidate, ARD-101, is an oral gut-restricted small-molecule agonist of certain TAS2Rs expressed in the gut lumen. In an open-label Phase 2 clinical trial evaluating ARD-101 in subjects with hyperphagia associated with PWS, ARD-101 demonstrated a reduction in HQ-CT score. We have received both Orphan Drug and Rare Pediatric Disease Designations from the FDA and have initiated our Phase 3 HERO trial to pursue development of ARD-101 to potentially transform the PWS treatment landscape and provide a potentially life-changing therapeutic option for an underserved patient base with only one currently approved therapy that we believe does not fully address the needs of the patient population both from an efficacy and safety standpoint. In preparing for this Phase 3 clinical trial, we expanded our clinical management and regulatory capabilities, including hiring clinical, regulatory and quality personnel, and we expect to continue to need to expand our clinical management and regulatory capabilities and to rely on third parties as we continue advancing this trial and other clinical trials. We initiated the Phase 3 HERO trial in December 2024. In February 2026, we voluntarily paused enrollment and dosing in the HERO trial based on reversible cardiac observations in a healthy volunteer study. We are conducting a comprehensive review of the data and collaborating with the FDA to determine next steps. We no longer anticipate topline data from the HERO trial in the third quarter of 2026 and the timing of additional staffing and operational expansion may be delayed as we evaluate next steps following the voluntary pause of the HERO trial and related clinical programs. We expect to provide further guidance in the second quarter of 2026.
- **Continue to innovate and expand our pipeline programs through our internal drug-discovery efforts.** We believe that the discovery and developmental expertise of our management team in TAS2R targeting can be applied to many adjacent therapeutic areas with large unmet needs. We plan to continue to leverage our deep know-how and capabilities to further build out our pipeline of early-stage and preclinical assets across metabolic, inflammatory and other adjacent indications.
- **Expand and maximize the potential of our product candidates and pipeline by selectively evaluating strategic collaborations.** Our team possesses experience in drug discovery, clinical development and commercialization. From time to time, we expect to selectively evaluate potential strategic collaborations with other biopharma companies with strong and proven commercial capabilities to build upon and expand the impact of our potential therapies in certain territories. In addition, for certain programs or indications, we may selectively evaluate opportunities to partner in order to accelerate and fund their development and commercialization.

TAS2R as a Therapeutic Target

TAS2R Overview

Bitterness is one of five basic taste sensations that play a crucial role in survival by helping guide organisms to avoid harmful toxins and noxious substances. The sensors for bitter compounds in vertebrates are the evolutionarily-conserved TAS2Rs, a class of GPCRs initially identified in type II taste receptor cells located in the taste bud. In the human genome, 26 TAS2R genes have been identified. They are located not only in the mouth and throat but are expressed widely throughout the body, for example in the intestines, skin, brain, bladder, and lower and upper respiratory tract. The expression of TAS2Rs throughout the body, as well as their

involvement in multiple physiologic processes, underscore TAS2Rs as compelling potential therapeutic targets for a wide array of diseases.

In the gut, TAS2Rs control the secretion of satiety regulating gut hormones and regulate gut motility, ultimately decreasing hunger, food intake and body weight. TAS2Rs are expressed on enteroendocrine cells in the gut lining and their activation by bitter molecules triggers the local release of peptides, including CCK, PYY and GLP-1, which subsequently act through the corresponding receptors in afferent sensory fibers of the vagus nerve or directly via the bloodstream to then transmit signals to the brain to control satiety and food intake. This approach is fundamentally different from other oral metabolic programs that attempt to mimic nutrient-driven gut hormone release. ARD-101 and ARD-201 activate the gut's protective chemosensory system via bitter taste receptors, engaging rapid vagal neural circuits that limit intake early and reinforce satiety through secondary hormone release. This non-nutritive, neural-first mechanism is designed to reduce hunger drive without inducing nausea and we believe this may overcome the physiologic ceiling that limits nutrient-mimic therapies.

CCK has long been recognized as a promising pharmaceutical target because its release is triggered with food and helps suppress feelings of hunger in addition to providing other therapeutic applications as shown in Figure 1 below. Major companies such as AbbVie, AstraZeneca, GSK and Novo Nordisk have attempted to pursue direct CCK receptor agonism through exogenous molecules. However, the limitations of this approach have remained a significant barrier to an effective therapy. Specifically, there were challenges with high systemic exposure, resulting in on-target, off-tissue toxicity leading to safety concerns and adverse effects, including pancreatitis.

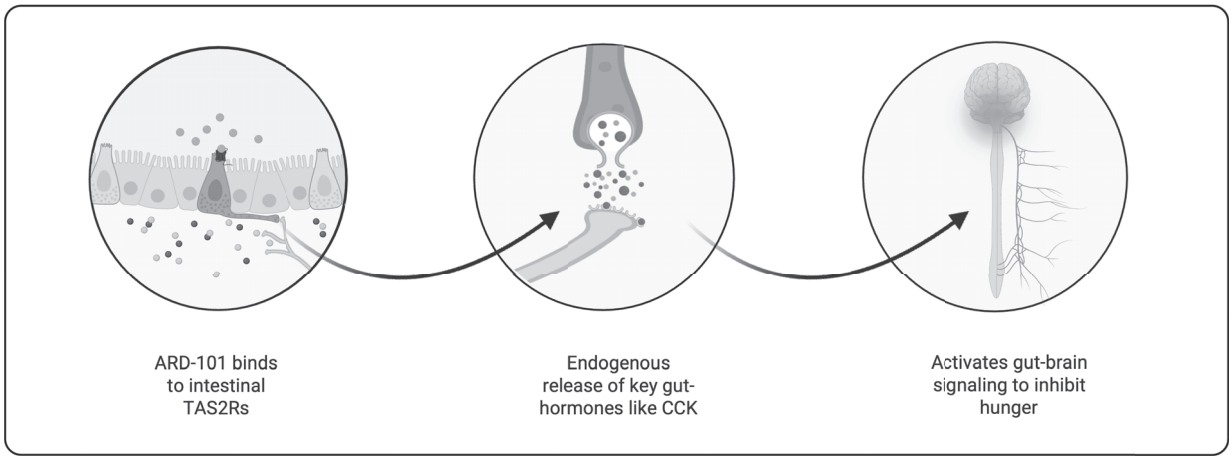
Figure 1: Potential Therapeutic Targets Involving CCK

Therapeutic Applications	Evidence
General Obesity	Encouraging weight-modulating effects of sub-chronic CCK-1 receptor agonism in murine models [1], [2]
Hyperphagia in Hypothalamic Obesity	Prior administration of CCK significantly reduced food consumption in the first eating period in HO subjects [3]
Hyperphagia in PWS	CCK infusion leading to physiological plasma levels suppresses food and energy intake, increasing satiety [4], [5] A blunted CCK response to a high-fat meal may contribute to hyperphagia in PWS subjects [6]
Diabetes	CCK-8 reduced the circulating glucose increase and potentiated the increase in circulating insulin after meal ingestion in healthy and diabetic subjects [7]
Inflammatory Bowel Disease	Wistar rat *in vivo* model of acetic acid induced colitis, CCK-8 (10 μg/kg), reduces macroscopic damage score [8]

[1] J Endocrinol. 2013;216(1):53-9.
[2] Biochim Biophys Acta. 2013;1830(8):4009-16.
[3] Am J Physiol. 1992;262(2 Pt 2):R241-4.
[4] Gastroenterology. 1994;106(6):1451-4.
[5] J Clin Endocrinol Metab. 2001;86(12):5830-7.
[6] Am J Med Genet. 2000;95(1):67-70.
[7] J Clin Endocrinol Metab. 2000;85(3):1043-8.
[8] Regul Pept. 2003;116(1-3):109-18.

Our lead product candidate, ARD-101, is an oral gut-restricted small-molecule targeting certain TAS2Rs expressed in the gut lumen. ARD-101 is composed of denatonium acetate monohydrate, and is one of the most potent TAS2R agonists identified. In our preclinical studies and clinical trials to date, we have found it to be approximately 99% restricted to the gut with minimal systemic exposure, which has led to local elevation of endogenous gut peptide hormones, such as CCK and GLP-1, within physiological levels. The selective local secretion avoids the off-target side effects seen with approaches using systemic exposure of artificial CCK analogue molecules. As shown in Figure 2 below, ARD-101 has the potential to affect hunger, metabolism and inflammation through gut-brain signaling.

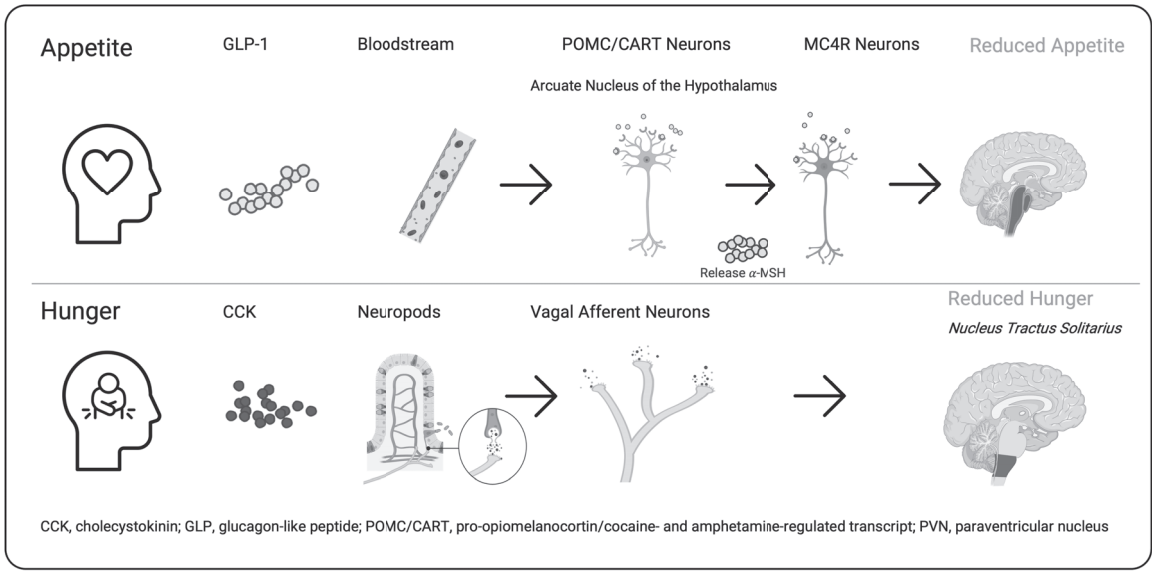
Figure 2: CCK Release Helps to Attenuate Hunger and Leads to Satiety



The Role of TAS2Rs in Hunger Versus Appetite

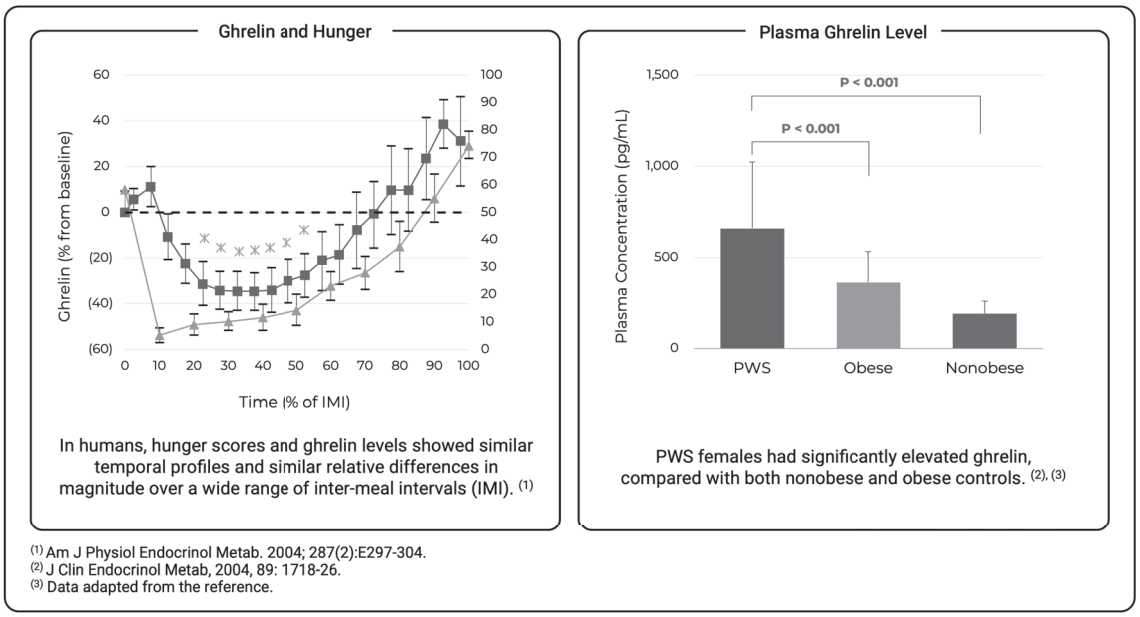
The key differentiating feature of gut lumen-based TAS2R agonism is its ability to stimulate local secretion of gut hormones such as CCK, which acts in an autocrine/paracrine-like manner to induce a gut-brain signal that abrogates sensations of hunger. Hunger and appetite are often subjectively perceived to be different sensations along the same axis. However, hunger and appetite represent different neurologically-based drives that guide human behavior and metabolic regulation, as shown in Figure 3 below. Appetite represents neurologic reward and pleasure seeking, whereas hunger represents the avoidance of pain and discomfort.

Figure 3: Hunger and Appetite are Distinct Neural Pathways



For certain hyperphagia-associated disorders, such as PWS, patients are driven to eat by hunger regardless of perceived desirability of food, even going so far as to eat garbage. For general obesity, addressing hunger along with appetite has the potential for a complementary effect. Current therapeutics that engage GLP-1RAs reduce sensations of appetite to drive reduced food consumption and therefore result in weight loss, yet cannot sufficiently attenuate or improve self-reported hunger levels. This increased hunger state is in part driven by GLP-1 induction of higher levels of serum ghrelin. Ghrelin is a hormone that, when elevated, is concordant with sensations of hunger. In humans, hunger scores and ghrelin levels show similar temporal profiles over a wide range of inter-meal intervals, and individuals with PWS have dramatically elevated ghrelin levels (Figure 4 below).

Figure 4: Ghrelin, Hunger, and Prader-Willi Syndrome: The Hormonal Connection



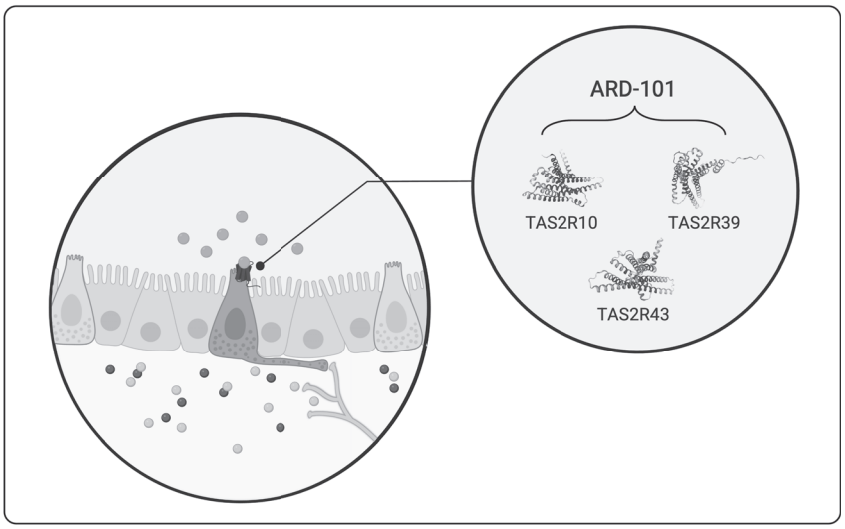
Previous attempts at pharmaceutical development of CCK receptor agonists included the development of long-acting systemic CCK analogues by chemically altering the natural CCK to extend its half-life and by administering it as a subcutaneous depot. These development programs were discontinued because of unintended on-target off-tissue toxicities, including pancreatitis. We believe that ARD-101 elicits expression of CCK in a localized manner in the peri-gut region to selectively elicit vagal gut-brain signaling without significant concomitant rise in systemic CCK. We believe ARD-101 offers a more anatomically targeted and selective approach to invoke the effects of CCK signaling.

ARD-101

ARD-101 Overview

Our lead product candidate, ARD-101, is an oral gut-restricted small-molecule agonist of certain TAS2Rs expressed in the gut lumen for the treatment of hyperphagia associated with PWS (Figure 5 below). We believe its unique ability to induce gut-localized CCK and GLP-1 secretion could result in a sustainable and clinically relevant reduction in hyperphagia with a profile designed for long-term dosing without dose-limiting safety or tolerability issues.

Figure 5: ARD-101 Targets Three TAS2Rs Expressed on Enteroendocrine Cells



Our Phase 1 clinical trial showed that ARD-101 was well-tolerated in healthy volunteers. Data from the first of two parts of our Phase 2 clinical trial of ARD-101 in subjects 17 years or older with hyperphagia associated with PWS showed a reduction from baseline in their HQ-CT 9 or Hyperphagia for Clinical Trial Questionnaire-13 (HQ-CT 13) scores, and it was well-tolerated with no serious adverse events (SAEs). In Part 2 of the trial, the four subjects that completed the trial per protocol showed a decrease in HQ-CT 9 of approximately eight points at 28 days.

We initiated our Phase 3 HERO trial for subjects 13 years or older with hyperphagia associated with PWS in December 2024. In August 2025, we submitted a protocol amendment to remove the use of anti-psychotics and insulin-requiring type 2 diabetes as exclusion criteria for the clinical trial. In October 2025, we reached alignment with the FDA on a protocol amendment to lower the minimum age of eligibility to participate in the trial from 13 to 10 years of age. This change broadens the eligible trial population and expands the potential addressable opportunity within PWS. In December 2025, we submitted an additional protocol amendment seeking to further lower the minimum age of eligibility to participate in the trial to 7 years of age.

On February 27, 2026, we announced a voluntary pause of enrollment and dosing in the HERO trial and the OLE trial following reversible cardiac observations identified during routine safety monitoring in a healthy volunteer study. We are conducting a comprehensive review of the data and collaborating closely with the FDA to inform next steps, including potential revisions to the trial design and protocol. We no longer anticipate announcing topline data from the HERO trial in the third quarter of 2026 and expect to provide further guidance in the second quarter of 2026.

The healthy volunteer study was designed to formally assess cardiac safety and satisfy anticipated requirements for a future New Drug Application for ARD-101. In this study, the first cohort of subjects received dosing directly at the supratherapeutic level of 1600 mg twice daily in February 2026 without prior dose escalation. In this cohort, two out of eight participants experienced increases in QRS duration of greater than 25% from baseline, and one additional participant had a QRS increase of less than <25% above baseline; these findings contributed to our decision to voluntary pause the HERO and OLE trials. In contrast, a dose-escalation approach was used in the HERO trial where patients receiving ARD-101 or placebo were dosed first at 200 mg twice daily for one week, then 400 mg twice daily for one week, then 800 mg twice daily for 10 weeks. Of note, a finding of QRS duration greater than 25% above baseline was considered significant per protocol. These observations were not reported as SAEs and were not accompanied by severe cardiac symptoms. No such cardiac signals were observed in our Phase 1 or Phase 2 clinical trials or in animal studies with oral dosing, and our preclinical ion channel assays suggested minimal ion channel liability relating to cardiac risk.

We subsequently conducted a follow-on cohort in the healthy volunteer study at the target dose of 800 mg twice daily for up to one week (without prior dose escalation) in which one of 23 participants experienced a transient increase in QRS duration of greater than 25% above baseline and one additional participant experienced an increase in QRS duration of less than 25% above baseline. These observations were not reported as SAEs and were not accompanied by serious cardiac symptoms. These findings in the 800 mg twice daily cohort were identified during subsequent data review approximately one week after our decision to pause the HERO and OLE trials.

While safety data from our healthy volunteer study demonstrated elongated QRS effects in some subjects, our preclinical studies included assays intended to screen for potential interactions of ARD-101 with cardiac ion channels and those studies did not indicate significant risk of cardiac liability. Animal studies with oral dosing at supratherapeutic doses, including doses up to approximately 350 mg/kg/day (175 mg/kg, BID) in non-human primates (NHP), had also shown no electrocardiogram changes or suggestions of compromised cardiac function. Based on body surface area and adjusted human equivalent dose comparisons, the no adverse effect level (NOAEL) from the 3-month NHP study provided a >4-fold safety margin over the 800 mg BID dose used in the HERO trial, while the NOAEL from the 39-week NHP study provided a 1.4-fold margin, which supported the 800 mg BID dose in clinical trials.

Additionally preliminary analysis of clinical data in the healthy volunteer study indicates a clear exposure–response relationship, where higher ARD-101 plasma concentrations are associated with an increased risk of QRS prolongation. Importantly, in exposure response modeling for lower doses, including the 200 mg twice daily dose, concentrations remain substantially below the threshold at which QRS effects were observed in the healthy volunteer study. This is consistent with findings from the Phase 2 trial, where no clinically meaningful cardiac events detected at these lower exposure levels. Together, these data support a predictable safety profile and dose selection within a well-characterized exposure range. In addition, we believe this relationship allows for proactive safety management through exposure monitoring and routine cardiac assessments, ensuring that any potential QRS changes can be identified and managed appropriately.

While our evaluation and comprehensive review of these observations is ongoing and final conclusions have not yet been determined, we believe ARD-101 can be administered at a dose that will provide therapeutic benefit within an acceptable margin of safety. We remain focused on the development of ARD-101 for the treatment of hyperphagia associated with PWS and are collaborating closely with the FDA to determine appropriate next steps for the program. Based on the ongoing activities in the ARD-101 program, we no longer anticipate announcing topline data from the HERO trial in the third quarter of 2026 and expect to provide further guidance in the second quarter of 2026.

PWS Background

PWS is a genetic neurodevelopmental disorder caused by a lack of expression of certain genes on paternal chromosome 15, impacting males and females equally. The cardinal clinical features of PWS include severe infantile hypotonia, developmental delay, short stature and, most notably, severe hyperphagia, which typically initially presents in PWS patients between the ages of 3 and 8 years old.

PWS-associated hyperphagia manifests as a chronic and life-threatening feeling of intense persistent hunger, food pre-occupation, extreme drive to food-seeking behaviors, and consumption of food, leading to early onset obesity and metabolic disorders. This disease's impact on quality of life affects both the patient and their family.

PWS is thought to have an incidence of approximately 1 in 15,000 births globally, with approximately 10,000 to 20,000 patients living with PWS in the United States. PWS is typically diagnosed at an early age, with many of the cases confirmed by genetic diagnoses within the first year of life. In the EU, there are approximately 15,000 PWS patients. Worldwide, there are estimated to be 350,000 to 400,000 PWS patients.

Role of CCK in Patients with PWS

CCK plays an important role in regulating hunger. In a healthy individual, when a meal is eaten, the food stimulates enteroendocrine cells to secrete CCK, which in turn stimulates the vagus nerve to send a signal to the brain through the gut-brain axis, alleviating hunger. Individuals with PWS have been found to have abnormalities in their regulation of CCK, ghrelin and other related hormones, which may drive their hyperphagia. While individuals with PWS are thought to have functioning CCK receptors, some have been observed to have irregular CCK levels, which may contribute to persistent hunger.

Additional observations imply that dysfunction of CCK secretion drives many signs and symptoms of PWS. For instance, CCK is known to facilitate gut motility and contraction of the gall bladder. Individuals with PWS often experience extremely slow gut transit times, up to 4 days, and often present with gallstones at an earlier age. Other studies have observed that CCK dysfunction may also be implicated in behavioral issues, such as anxiety, often experienced by individuals with PWS. Animal studies also support the role of CCK in controlling the perception of hunger as CCK receptor knock-out rats display hyperphagia signs similar to those in individuals with PWS.

Limitations of the Current Standard of Care for PWS

Despite the approval of one treatment for hyperphagia associated with PWS, there currently is no single therapy that fully addresses the severity of hyperphagia across the entire PWS population, and patients' symptoms continue to be managed through a combination of such approved therapy and behavioral, dietary and food-access interventions. Patient management frequently includes restricting access to all food in the environment in order to limit food-seeking behavior. Such hyperphagia-driven limitations impact not only the patients, but also their caregivers. Bariatric surgery is not a safe option for PWS patients due to the risk of stomach rupture from overeating.

There is currently one approved drug for hyperphagia associated with PWS. The only other approved drug for PWS patients is growth hormone to address certain non-hyperphagia aspects of the disease, notably growth. A variety of other drugs, including incretins, have been tried off-label and in clinical trials to attempt to treat hyperphagia, but are not used routinely because of limited impact on hyperphagia symptoms.

ARD-101 for the Treatment of Hyperphagia Associated with PWS

ARD-101 is a proprietary bitter taste receptor agonist. It is an oral tablet coated to avoid conscious bitter taste perception. A key differentiating feature of ARD-101 is its ability to stimulate local secretion of the satiety hormone CCK, which acts in an autocrine/paracrine-like manner to induce a gut-brain signal that abrogates sensations of hunger and may have additional effects regulating metabolism and inflammation.

The role of abnormal CCK secretion in PWS led us to consider stimulation of the TAS2R pathway as a means to upregulate production of endogenous CCK to restore satiety and possibly address other clinical features prominent in PWS.

We completed a Phase 1 clinical trial that consisted of Single Ascending Dose (SAD) and Multiple Ascending Dose (MAD) segments in healthy volunteers. The trial demonstrated that ARD-101 was well-tolerated and was approximately 99% restricted to the gut with minimal systemic exposure.

We also evaluated ARD-101 in an open-label Phase 2 clinical trial in hyperphagia associated with PWS, which consisted of two parts: Part 1 was a consistent dose segment and Part 2 was an intra-subject dose escalation segment. Data from Part 1 of the trial showed notable reductions in hunger levels and that ARD-101 was well-tolerated, with no dose-limiting safety issues at the dose levels evaluated in those studies. In Part 2 of the trial, the four subjects that completed the trial per protocol showed a decrease in HQ-CT 9 of approximately eight points at 28 days. We believe this effect on hunger is attributed to ARD-101's effect on regulating CCK release and gut-brain signaling. DEXA scans from the PWS Phase 2 trial data measuring body composition indicate a trend toward decreased body fat (approximately 1.5%) and increased lean muscle (over 2%) following 28 days of ARD-101 dosing.

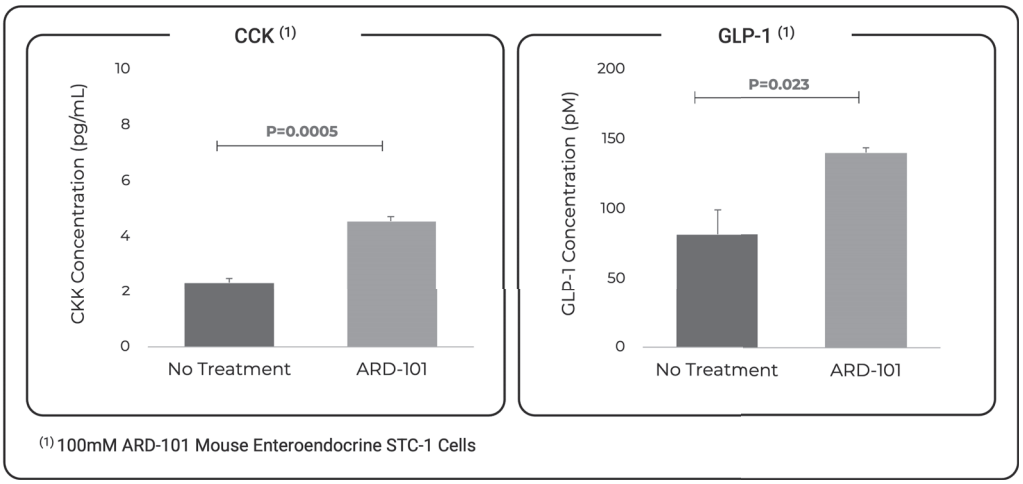
In December 2024, we initiated a Phase 3 clinical trial, which we refer to as the HERO (**H**unger **E**limination or **R**eduction **O**bjective) trial, for subjects with hyperphagia associated with PWS. In preparing for this Phase 3 clinical trial, we expanded our clinical management and regulatory capabilities, including hiring clinical, regulatory and quality personnel, and we expect to continue to need to expand our clinical management and regulatory capabilities and to rely on third parties as we plan to continue advancing this trial and other clinical trials. However, the timing of additional staffing and operational expansion may be delayed as we evaluate next steps following the voluntary pause of the HERO trial and related clinical programs. We believe ARD-101 has the potential to transform the treatment landscape of hyperphagia associated with PWS.

ARD-101 Preclinical and PK/PD Data Summary

We have evaluated the tolerability and efficacy of ARD-101 in proof-of-concept preclinical models that support ARD-101's potential to address the hyperphagia in hypothalamic syndromes, including PWS as well as obesity and obesity-related conditions. Our preclinical studies suggest that ARD-101 shows potential to be a well-tolerated, satiety-inducing drug. Animal models of obesity showed ARD-101's potential to decrease food intake and body weight without treatment tachyphylaxis, or rapidly diminishing response to successive doses of a drug, even with chronic daily administration.

In an *in vitro* experiment, ARD-101 significantly stimulated the release of CCK from mouse and human enteroendocrine cell lines (representative data shown in Figure 6 below).

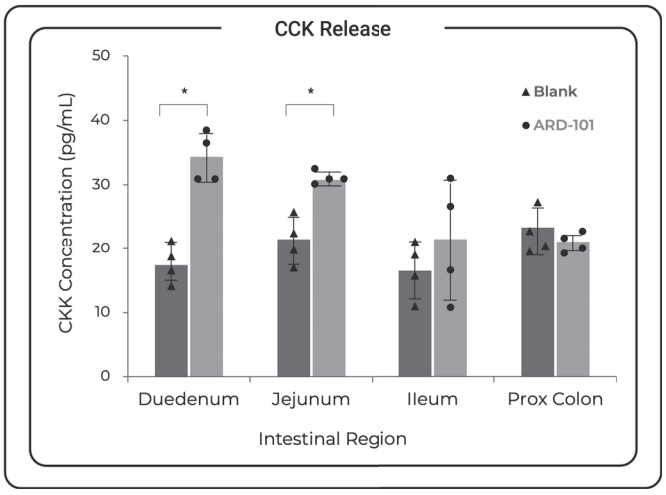
Figure 6: Upregulation of CCK



In an ex vivo study, we further investigated the effect of ARD-101 to induce CCK secretion in various regions of the gastrointestinal tract. Porcine duodenum, jejunum, ileum and proximal colon tissue were isolated and incubated in 6-well plates with ARD-101 at 300 mmol. A blank 6-well plate was included in the study, as well as a 24-well plate incubated with a mixture of non-radiolabeled and radiolabeled mannitol and caffeine as a reference control. Gut-tissue samples after one hour of exposure to ARD-101 were analyzed for the release of CCK, as determined by an enzyme-linked immunosorbent assay.

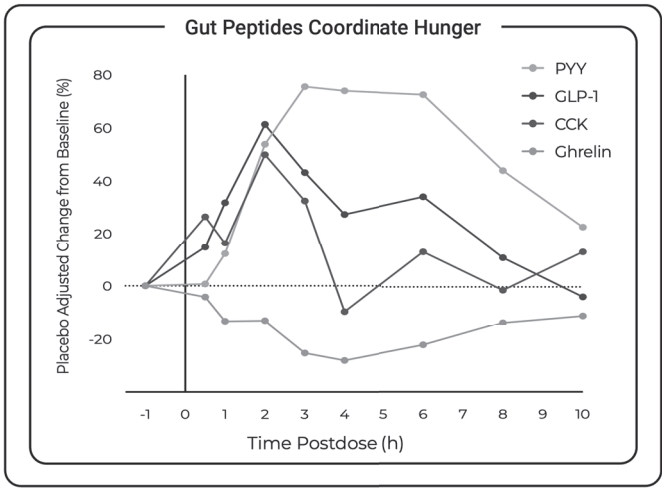
Major effects on hormone release were observed for ARD-101, resulting in a notable increase in the gut-tissue release of CCK in most intestinal regions, as seen in Figure 7 below.

Figure 7: CCK Release in the Porcine Gastrointestinal Tract



In a double-blind, randomized, placebo-controlled study, healthy participants were treated with ARD-101 (800 mg, once daily) or placebo for two days to assess the effect on plasma gut hormone levels. On day two under fasting conditions, ARD-101 increased baseline placebo normalized levels of GLP-1, CCK and PYY, with both GLP-1 and PYY levels being substantially greater in ARD-101-treated participants, and decreased ghrelin levels (Figure 8).

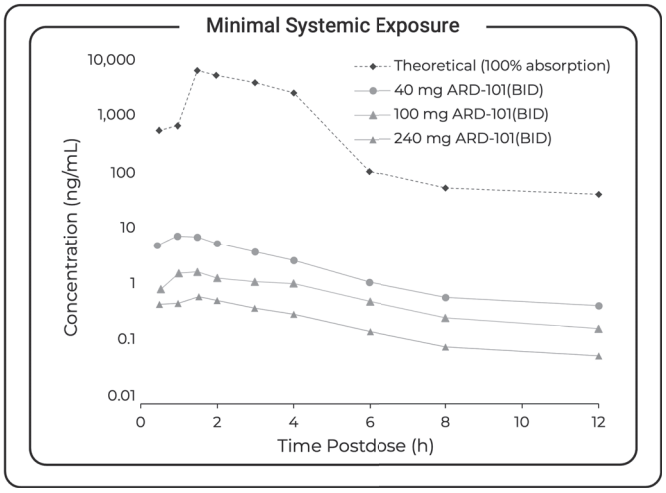
Figure 8: Effects of ARD-101 on plasma levels of GLP-1, PYY, CCK, and ghrelin in fasted healthy adults



In a randomized, single-blind, placebo-controlled Phase 2 proof of concept trial, 20 adults with obesity were treated with either ARD-101 (200 mg, twice daily) or placebo for 28 days. ARD-101 was well tolerated, with one case of transient nausea and one case of acid reflux considered related to ARD-101. The Control of Eating Questionnaire (CoEQ) is a 21-item visual-analog-scale measure of eating behaviors, including hunger and cravings (0 "not at all" to 10 "extremely"). At Day 28, CoEQ hunger (Question 1, "How hungry have you felt?") decreased by 34% from screening in ARD-101 recipients ($P < 0.001$ within group) and was lower than placebo at Day 28 ($P = 0.003$). Notably, ARD-101 reduced hunger and certain food cravings without adversely affecting eating-related mood measures. Taken together with the gut-hormone findings described above, these results provide additional evidence of ARD-101's pharmacologic activity consistent with its proposed gut–brain mechanism. These data were recently published in a peer-reviewed manuscript in the journal Molecular Metabolism (Mol Metab. 2026 Mar 14:106:102340. doi: 10.1016/j.molmet.2026.102340).

Additionally, orally administered ARD-101 was observed to have minimal systemic exposure, as seen in Figure 9 below, with approximately 99% of ARD-101 staying in the digestive tract, as evidenced by less than 1% bioavailability observed in mouse and monkey pharmacokinetic models, along with high fecal concentrations in mice following oral administration of ARD-101.

Figure 9: Localized CCK and GLP-1 Release with Minimal Systemic Exposure in Humans

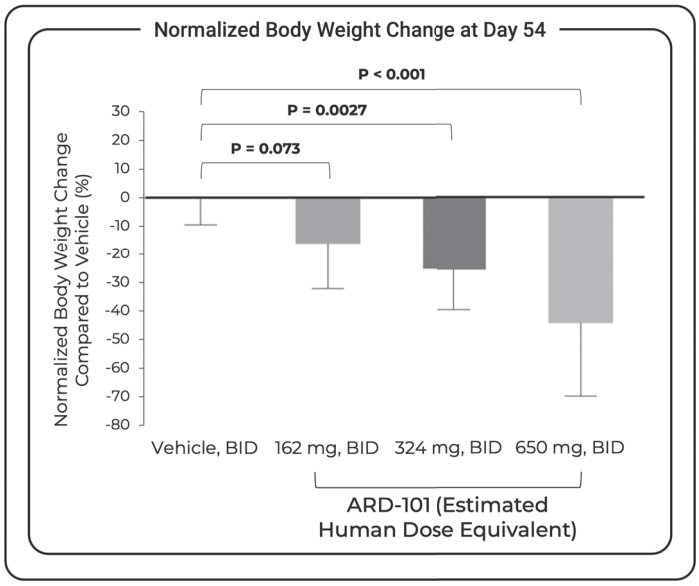


In an *in vivo* study with diet-induced obese (DIO) mice, the mice were randomly assigned to different groups (12 per group based on body weight) to receive either vehicle or ARD-101 at assigned dose regimens (20, 40 and 80 mg/kg BID) for 8 weeks. Estimated corresponding human doses are 162, 324 and 650 mg BID. The mice were weighed at least three times weekly. Blood was collected from fasted animals at baseline, at the study mid-point (day 28), and at termination; and serum was evaluated for metabolic parameters, including blood glucose, HbA1c, insulin, triglycerides (TG), bile acids (BA), LDL, HDL and total cholesterol (TC).

ARD-101 dosing by various regimens was well-tolerated with no notable discrepancies in metabolic parameters. As seen in Figure 10 below, all dosing regimens prevented high-fat diet-induced body weight gain in DIO mice at the 8-week treatment mark and exhibited a dose-dependent pattern.

Our preclinical studies included assays intended to screen for potential interactions of ARD-101 with cardiac ion channels and did not indicate significant risk of cardiac liability in those studies. Animal studies with oral dosing at supratherapeutic doses, including doses up to approximately 350 mg/kg/day (175 mg/kg, BID) in NHPs, had also shown no electrocardiogram changes or suggestions of compromised cardiac function. Based on body surface area and adjusted human equivalent dose comparisons, the NOAEL from the 3-month NHP study provides a >4-fold safety margin over the 800 mg BID dose used in the HERO trial, while the NOAEL from the 39-week NHP study provides a 1.4-fold margin, supporting the 800 mg BID dose in the clinical trials.

Figure 10: Preclinical Modeling Doses Above 200 mg BID



Our Completed Phase 1 Clinical Trial in Healthy Volunteers

We completed a Phase 1 clinical trial of ARD-101 in healthy volunteers in 2021. In the SAD segment, we administered ARD-101 at 40 mg, 100 mg or 240 mg orally once daily to healthy adult subjects after eight hours of fasting. In the MAD segment of the clinical trial, we administered oral doses of ARD-101 at 40 mg, 100 mg or 240 mg BID for 14 days in healthy adult subjects. ARD-101 was well-tolerated by subjects. Investigator-identified treatment-emergent adverse events (TEAEs) were limited to grade 1 or 2, as shown in Figure 11 below.

Figure 11: Summary of TEAEs in ARD-101 Phase 1 Clinical Trial

Treatment Emergent Adverse Events Considered Related to ARD-101 in Phase 1

	SAD Treatment Group (N=24)	MAD Treatment Group (N=19)			
	All Grades [1]	Grade 1 Mild	Grade 2 Moderate	Grade 3 Severe	All Grades
Diarrhea	0 (0.0%)	2	--	--	2 (10.5%)
Dyspepsia	0 (0.0%)	2	--	--	2 (10.5%)
Headache [4]	0 (0.0%)	2	--	--	2 (10.5%)
Nausea	0 (0.0%)	2	--	--	2 (10.5%)
Urticaria	0 (0.0%)	--	2 [2]	--	2 (10.5%)
Abdominal distension	0 (0.0%)	1	--	--	1 (5.3%)
Abdominal Pain	0 (0.0%)	1	1	--	2 (5.3%) [3]
Dizziness	0 (0.0%)	1	--	--	1 (5.3%)
Dysgeusia	0 (0.0%)	1	--	--	1 (5.3%)
Flatulence [4]	0 (0.0%)	1	--	--	1 (5.3%)
Palpitations	0 (0.0%)	1	--	--	1 (5.3%)

[1] There were no treatment-emergent adverse events (TEAEs) in SAD treatment group.
[2] One TEAE of moderate urticaria led to subject withdrawal from the study.
[3] Abdominal pain Grade 1/mild and Grade 2/moderate was experienced by the same subject.
[4] 1 patient (placebo group) had 1 event of flatulence, and 1 event of headache considered related by the investigator.

Pharmacokinetic parameters for ARD-101 following repeat BID oral doses of 40 mg, 100 mg and 240 mg in healthy subjects were consistent with animal models and confirmed the drug was gut-restricted, with approximately 1% detectable in systemic circulation. Of the minor amount that was in circulation, ARD-101 reached a steady state before day 11 at all tested dose levels by evaluating trough plasma concentrations (C_{trough}) on days 11, 12 and 13, demonstrating overall favorable pharmacokinetic properties across test subjects. A summary of PK data following oral doses of ARD-101 is shown in Figure 12 below.

Figure 12: Summary of Pharmacokinetic Data from Phase 1 SAD and MAD Dosing

Summary of the Pharmacokinetic Parameters for ARD-101 Following Single Oral Doses in Healthy Subjects

Table 14: Summary of the Pharmacokinetic Parameters for ARD-101 Following Single Oral Doses in Part 1 for Protocol AARD-101

Matrix: Plasma; Analyte: ARD-101; Profile Day: 1

Parameter	40 mg ARD-101 (N = 6)	100 mg ARD-101 (N = 6)	240 mg ARD-101 (N = 6)
AUC_{last} (h*ng/mL)	4.81 (281.4) [6]	15.9 (61.1) [6]	53.1 (45.8) [6]
$DAUC_{last}$ (h*ng/mL/mg)	0.120 (281.4) [6]	0.159 (61.1) [6]	0.221 (45.8) [6]
AUC_{inf} (h*ng/mL)	12.4 (106.8) [4]	17.5 (57.6) [6]	55.8 (45.2) [6]
$DAUC_{inf}$ (h*ng/mL/mg)	0.310 (106.8) [4]	0.175 (57.6) [6]	0.232 (45.2) [6]
C_{max} (ng/mL)	0.999 (259.4) [6]	3.04 (76.2) [6]	12.4 (53.7) [6]
DC_{max} (ng/mL/mg)	0.0250 (259.4) [6]	0.0304 (76.2) [6]	0.0515 (53.7) [6]
t_{max} (h)	1.33 (0.667-4.00) [6]	1.21 (0.667-2.00) [6]	1.08 (0.667-1.33) [6]
$t_{1/2}$ (h)	8.27 (14.4) [4]	11.1 (39.0) [6]	18.4 (39.0) [6]
CL/F (L/h)	3220 (106.8) [4]	5710 (57.6) [6]	4300 (45.2) [6]
V_z/F (L)	38400 (114.0) [4]	91700 (30.1) [6]	114000 (56.9) [6]

AUC_{inf} = area under the concentration-time curve from time 0 extrapolated to infinity; AUC_{last} = area under the concentration-time curve from time 0 to the time of the last quantifiable concentration (t_{last}); CL/F = apparent total clearance following oral administration; C_{max} = maximum observed concentration; CV = coefficient of variation (%); n = number of subjects with valid observations; $t_{1/2}$ = apparent terminal elimination half-life; t_{max} = time of the maximum observed concentration; V_z/F = apparent volume of distribution during the terminal phase
Parameter starting with 'D' letter signifies the corresponding parameter was normalized by dose administered.
Geometric mean (CV) [n] statistics presented; for t_{max} median (min-max) [n] statistics presented.
Reference: Table 14.2.1-2.1
Program Location: /cvn/projects/prj/ecb/programs/000000207211/dev/tables/t_pp_itt.sas
Program Status: FINAL Program Run: 02JUN2021 Protocol Reference: AARD-101

Summary of the Pharmacokinetic Parameters for ARD-101 Following Oral BID. Dosing for 14 days in Healthy Subjects [1]

Matrix: Plasma; Analyte: ARD-101

Parameter	40 mg ARD-101 (BID) (N = 4)		100 mg ARD-101 (BID) (N = 5)		240 mg ARD-101 (BID) (N = 4)	
	Profile Day 1	Profile Day 14	Profile Day 1	Profile Day 14	Profile Day 1	Profile Day 14
AUC_{tau} (h*ng/mL)	2.31 (187.9) [4]	5.51 (83.5) [4]	8.48 (63.0) [5]	16.4 (55.3) [4]	27.6 (80.3) [4]	46.3 (46.7) [4]
$DAUC_{tau}$ (h*ng/mL/mg)	0.0577 (187.9) [4]	0.138 (83.5) [4]	0.0848 (63.0) [5]	0.164 (55.3) [4]	0.115 (80.3) [4]	0.193 (46.7) [4]
$R_{acc,AUC}$	NA	2.39 (692) [4]	NA	2.02 (61.5) [4]	NA	1.68 (26.9) [4]
C_{max} (ng/mL)	0.584 (235.9) [4]	1.27 (141.3) [4]	1.85 (85.9) [5]	3.02 (86.1) [4]	7.64 (135.9) [4]	9.13 (59.6) [4]
DC_{max} (ng/mL/mg)	0.0146 (235.9) [4]	0.0317 (141.3) [4]	0.0185 (85.9) [5]	0.0302 (86.1) [4]	0.0318 (135.9) [4]	0.0380 (59.6) [4]
$R_{acc,Cmax}$	NA	2.17 (49.5) [4]	NA	1.66 (129.3) [4]	NA	1.20 (50.1) [4]
t_{max} (h)	1.50 (0.500-4.00) [4]	1.75 (1.08-4.00) [4]	1.50 (1.08-2.00) [5]	1.08 (0.500-4.00) [4]	1.75 (1.15-3.00) [4]	1.08 (0.500-2.00) [4]
C_{av} (ng/mL)	NA	0.459 (83.5) [4]	NA	1.37 (55.3) [4]	NA	3.86 (46.7) [4]
C_{min} (ng/mL)	NA	0.119 (33.9) [4]	NA	0.419 (25.1) [4]	NA	1.21 (26.1) [4]
CL_{tau}/F (L/h)	NA	7260 (83.5) [4]	NA	6090 (55.3) [4]	NA	5180 (46.7) [4]

AUC_{tau} = area under the concentration-time curve over a dosing interval; C_{av} = average concentration over a dosing interval; CL_{tau}/F = apparent total body clearance at steady state following oral administration; C_{max} = maximum observed concentration; C_{min} = minimum observed concentration over a dosing interval; CV = coefficient of variation (%); n = number of subjects with valid observations; NA = not applicable; R_{acc} = accumulation ratio; t_{max} = time of the maximum observed concentration
Parameter starting with 'D' letter signifies the corresponding parameter was normalized by dose administered.
Geometric mean (CV) [n] statistics presented; for t_{max} median (min-max) [n] statistics presented.
Reference: Table 14.2.1-2.2
Program Location: /cvn/projects/prj/ecb/programs/000000207211/dev/tables/t_pp1_itt.sas
Program Status: FINAL Program Run: 02JUN2021 Protocol Reference: AARD-101

[1] Clin Pharmacol Drug Dev. 2022 Aug;11(8):997-1006. doi: 10.1002/cpdd.1100.

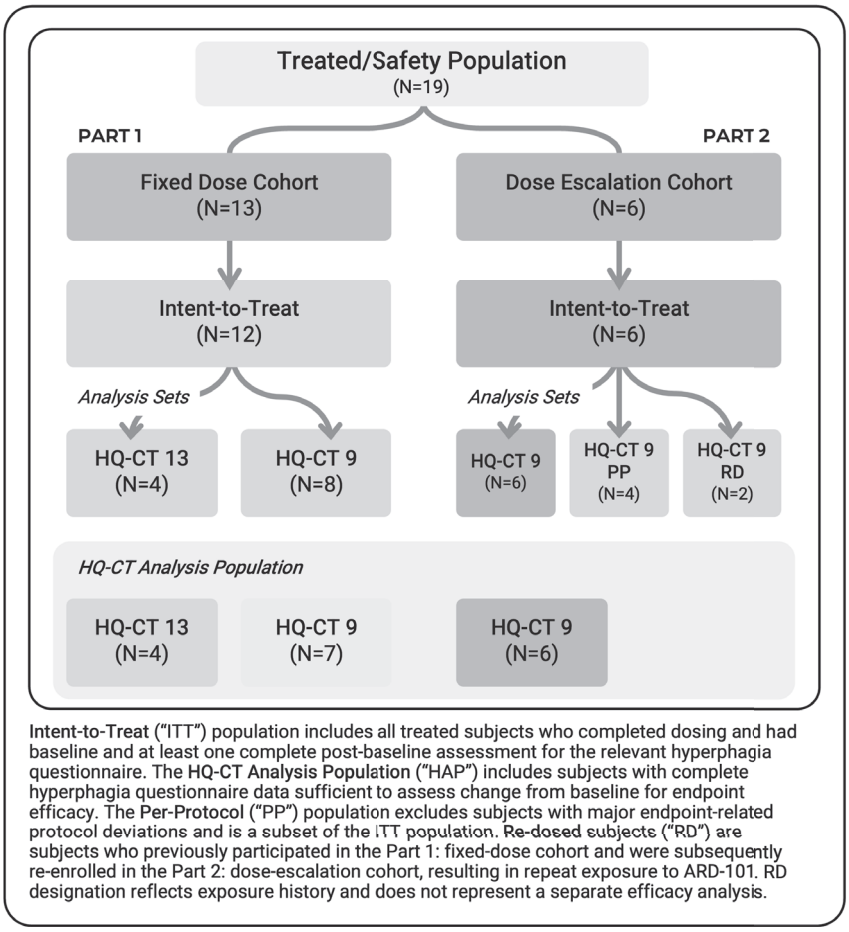
Our Completed Open-Label Phase 2 Clinical Trial in Hyperphagia Associated with PWS

We evaluated ARD-101 in an open-label, two-part Phase 2 clinical trial in subjects with hyperphagia associated with PWS. Both parts of the trial included a 28-day treatment period followed by a 14-day withdrawal period. To participate, the study protocols required subjects to be between 17 and 65 years old (inclusive), have a HQ-CT score of at least 10, and be at a stable weight for two months. As illustrated in Figure 13 below, a total of 19 subjects received at least one dose of ARD-101 in our Phase 2 trial.

In Part 1 of the trial, subjects received a fixed 200 mg dose of ARD-101 twice daily for 28 days. Study assessments were conducted at baseline and on days 15 and 28 during the treatment period. Of the 13 subjects that enrolled, 12 completed dosing and were included in the intent-to-treat (ITT) population, as shown in Figure 13 below. The one subject excluded from the ITT population withdrew prior to completing dosing and was therefore not included. Of the 12 subjects that were included in the ITT population, four subjects received HQ-CT 13 and eight subjects received HQ-CT 9. Although both versions are informative, they differ in scaling and item wording, which precludes direct comparison between the two questionnaires. The HQ-CT 9 is also the only FDA-validated endpoint assessment tool for hyperphagia. Of the four subjects that received HQ-CT 13, all had complete hyperphagia questionnaire data available to support an assessment of change from baseline for endpoint efficacy. However, of the eight subjects that received the HQ-CT 9, only seven subjects had complete hyperphagia questionnaire data available to support the same assessment. In total, 11 subjects met the criteria for inclusion in the HQ-CT Analysis Population: four subjects that completed the HQ-CT 13 and seven subjects that completed the HQ-CT 9.

In Part 2 of the trial, subjects received ARD-101 using an intra-subject dose-escalation regimen, with BID dosing that increased from 400 mg to 600 mg, then to 800 mg over the same 28-day treatment period. Study assessments were conducted according to the Part 1 schedule, with an additional assessment on day 8 to monitor safety during dose escalation. A total of six subjects received ARD-101 in Part 2, including four ARD-101 naïve subjects and two subjects that had previously participated in Part 1. All six subjects in Part 2 completed dosing, had complete endpoint assessments, and were included in the ITT and HQ-CT Analysis Population. While two subjects had major endpoint-related protocol deviations and were excluded from per-protocol (PP) analyses, both are still included in ITT analyses. Subjects that had previously participated in Part 1 and were re-enrolled in Part 2 are designated as re-dosed as shown in Figure 13 below.

Figure 13: Subject Disposition and Analysis Populations of ARD-101 Phase 2 Clinical Trial (Parts 1 and 2)

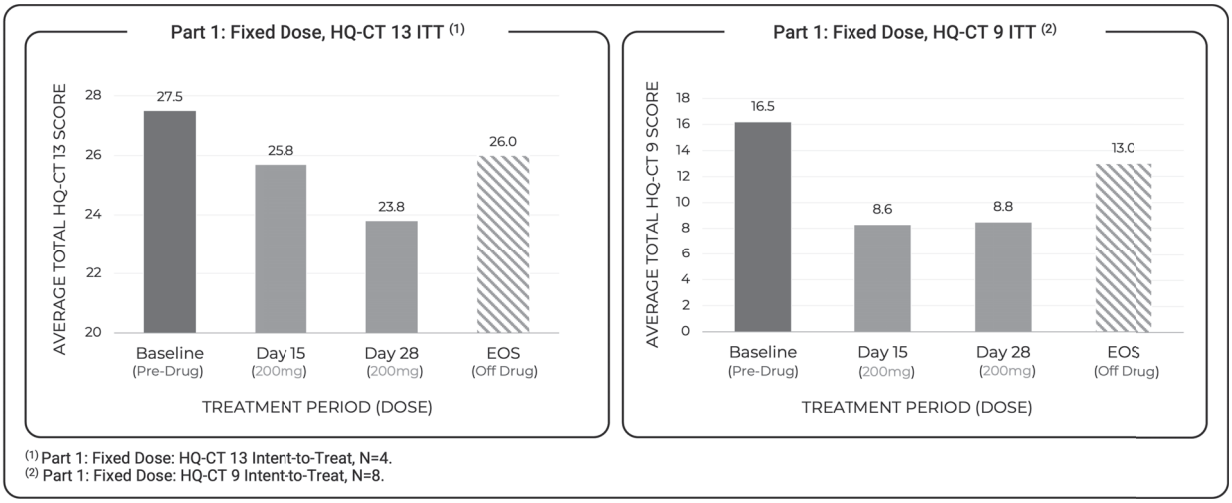


Intent-to-Treat ("ITT") population includes all treated subjects who completed dosing and had baseline and at least one complete post-baseline assessment for the relevant hyperphagia questionnaire. The HQ-CT Analysis Population ("HAP") includes subjects with complete hyperphagia questionnaire data sufficient to assess change from baseline for endpoint efficacy. The Per-Protocol ("PP") population excludes subjects with major endpoint-related protocol deviations and is a subset of the ITT population. Re-dosed subjects ("RD") are subjects who previously participated in the Part 1: fixed-dose cohort and were subsequently re-enrolled in the Part 2: dose-escalation cohort, resulting in repeat exposure to ARD-101. RD designation reflects exposure history and does not represent a separate efficacy analysis.

Phase 2 Part 1 Analysis

Results from Part 1 of the Phase 2 trial demonstrated significant reductions in hyperphagia scores across all HQ-CT Analysis Populations as defined on the left side of Figure 13 above. Figure 14 below presents the average total HQ-CT scores over time for both Part 1 ITT populations. Both questionnaire versions (HQ-CT 13 and HQ-CT 9) showed reductions in hyperphagia during the treatment period with scores rebounding following treatment discontinuation.

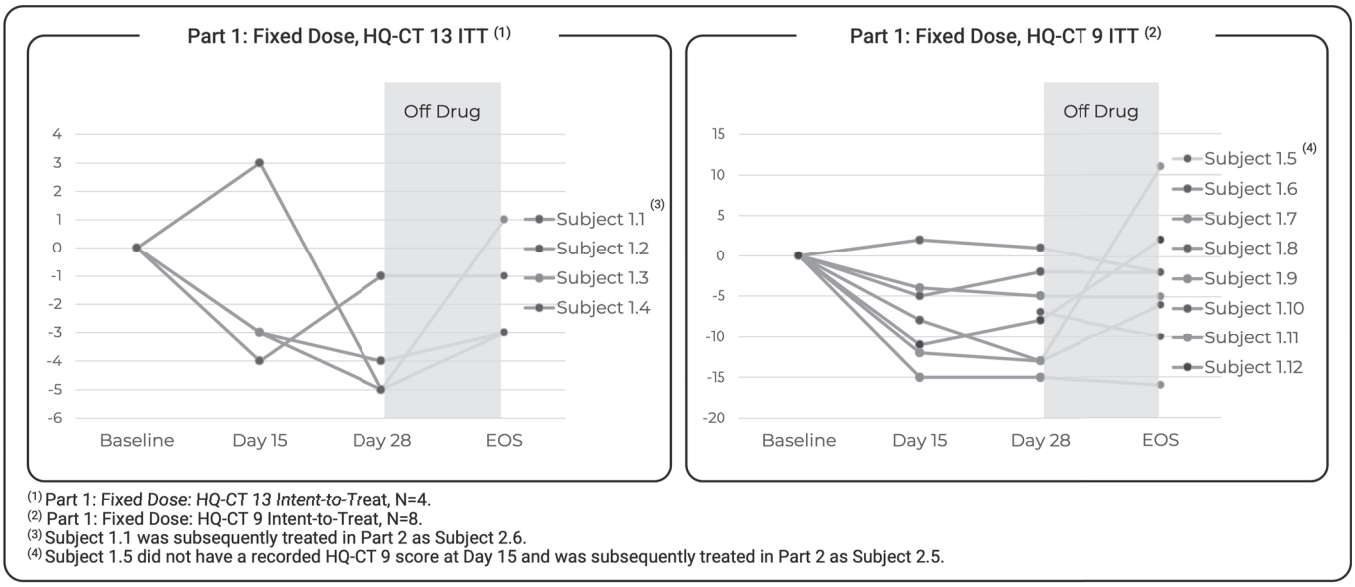
Figure 14: HQ-CT Data Observed in Part 1 of the Phase 2 Trial



(1) Part 1: Fixed Dose: HQ-CT 13 Intent-to-Treat, N=4.
(2) Part 1: Fixed Dose: HQ-CT 9 Intent-to-Treat, N=8.

Figure 15 below depicts the individual point change from baseline HQ-CT score (normalized to origin) for all subjects included in the ITT population. The average reduction in HQ-CT score among subjects evaluated on HQ-CT 9 was approximately eight points at 28 days. Based on this data, we received Orphan Drug Designation from the FDA.

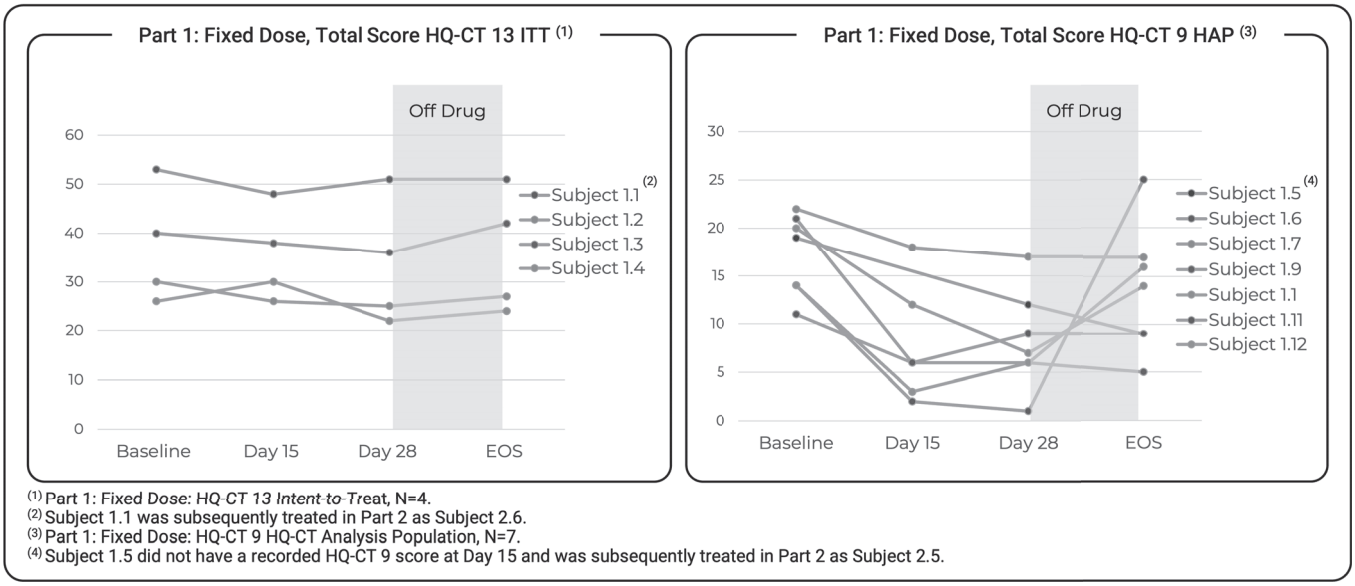
Figure 15: Individual Subject Change in HQ-CT Data Observed in Part 1 of the Phase 2 Trial



(1) Part 1: Fixed Dose: HQ-CT 13 Intent-to-Treat, N=4.
(2) Part 1: Fixed Dose: HQ-CT 9 Intent-to-Treat, N=8.
(3) Subject 1.1 was subsequently treated in Part 2 as Subject 2.6.
(4) Subject 1.5 did not have a recorded HQ-CT 9 score at Day 15 and was subsequently treated in Part 2 as Subject 2.5.

Figure 16 below shows the absolute HQ-CT scores of the HQ-CT Analysis Population, which includes only subjects with validated hyperphagia questionnaire data. Of the four subjects that completed HQ-CT 13 in the ITT population, all met the criteria for inclusion in the HQ-CT Analysis Population. Of the eight subjects that completed HQ-CT 9 in the ITT population, seven met the criteria for inclusion in the HQ-CT Analysis Population.

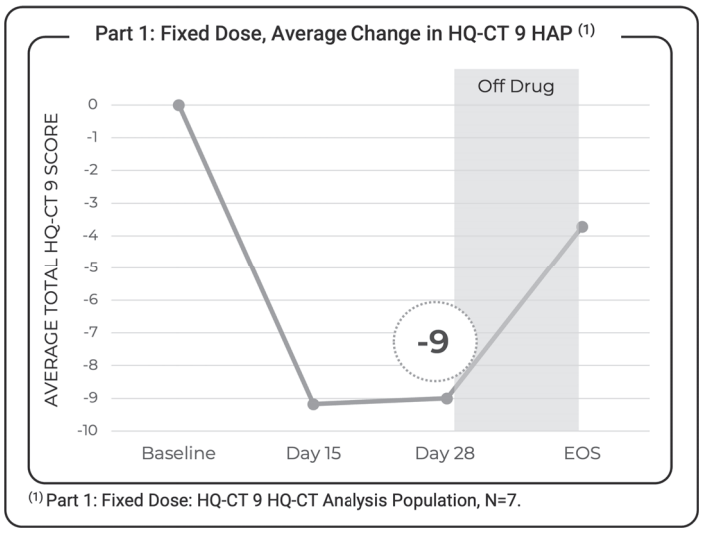
Figure 16: Individual Subject Absolute HQ-CT Scores Observed in Part 1 of the Phase 2 Trial



(1) Part 1: Fixed Dose: HQ-CT 13 Intent-to-Treat, N=4.
(2) Subject 1.1 was subsequently treated in Part 2 as Subject 2.6.
(3) Part 1: Fixed Dose: HQ-CT 9 HQ-CT Analysis Population, N=7.
(4) Subject 1.5 did not have a recorded HQ-CT 9 score at Day 15 and was subsequently treated in Part 2 as Subject 2.5.

Figure 17 below presents the average HQ-CT scores over time for the seven subjects in the HQ-CT 9 Analysis Population, demonstrating a mean 9-point reduction in hyperphagia score among subjects using the FDA-validated endpoint.

Figure 17: Average Change from Baseline in Part 1 of the Phase 2 trial: HQ-CT 9 Score (HQ-CT Analysis Population)



Phase 2 Part 2 Analysis

Based on preclinical modeling that showed doses of ARD-101 above 200 mg BID had the potential for greater efficacy as well as clinical observations that demonstrated ARD-101 was generally well-tolerated, we initiated Part 2 of the Phase 2 trial (the dose-escalation portion) approximately a year after Part 1. Subjects in Part 2 were dosed at 400 mg BID for one week, 600 mg BID for a second week, and 800 mg BID for the final two weeks of the trial. Six subjects participated in Part 2 of the trial, including four ARD-101 naïve subjects and two subjects that were re-dosed following prior participation in Part 1. Each of the six subjects that enrolled in Part 2 completed dosing; however, two subjects committed significant protocol deviations, as further described below. Of the subjects that adhered to the trial protocol, each experienced a reduction in hyperphagia score, with the majority of subjects experiencing a deepening benefit over time.

Figures 18 and 19 below show the average HQ-CT 9 scores from all six subjects that completed Part 2 of the Phase 2 trial, as well as the subset of subjects that did not deviate from protocol. Each group exhibited average reductions in hyperphagia, with scores returning toward baseline during the withdrawal portion of the study. A greater magnitude of hyperphagia reduction was observed among subjects that adhered to protocol, with members of the PP population experiencing an average decrease of 7.8 points in HQ-CT 9 score at day 28.

Figure 18: Average HQ-CT Data Observed in Part 2 of the Phase 2 Trial

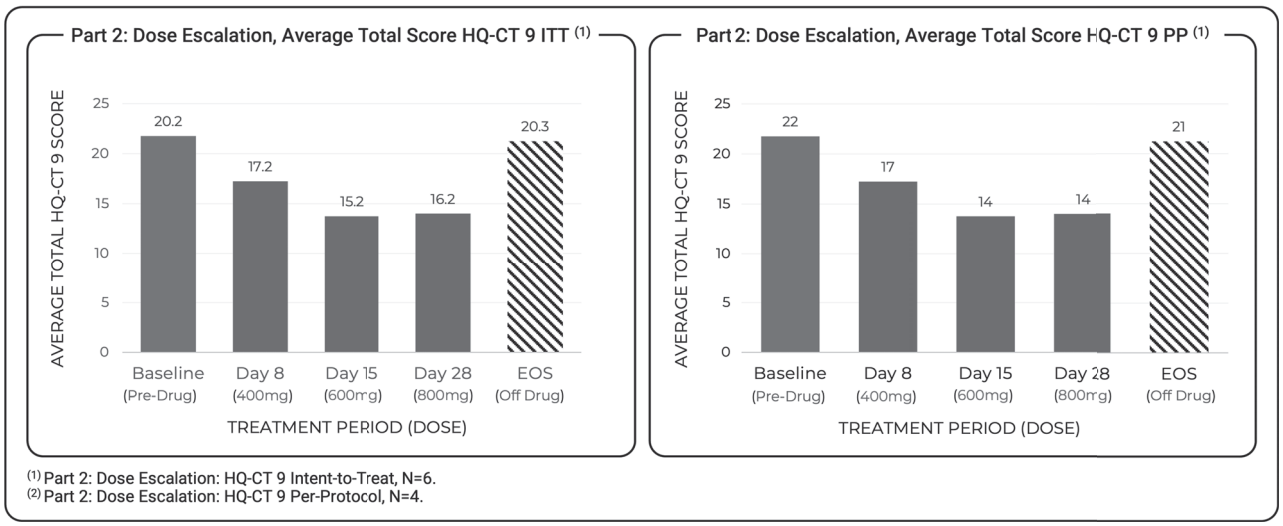


Figure 19: Average Change from Baseline in Part 2: HQ-CT 9 Score

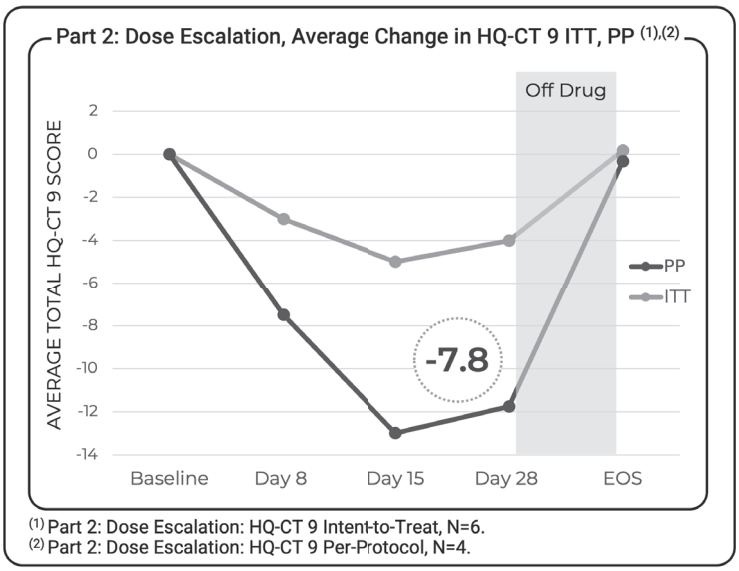
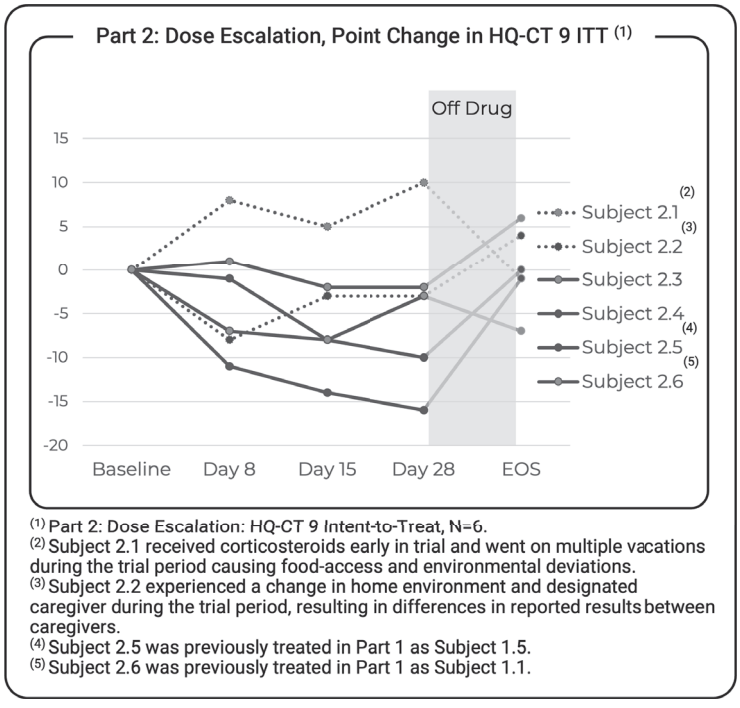


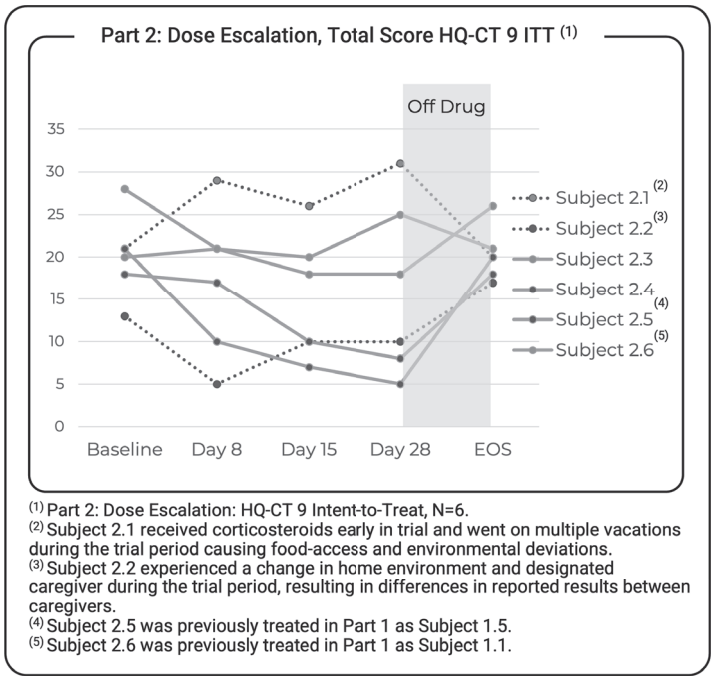
Figure 20 below depicts the individual point change from baseline HQ-CT score (normalized to origin) for the six subjects that completed dosing in Part 2, with the solid lines representing subjects that adhered to protocol and the dotted lines representing those who deviated from protocol. As mentioned above, two subjects had major protocol deviations in the endpoint assessment and were excluded from the PP analysis of our Phase 2 trial. Subject 2.1 received a high dose of steroids known to cause significant weight gain from a primary care physician not involved in the trial. This subject also took two vacations during the 28-day trial period, causing food access environment-related deviations. Subject 2.2 experienced a change in their home environment and designated caregiver between day 8 and day 15 of the trial period, resulting in inconsistencies in reported results between the two caregivers.

Figure 20: Detailed HQ-CT Data Observed in Part 2 of the Phase 2 Trial



For additional reference, Figure 21 below is a graph showing absolute HQ-CT scores of subjects that participated in Part 2 of our Phase 2 trial.

Figure 21: Detailed Subject Level Absolute HQ-CT Data Observed in Part 2 of the Phase 2 Trial

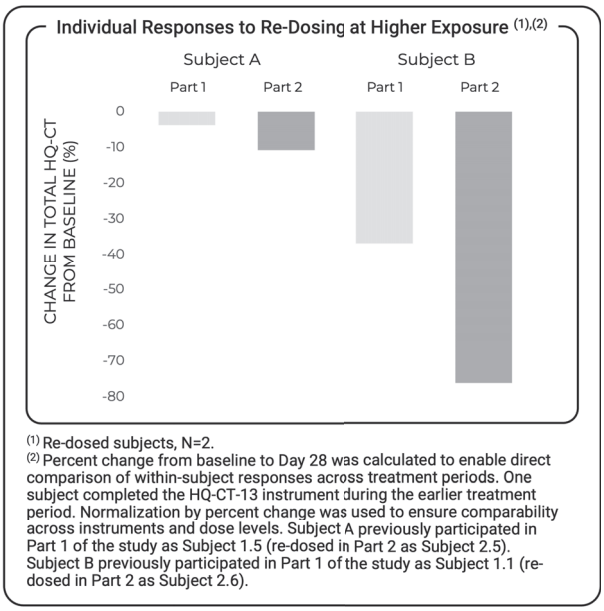


(1) Part 2: Dose Escalation: HQ-CT 9 Intent-to-Treat, N=6.
(2) Subject 2.1 received corticosteroids early in trial and went on multiple vacations during the trial period causing food-access and environmental deviations.
(3) Subject 2.2 experienced a change in home environment and designated caregiver during the trial period, resulting in differences in reported results between caregivers.
(4) Subject 2.5 was previously treated in Part 1 as Subject 1.5.
(5) Subject 2.6 was previously treated in Part 1 as Subject 1.1.

Signal of Dose Dependency

As described above, two subjects that participated in Part 1 were subsequently re-dosed with ARD-101 in Part 2. One re-dosed subject completed the same hyperphagia assessment (HQ-CT 9) during both parts of the trial, while the second re-dosed subject completed HQ-CT 13 in Part 1 and HQ-CT 9 in Part 2. Figure 22 below presents the percent change from baseline in the HQ-CT score for both re-dosed subjects across both trial parts. Percent change was used to enable within-subject comparison across treatment periods and to allow comparability between questionnaire versions, which are reported on different scales. Both subjects exhibited dose-dependent reductions in HQ-CT score.

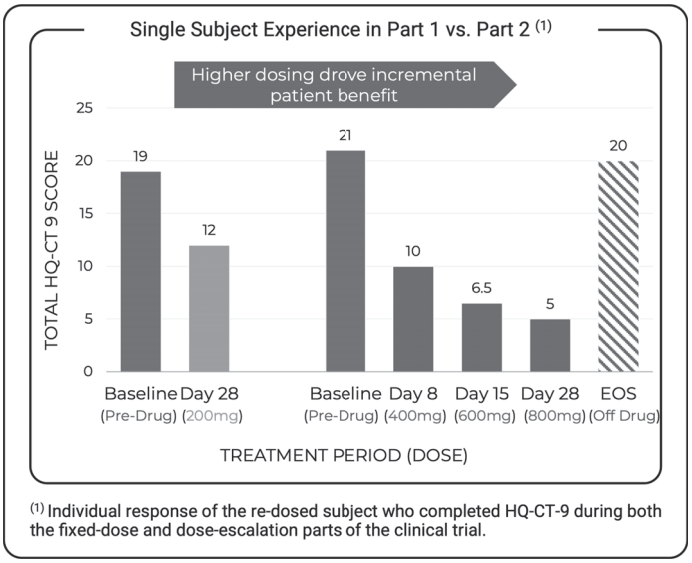
Figure 22: Within-Subject Percent Change from Baseline in HQ-CT Score for Re-Dosed Subjects



(1) Re-dosed subjects, N=2.
(2) Percent change from baseline to Day 28 was calculated to enable direct comparison of within-subject responses across treatment periods. One subject completed the HQ-CT-13 instrument during the earlier treatment period. Normalization by percent change was used to ensure comparability across instruments and dose levels. Subject A previously participated in Part 1 of the study as Subject 1.5 (re-dosed in Part 2 as Subject 2.5). Subject B previously participated in Part 1 of the study as Subject 1.1 (re-dosed in Part 2 as Subject 2.6).

For the re-dosed subject that completed the HQ-CT 9 assessment in both Part 1 and Part 2, a detailed individual-subject trajectory is shown in Figure 23 below (Subject B in Figure 22). During treatment in Part 2 of the trial, this subject exhibited a 16-point reduction in HQ-CT 9 score from baseline to day 28, followed by a return toward baseline hyperphagia scores approximately 14 days after discontinuation of study drug.

Figure 23: Detailed Subject-Level Change in HQ-CT Data Observed in Part 2 of the Phase 2 Trial



Phase 2 Data on Body Composition

In addition to reductions in hyperphagia, ARD-101 also demonstrated a reduction in body fat. DEXA scans analysis from the Phase 2 trial data measuring body composition indicated a trend toward decreased body fat (approximately 1.5%) and increased lean muscle (over 2%) following 28 days of ARD-101 dosing.

Phase 2 Safety Data

Figure 24 below summarizes the adverse events (AEs) from Part 1 and Part 2 of the Phase 2 clinical trial. Across both parts, a total of 19 subjects with PWS received at least one dose of ARD-101 and were included in the safety population in Figure 24 below (fixed-dose N=13, dose-escalation N=6). AEs considered related to ARD-101 were generally mild to moderate in severity. No Grade 3 or higher treatment-related AEs were observed. In the fixed-dose cohort, one subject discontinued treatment due to a drug hypersensitivity reaction at the 200 mg BID dose. In Part 2 of the Phase 2 trial, treatment-related AEs were limited to Grade 1 and did not result in treatment discontinuation.

Within the dose ranges evaluated in this Phase 2 trial, no increases in the severity of the treatment-related AEs were observed with increasing dose levels.

Figure 24: Summary of AEs in ARD-101 in Two-Part Phase 2 Clinical Trial in PWS

Adverse Events Considered Related to ARD-101 in the First Part of Phase 2 [1]				
	Fixed 200mg Dose (N=13)			
	Grade 1 Mild	Grade 2 Moderate	Grade 3 Severe	All Grades [2]
Edema-Limbs	--	1	--	1 (8%) [3]
Rash-maculopapular	1	--	--	1 (8%) [3]
Adverse Events Considered Related to ARD-101 in the Second Part of Phase 2 [1]				
	Dose Escalation from 400mg to 800mg (N=6)			
	Grade 1 Mild	Grade 2 Moderate	Grade 3 Severe	All Grades [4]
Nausea [5]	1 (400mg)	--	--	1 (17%)
Bitter Taste in Back of Throat [6]	1 (400mg)	--	--	1 (17%)
Headache [5]	1 (600mg)	--	--	1 (17%)
Increased Irritability	1 (600mg)	--	--	1 (17%)
Diarrhea	1 (800mg)	--	--	1 (17%)

[1] Company internal data, AARD-203 Clinical Trial.
[2] Denominator is N=13 subjects, 12 completed dosing on ARD-101 200 mg BID orally for 28 days.
[3] The AEs listed above were with the same subject. Subject had early withdrawal.
[4] Denominator is N=6 subjects dosed with ARD-101 for 28 days, 400mg BID x1 week, 600mg BID x1 week, 800 mg BID x2 weeks.
[5] Investigator at site 100 considered two events (nausea and headache in a single subject) as having an "unknown" relationship to study drug. These are conservatively included as related events.
[6] The AE of "Bitter Taste in Back of Throat" is noted in verbatim term to be "due to underlying GE Reflux in Medical History" but the Case Report Form indicates that this is a "related" event.

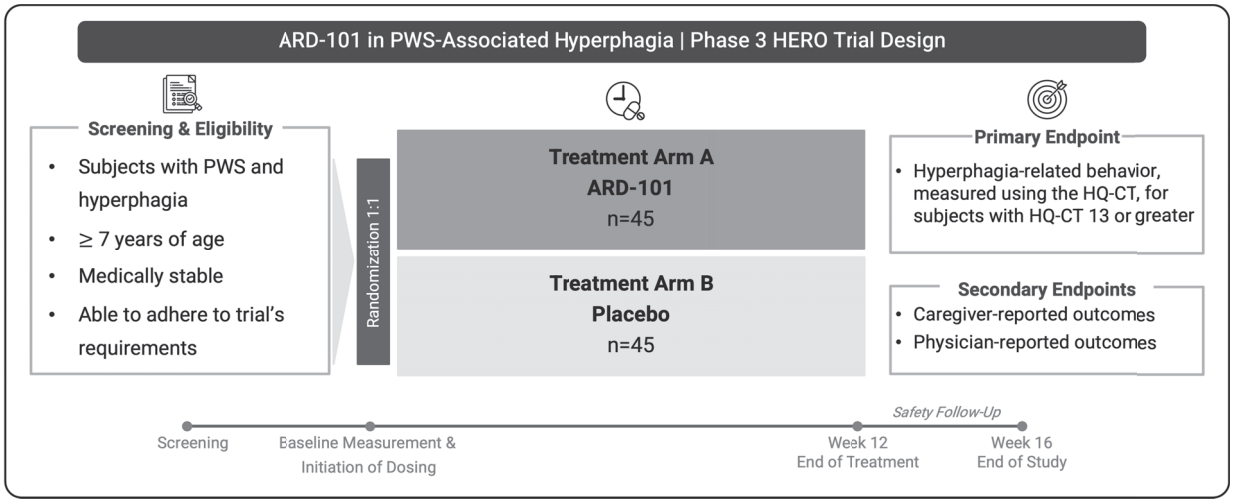
Phase 3 Clinical Trial in Hyperphagia Associated with PWS

Following discussions with the FDA during pre-IND meetings, we submitted an IND for ARD-101 for the treatment of hyperphagia associated with PWS on August 30, 2024. In September 2024, following correspondence with the FDA regarding the BID dosing and titration strategy in the Phase 3 clinical trial, the FDA determined that the Phase 3 clinical trial may proceed. We designed a Phase 3, randomized, double-blind, placebo-controlled clinical trial, which we refer to as the HERO (**H**unger **E**limination or **R**eduction **O**bjective) trial (see Figure 25 below for a graphical depiction of the trial design). The trial was designed to treat subjects over 12 weeks to support the further development of ARD-101 in subjects with PWS-associated hyperphagia. The primary objective of the Phase 3 HERO trial was to evaluate the effect of ARD-101 on hyperphagia-related behavior, using the HQ-CT questionnaire. Secondary objectives included evaluating caregiver-reported outcomes and physician-reported outcomes. Additionally, exploratory objectives aimed to assess the effects of ARD-101 on various health markers, such as body weight, lean body mass, waist circumference, inflammatory cytokines, lipid parameters, glycemic control and food safety practices.

Enrollment criteria for this trial were designed to ensure that eligible subjects had a confirmed diagnosis of PWS and hyperphagia, were medically stable and were able to adhere to the trial's requirements, with only subjects with a baseline HQ-CT score of 13 or greater expected to be included in the efficacy analysis. In November 2025, we announced that the minimum age of eligibility for HERO was reduced from 13 to 10 years old following alignment with the FDA. In December 2025, we submitted a protocol amendment seeking to lower the minimum age of eligibility to participate in the trial to 7 years of age. The trial protocol allowed dose modification in case a higher dose was not tolerated by a subject. An interim analysis was to be used to help determine the statistical power of the trial, triggered by enrollment milestones. Following the voluntary pause of the HERO trial in February 2026, we are reviewing the trial design and protocol in collaboration with the FDA and the previously agreed protocol elements may be revisited.

We initiated the Phase 3 HERO trial in December 2024. In February 2026, we voluntarily paused enrollment and dosing in the HERO trial based on reversible cardiac observations in a healthy volunteer study, and we are conducting a comprehensive review of the data in collaboration with the FDA. We no longer anticipate topline data readout in the third quarter of 2026.

Figure 25: Phase 3 HERO Trial Design for ARD-101 in PWS-Associated Hyperphagia



ARD-201

Our second program, ARD-201, was planned to be a fixed-dose combination of our proprietary bitter taste receptor agonist, ARD-101 (denatonium acetate monohydrate), and a DPP-4 inhibitor. Because ARD-201 contains ARD-101 as a component of the planned combination therapy, we are assessing the potential implications of the voluntary pause of the HERO trial on the ARD-201 program. Following this assessment, we have voluntarily paused the POWER and STRENGTH clinical trials while we complete our ongoing evaluation of the safety observations identified in the healthy volunteer study of ARD-101 and continue discussions with the FDA regarding next steps for the ARD-101 program. We no longer anticipate preliminary or interim data for the POWER trial to be available in the second half of 2026, nor do we plan to initiate the STRENGTH trial in the first half of 2026. We expect to provide further guidance in the second quarter of 2026.

Our Other Programs

Beyond our lead product candidate, ARD-101, we are also developing other programs for the potential treatment of indications with high unmet need, including other indications mediated by TAS2R signaling.

We also have a clinical program in development not related to TAS2R that is a low-dose liquid extended-release naltrexone formulation for the treatment of autism.

Competition

The biotechnology and pharmaceutical industries are characterized by rapid evolution of technologies, fierce competition and strong defense of intellectual property. While we believe that our platform and our knowledge, experience and scientific resources provide us with competitive advantages, we face competition from major pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions, among others.

If any of our product candidates are approved for the indications for which we expect to conduct clinical trials, we anticipate they will compete with marketed drugs, as well as any drugs potentially in development. It is also possible that we will face competition from other pharmaceutical approaches as well as other types of therapies. The key competitive factors affecting the success of all our programs, if approved, are likely to be their potency, tolerability, convenience, price, level of generic competition and availability of reimbursement.

With respect to ARD-101, VYKAT XR from Soleno Therapeutics is the only FDA-approved treatment for hyperphagia in patients with PWS. We are also aware of other clinical-stage therapeutic candidates being evaluated for hyperphagia and related conditions, including those from Rhythm Pharmaceuticals, Relmada Therapeutics and Bright Minds Biosciences Inc.

Many of our current or potential competitors, either alone or with their collaboration partners, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical studies, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. These competitors also compete with us in recruiting and retaining

qualified scientific and management personnel and establishing clinical trial sites and subject registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Mergers and acquisitions in the biopharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that have fewer or less severe side effects, are more potent, are more convenient, are less expensive or are sold more effectively than any products that we may develop. Our competitors also may obtain FDA or other applicable regulatory authority approval for their product candidates 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. 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. Competitive products may make any products we develop obsolete or noncompetitive before we recover the expense of developing and commercializing our product candidates.

Manufacturing

We do not own or operate manufacturing facilities for the production of our product candidates and currently have no immediate plans to build our own clinical or commercial scale manufacturing capabilities. We currently engage with third-party contract manufacturing organizations (CMOs), for the manufacture of our product candidates. We rely on and expect to continue to engage third-party manufacturers for the production of both drug substance and finished drug product. We currently obtain our supplies from these manufacturers on a purchase order basis and do not have long-term supply arrangements in place. Should any of these manufacturers become unavailable to us for any reason, we believe that there are a number of potential replacements, although we may incur some delay in identifying and qualifying such replacements.

Sales and Marketing

We have not yet defined our sales, marketing or product distribution strategy for our product candidates because they are still in development. Our commercial strategy may include the use of strategic partners, distributors, a contract sales force or the establishment of our own commercial sales force. We plan to further evaluate these alternatives as we approach approval for our product candidates.

Intellectual Property

Intellectual property, including patents, trade secrets, trademarks and copyrights, is important to our business. Our commercial success depends in part on our ability to obtain and maintain proprietary intellectual property protection for our product candidates, as well as for future product candidates and novel discoveries, product development technologies and know-how. Our commercial success also depends in part on our ability to operate without infringing on the proprietary rights of others and to prevent others from infringing our proprietary rights. Our policy is to develop and maintain protection of our proprietary position by, among other methods, filing applications for U.S. and foreign patents relating to our product candidates and their methods of use.

Our patent portfolio is built with a goal of establishing broad protection that generally includes, for the product candidates, claims directed to compositions of matter, pharmaceutical compositions or formulations, methods of manufacturing and methods of treatment. We are seeking and maintaining patent protection in the United States and key foreign jurisdictions where we intend to market our product candidates, if they are approved. As of February 28, 2026, our patent portfolio comprises 26 distinct patent application families protecting our technology relating to our product candidates and include 22 issued U.S. patents, 25 issued foreign patents (not including validated European patents in individual countries) and 69 pending patent applications, of which 17 are Patent Cooperation Treaty (PCT) or U.S. patent applications and the remainder are foreign.

We are developing our lead product candidate, ARD-101, for, among others, the treatment of hyperphagia associated with PWS. We have an issued patent for an oral formulation of the acetate salt, as well as several other salts, of denatonium. U.S. Patent No. 10,835,505 generally and specifically claims oral formulations of denatonium salts as products as well as methods for both effecting weight loss and treating adult-onset diabetes. U.S. Patent No. 10,835,505 is set to expire in 2038. Members of the same patent family have also been filed in Australia, Canada, China, Europe, Hong Kong, Japan and South Korea. We have also obtained an orphan drug designation for the treatment of PWS. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if, in relevant part, it is a drug intended to treat a rare disease or condition, defined as a patient population of fewer than 200,000 in the United States. If ARD-101 receives the first marketing approval for the treatment of PWS, then it would be entitled to marketing exclusivity

for seven years, which precludes the FDA from approving another marketing application for the same drug for the same use or indication for seven years after ARD-101's marketing approval.

ARD-101 is further covered by additional patents and applications. We are pursuing patent applications directed to solid-state forms of denatonium acetate monohydrate, filed in the United States (U.S. Ser. No. 18/631,587), Australia, Canada, China, Europe, Taiwan and Japan. This family contains composition of matter claims and process claims and is expected to expire in 2042. U.S. Patent No. 12,268,660 is directed to treatment of pulmonary hypertension with certain denatonium salts, which contains use claims and is projected to expire in 2041 (use claims in the U.S. take the form of methods of treatment). In addition, we are pursuing a patent application directed to treatment of asthma with certain denatonium salts, filed in the United States (U.S. Ser. No. 17/256,212), which contains use claims and is projected to expire in 2039. We are also pursuing patent applications directed to treatment of certain inflammatory disorders with certain denatonium salts, filed in the United States (U.S. Ser. No. 17/845,399), Australia, Canada, China, Europe, Hong Kong, Japan and South Korea. This family contains use claims, and patents issuing from this family are projected to have expiration dates in 2039. We are also pursuing patent applications directed to treatment of fatty liver diseases with certain denatonium salts, filed in the United States (U.S. Ser. No. 18/274,180), Australia, Canada, China, Europe, Hong Kong, Japan and South Korea. This family contains use claims, and patents issuing from this family are projected to have expiration dates in 2041. U.S. Patent No. 12,427,125 is directed to treatment of Severe Acute Respiratory Syndrome or prevention of acute respiratory distress syndrome with certain denatonium salts, which contains use claims and is projected to have an expiration date in 2042. We are also pursuing patent applications directed to abuse-deterrent pharmaceutical compositions comprising a controlled pharmaceutical substance and a bitter agonist compound, filed in the United States (U.S. Ser. No. 18/924,880), Europe, Canada and Australia. This family contains product claims and is projected to expire in 2043. U.S. Patent No. 11,253,490, relating to treating or alleviating a symptom of cognitive impairment in a subject with a COVID-19 infection, contains use claims and is projected to expire in 2041.

Related to ARD-201, we are pursuing patent applications directed to combinations of certain denatonium salts and a DPP-4 inhibitor and treatment of obesity and certain related disorders, filed in the United States (U.S. Ser. No. 18/557,182), Australia, Canada, China, Europe, Hong Kong and Japan. This family contains product and use claims, and patents issuing from this family are projected to have expiration dates in 2041.

The term of individual patents in our portfolio depends upon the legal term of patents in the countries in which they are obtained. In most countries in which we file, including the United States, the patent term is 20 years from the earliest date of filing a non-provisional patent application. In the United States, the term of a patent may be eligible for patent term adjustment, which permits patent term restoration as compensation for delays incurred at the U.S. Patent and Trademark Office (the USPTO), during the patent prosecution process. In addition, for patents that cover an FDA-approved drug, the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act) permits a patent term extension of up to five years beyond the expiration of the patent. While the length of the patent term extension is related to the length of time the drug is under regulatory review, patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, and only one patent per approved drug may be extended under the Hatch-Waxman Act. Similar provisions are available in Europe and other foreign jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our products receive FDA approval, we expect to apply for patent term extensions on patents covering those products. We plan to seek any available patent term extension to any granted patents in any jurisdiction where such extensions are available; however, there is no guarantee that the applicable authorities, including the FDA in the United States, will agree with our assessment of whether such extensions should be granted, and if granted, the length of such extensions.

We may also rely on trade secrets relating to our discovery programs and product candidates, and seek to protect and maintain the confidentiality of proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us, and for employees and consultants to enter into invention assignment agreements with us.

Governmental Regulations

U.S. Regulation

As a biopharmaceutical company that operates in the United States, we are subject to extensive regulation. Our product candidates will be required to comply with applicable regulatory requirements, including that production of our products must occur in registered facilities in compliance with current Good Manufacturing Practice requirements (cGMPs).

Government authorities in the United States (at the federal, state and local level) and in other countries extensively regulate, among other things, the research, development, testing, manufacturing, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of

biopharmaceutical products such as those we are developing. Our product candidates must be approved by the FDA before they may be legally marketed in the United States and by the comparable foreign regulatory authority before they may be legally marketed in foreign countries. Generally, our activities in other countries will be subject to regulation that is similar in nature and scope as that imposed in the United States, although there can be important differences. Additionally, some significant aspects of regulation in Europe are addressed in a centralized way, but country-specific regulation remains essential in many respects. We, along with our CMOs, contract research organizations (CROs), and third-party vendors, will be required to satisfy these requirements in each of the countries in which we wish to conduct studies or seek approval of our product candidates. The process for obtaining regulatory marketing approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources.

U.S. Drug Product Development

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act (the FDCA) and its implementing regulations and associated guidance. Drugs are also subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may result in delays to the conduct of a study, regulatory review and approval, or subject an applicant to administrative or judicial sanctions. These sanctions could include, among other actions, the FDA's refusal to approve pending applications, withdrawal of an approval, refusal to allow an applicant to proceed with clinical trials, imposition of a clinical hold, issuance of untitled or warning letters, product recalls or withdrawals from the market, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement of profits or civil or criminal investigations or penalties. Any agency or judicial enforcement action could have a material adverse effect on Aardvark.

Our product candidates must be approved by the FDA through the NDA process before they may be legally marketed in the United States. The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of extensive nonclinical, sometimes referred to as preclinical, laboratory tests, animal studies and formulation studies in accordance with applicable regulations, including the FDA's Good Laboratory Practice (GLP) regulations and standards;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- approval by an Institutional Review Board (IRB), representing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with applicable IND regulations, Good Clinical Practices (GCPs), and other clinical trial-related regulations to establish the safety and efficacy of the proposed drug product candidate for its proposed indication;
- submission to the FDA of a New Drug Application (NDA), requesting marketing approval for one or more proposed indications, which includes not only the results of the clinical trials, but also detailed information on the chemistry, manufacturing and quality controls for the product candidate and proposed labeling;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities where the product is produced, including those of third parties, to assess compliance with the FDA's cGMP requirements to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality, and purity;
- satisfactory completion of FDA audit(s) of clinical trial sites to assure compliance with GCPs and the integrity of the clinical data;
- FDA review and approval of the NDA prior to any commercial marketing or sale of the product in the United States; and
- compliance with any post-approval requirements, including REMS and post-approval studies required by the FDA.

The data required to support an NDA is generated in two development stages: preclinical and clinical. The preclinical development stage generally involves laboratory evaluations of drug chemistry, manufacturing and controls, as well as studies to evaluate toxicity in animals, which support subsequent clinical testing. The conduct of the preclinical studies must comply with federal regulations, including GLPs. The sponsor must submit the results of the preclinical studies together with manufacturing information, analytical data, clinical data (if available from studies conducted outside the United States pre-IND) or literature and a proposed clinical protocol, as well as other information, to the FDA as part of the IND. An IND is a request for authorization from the FDA to administer an investigational drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for human trials. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions regarding the proposed clinical trials and places the IND on full clinical hold or partial

clinical hold within that 30-day time period. Under a full clinical hold, the IND sponsor must resolve any outstanding concerns before the clinical trial can begin. Under a partial clinical hold, there may be a delay or suspension of only part of the clinical work requested under the IND. Following issuance of a clinical hold or partial clinical hold, a clinical trial (or full clinical trial in the case of a partial clinical hold) may only resume after the FDA has notified the sponsor that the trial may proceed. The FDA will base that determination on information provided by the sponsor correcting the deficiencies previously cited or otherwise satisfying the FDA that the clinical trial can proceed. The FDA may also impose clinical holds on a drug product candidate at any time before or during clinical trials due to safety concerns, non-compliance or other issues affecting the integrity or utility of the trial.

Accordingly, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that could cause the trial to be suspended or terminated.

The clinical stage of development generally involves the administration of the drug product candidate to human subjects under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control, in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety and assess efficacy. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND before a trial commences. Further, each clinical trial must be reviewed and approved by an IRB at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. Additionally, some trials are overseen by an independent group of qualified experts organized by the sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether or not a trial may move forward at designated check points based on access that only the group maintains to available data from the study. The FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk.

A sponsor may choose, but is not required, to conduct a foreign clinical trial under an IND. When a foreign clinical trial is conducted under an IND, all FDA IND requirements must be met unless waived. When the foreign clinical trial is not conducted under an IND, the sponsor must ensure that the study is conducted in accordance with GCP, including review and approval by an independent ethics committee (IEC) and informed consent from subjects. The GCP requirements are intended to help ensure the protection of human subjects enrolled in non-IND foreign clinical trials, as well as the quality and integrity of the resulting data. FDA must also be able to validate the data from the study through an on-site inspection if necessary. There are also requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries. Sponsors of certain clinical trials of FDA-regulated products are required to register and disclose certain clinical trial information, which is made publicly available at www.clinicaltrials.gov.

Clinical trials are generally conducted in three sequential phases, known as Phase 1, Phase 2 and Phase 3, and may overlap. Phase 1 clinical trials generally involve a small number of healthy volunteers who are initially exposed to a single dose and then multiple doses of the drug product candidate. The primary purpose of these clinical trials is to assess the metabolism, pharmacologic action, tolerability, adverse effects, dosage, distribution, excretion, safety of the drug product candidate and, if possible, to gain early evidence on effectiveness and to determine maximal dosage. Phase 2 clinical trials typically involve studies in disease-affected subjects to determine dosage tolerance and the optimal dose required to produce the desired benefits. At the same time, safety and further pharmacokinetic and pharmacodynamic information is collected, as well as identification of possible adverse effects and safety risks and preliminary evaluation of efficacy. Phase 3 clinical trials (also referred to as confirmatory trials, pivotal trials, registrational trials or adequate and well-controlled trials) generally involve large numbers of subjects at multiple sites, in multiple countries, and are designed to provide the data necessary to demonstrate the efficacy of the product for its intended use and its safety in use, and to establish the overall benefit/risk relationship of the product and provide an adequate basis for product approval. Phase 3 clinical trials may include comparisons with placebo and/or other comparator treatments. The duration of treatment is often extended to mimic the intended use of a product during marketing. Generally, two adequate and well-controlled Phase 3 clinical trials demonstrating that the statutory standard is met are required by the FDA for approval. In certain instances, FDA may condition approval of an NDA on the sponsor's agreement to conduct additional clinical trials or preclinical studies (post-marketing commitments or post-marketing requirements) to further assess the drug's safety and effectiveness after approval. Such post-approval trials are sometimes referred to as Phase 4 clinical trials. These trials are used to gain additional experience from the treatment of subjects in the intended therapeutic indication and, in the case of drugs approved under Accelerated Approval, confirm clinical benefit seen with a surrogate endpoint using a long-term clinical outcome endpoint. Failure to exhibit due diligence with regard to conducting such Phase 4 clinical trials could result in withdrawal of approval for products or other consequences.

Progress reports detailing the results of the clinical trials, among other information, must be submitted at least annually to the FDA; written IND safety reports must be submitted to the FDA and the investigators for Serious and Unexpected Suspected Adverse Reactions, findings from other studies suggesting a significant risk to humans exposed to the drug, findings from animal or in vitro

testing that suggest a significant risk for human subjects and any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. Additionally, a data safety monitoring board or committee may halt the clinical trial if it determines that there is an unacceptable safety risk. We may also suspend or terminate a clinical trial based on evolving business objectives and/or competitive climate.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug product candidate as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug product candidate and, among other things, must develop methods for testing the identity, strength, quality, purity and potency of the final product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the drug product candidate does not undergo unacceptable deterioration over its shelf life.

FDA Review Process

Following completion of each clinical trial and trial phase, trial data are analyzed to assess safety and efficacy. The results of preclinical studies and clinical trials are then submitted to the FDA as part of an NDA, along with proposed labeling for the product and information about the manufacturing process and facilities that will be used to ensure product quality, results of analytical testing conducted on the chemistry of the product candidate and other relevant information. The NDA is a request for approval to market the drug for one or more specified indications, which is demonstrated by extensive non-clinical and clinical testing. The application may include both negative or ambiguous results of preclinical and clinical trials as well as positive findings. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a use of a product, or from a number of alternative sources, including studies initiated by investigators, with appropriate rights of reference. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the investigational product for the specified indication(s) to the satisfaction of the FDA. FDA approval of an NDA must be obtained before a drug may be marketed in the United States.

Under the Prescription Drug User Fee Act, as amended (PDUFA), each NDA must be accompanied by a significant user fee, which is adjusted on an annual basis. PDUFA also imposes an annual prescription drug product program fee. Fee waivers, reductions or exemptions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business (with fewer than 500 employees) and for applications seeking approval for orphan drugs.

Once an NDA is submitted, the FDA has 60 days to file the NDA, at which time the FDA begins its review process. Incomplete applications are subject to a Refuse-to-File decision. The FDA's stated goal is to review NDAs within 10 months of the filing date for standard review or six months of the filing date for priority review. Products are eligible for priority review (a status assigned by the FDA at filing) if the application is for a product intended to treat a serious or life-threatening condition and the product, if approved, would provide a significant improvement in safety or effectiveness compared to any existing licensed products for the same intended use. The FDA has substantial discretion in the approval process and may refuse to file any application or not approve an NDA if the FDA determines that the data are insufficient for approval. The FDA may also require additional preclinical, clinical or other studies before it accepts the filing. Additionally, the review process is often significantly extended by FDA requests for additional information or clarification.

After the NDA is accepted for filing, the FDA reviews the NDA to determine, among other things, whether the proposed product candidate is safe and effective for its intended use, and whether the product candidate is being manufactured in accordance with cGMP requirements. The FDA may refer applications for drug product candidates which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. The FDA conducts its own analysis of the clinical trial data, which could result in extensive discussions between the FDA and us during the review process. The review and evaluation of an NDA by the FDA is extensive and time-consuming and may take longer than originally planned to complete, and we may not receive a timely approval, if at all.

Before approving an NDA, the FDA will generally conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether the facilities comply with cGMPs. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. In addition, before approving an NDA, the FDA may also audit data from clinical trials to ensure compliance with GCP requirements. After the FDA evaluates the application, manufacturing process and manufacturing facilities, it may issue an Approval Letter or a Complete Response Letter. An Approval Letter authorizes commercial marketing of the product with specific prescribing information for specific indications and conditions of use. A Complete Response Letter indicates that the review cycle of the application is complete and the application will not be approved in its present form. A Complete Response Letter describes the deficiencies in the NDA identified by the FDA. Responding to a Complete Response Letter may require additional clinical data and/or an additional pivotal Phase 3 clinical trial(s), and/or other significant and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. If a Complete Response Letter is issued, the applicant may either resubmit the NDA, addressing all of the deficiencies identified in the letter, withdraw the application, or engage in a dispute resolution proceeding or request a hearing. Even if additional data and information is submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive, and the FDA may interpret data differently than we interpret the same data.

There is no assurance that the FDA will ultimately approve a product for marketing in the United States, and we may encounter significant difficulties or costs during the review process. If a product receives marketing approval, the approval may be significantly limited to specific populations, severities of the condition being treated, and dosages, or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Furthermore, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling or may condition the approval of the NDA on other changes to the proposed labeling, development of adequate controls and specifications, or a commitment or requirement to conduct post-market testing or clinical trials and surveillance to monitor the effects of approved products. For example, the FDA may require Phase 4 trials designed to further assess the product's safety and effectiveness and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized, including long-term follow up for certain cellular products. The FDA may also place other conditions on approvals including the requirement for a REMS, to assure the safe use of the product. If the FDA concludes a REMS is needed, the sponsor of the NDA must submit a proposed REMS. The FDA will not approve the NDA without an approved REMS, if required. A REMS could include medication guides, physician communication plans, or elements to assure safe use (ETASU), such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory standards or based on the results of post-market studies or surveillance programs. Additionally, post-approval, many types of changes to the approved product, such as adding new indications, changing manufacturing processes and adding labeling claims, are subject to further testing requirements and FDA review and approval. Such post-approval requirements can be costly and time-consuming and can affect the potential market and profitability of the product.

Orphan Designation and Exclusivity

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

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

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

In *Catalyst Pharms., Inc. v. Becerra*, 14 F.4th 1299 (11th Cir. 2021), the court disagreed with the FDA's longstanding position that the orphan drug exclusivity only applies to the approved use or indication within the relevant orphan drug designation. This decision created uncertainty in the application of the orphan drug exclusivity. In January 2023, the FDA published a notice in the Federal Register to clarify that while the FDA complies with the court's order in *Catalyst*, the FDA intends to continue to apply its longstanding interpretation of the regulations to matters outside of the scope of the *Catalyst* order – that is, the agency will continue tying the scope of orphan-drug exclusivity to the uses or indications for which a drug is approved, which permits other sponsors to obtain approval of a drug for new uses or indications within the same orphan designated disease or condition that have not yet been approved. In February 2026, legislation amended the FDCA to clarify the scope of the orphan-drug exclusivity to the same approved use or indication within the rare designation for which the drug is approved. It is unclear how future litigation and administrative actions will impact the scope of the orphan drug exclusivity.

Rare Pediatric Disease Priority Review Voucher Program

Under the Rare Pediatric Disease Priority Review Voucher program, the FDA may award a priority review voucher to the sponsor of an approved marketing application for a drug that is for the prevention or treatment of a rare pediatric disease. The sponsor can use the voucher to obtain priority review for a subsequent human drug or biologic application. The sponsor can also transfer or sell the voucher to another company.

To be eligible for a rare pediatric disease priority review voucher, the NDA must be for a drug that prevents or treats a "rare pediatric disease" defined to mean a serious or life-threatening disease in which the serious or life-threatening manifestations primarily affect individuals aged from birth to 18 years and the disease affects fewer than 200,000 individuals in the U.S., or affects 200,000 or more individuals in the U.S. but for which there is no reasonable expectation that the cost of developing the drug will be recovered from sales of the drug in the U.S. Additionally, the NDA must be deemed eligible for priority review, rely on clinical data derived from studies examining a pediatric population and dosages of the drug intended for that population, not seek approval for a different adult indication in the original rare pediatric disease product application and be for a drug that does not include a previously approved active ingredient. A sponsor may request rare pediatric disease designation from the FDA prior to the submission of the NDA; however rare pediatric disease designation does not guarantee that a sponsor will receive a priority review voucher upon approval of the NDA.

The Rare Pediatric Disease Priority Review Voucher program began to sunset in December 2024 but was reauthorized in February 2026. Under this reauthorization, the FDA may award a rare pediatric disease priority review voucher if the NDA for the product is approved before September 30, 2029.

Expedited Development and Review Programs

Fast-Track Designation and Accelerated Approval Pathway

The FDA has a fast track designation program that is intended to expedite or facilitate the process for reviewing new drugs and biological products that meet certain criteria. Specifically, new drugs and biological products are eligible for fast track designation if they are intended to treat a serious or life-threatening condition and nonclinical or clinical data demonstrate the potential to address unmet medical needs for the condition. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a new drug or biologic may request the FDA to designate the drug or biologic as a fast track product concurrently with, or at any time after, submission of an IND, and the FDA must determine if the product qualifies for fast track designation within 60 days of receipt of the sponsor's request. Under the fast track designation, the FDA may consider for review sections of the marketing 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 application and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the application.

Any product submitted to the FDA in a marketing application, including a fast track designated product, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. Any product intended to treat a serious or life-threatening condition is eligible for priority review, or review within a six-month timeframe from the date a complete NDA is accepted for filing, if it has the potential to provide a significant improvement in safety and effectiveness compared to available therapies for the same intended use. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug or biological product designated for priority review in an effort to facilitate the review.

Additionally, a product may be eligible for accelerated approval if it treats a serious or life-threatening condition and generally provides a meaningful advantage over available therapies and demonstrates an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality (IMM), that is reasonably likely to predict an effect on IMM or other clinical benefit. As a condition of approval, the FDA will require that a sponsor of a drug or biological product receiving accelerated approval perform a post-approval confirmatory study and, under the Food and Drug Omnibus Reform Act of 2022 (FDORA), the FDA is now permitted to require, as appropriate, that such trials be underway prior to approval or within a specific time period after the date of approval for a product approved under the accelerated approval pathway.

FDA has issued draft guidance that proposes criteria it will evaluate to determine if a trial is underway, including whether enrollment in the trial has been initiated. Since the FDORA amendments, the FDA has increased authority for expedited procedures to withdraw approval of a drug or indication approved under accelerated approval if, for example, the confirmatory trial fails to verify the predicted clinical benefit of the product. In addition, the FDA currently requires as a condition for accelerated approval pre-approval review of promotional materials, which could adversely impact the timing of the commercial launch of the product. Fast track designation, priority review and accelerated approval do not change the standards for approval but may expedite the development or approval process.

Breakthrough Therapy Designation

A product can be designated as a Breakthrough Therapy if it is intended to treat a serious or life-threatening condition and preliminary clinical evidence indicates that it may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. A sponsor may request that a drug product candidate be designated as a Breakthrough Therapy concurrently with, or at any time after, the submission of an IND, and the FDA must determine if the drug product candidate qualifies for Breakthrough Therapy designation within 60 days of receipt of the sponsor's request. If so designated, the FDA shall act to expedite the development and review of the product's marketing application, including by meeting with the sponsor throughout the product's development, providing timely advice to the sponsor to ensure that the development program to gather preclinical and clinical data is as efficient as practicable, involving senior managers and experienced review staff in a cross-disciplinary review, assigning a cross-disciplinary project lead for the FDA review team to facilitate an efficient review of the development program and to serve as a scientific liaison between the review team and the sponsor, and taking steps to ensure that the design of the clinical trials is as efficient as practicable. Breakthrough Therapy designation does not change the standards for approval but may expedite the development or approval process.

Pediatric Trials

Under the Pediatric Research Equity Act, a marketing application for a drug or biological product for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration must contain data to assess the safety and efficacy of the product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDCA requires that a sponsor submit an initial Pediatric Study Plan (PSP) within 60 days of an end-of-Phase 2 meeting or as may be agreed between the sponsor and the FDA. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA and the sponsor must reach agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from nonclinical studies, early phase clinical trials and/or other clinical development programs. The FDA may, on its own initiative or at the request of the sponsor, grant deferrals for submission of data or full or partial waivers. Furthermore, with some exceptions, requirements under the Pediatric Research Equity Act generally do not apply to a drug for an indication for which orphan drug designation has been granted.

Post-Approval Requirements

Following approval of a new product, the manufacturer of the approved product is subject to continuing regulation by the FDA, including, among other things, monitoring and recordkeeping activities, reporting to the applicable regulatory authorities of adverse experiences with the product, providing the regulatory authorities with updated safety and efficacy information, product sampling, distribution, and tracking and tracing requirements and complying with promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting products for uses or in patient populations that are not described in the product's approved labeling (known as off-label use), limitations on industry-sponsored scientific and educational activities and requirements for promotional activities involving the internet. Although physicians may prescribe legally available drugs and biologics for off-label uses, manufacturers may not market or promote such off-label uses.

Modifications or enhancements to the product or its labeling or manufacturing changes are often subject to the approval of the FDA and comparable foreign regulatory authorities, which may result in a lengthy review process and additional fees in certain cases. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use.

In the United States, once a product is approved, its manufacturer is subject to comprehensive and continuing regulation by the FDA. The FDA regulations require that products be manufactured in specific approved facilities and in accordance with cGMPs. We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products in accordance with cGMP regulations. cGMP regulations require, among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Manufacturers and other entities involved in the manufacture and distribution of approved products 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 and other laws. Manufacturers are also subject to record requests from the FDA that demonstrate cGMP compliance through data and other information. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance and oversight. These regulations also impose certain organizational, procedural and documentation requirements with respect to manufacturing and quality assurance activities. NDA holders using contract manufacturers, laboratories, or packagers are responsible for the selection and monitoring of qualified firms, and, in certain circumstances, qualified suppliers to these firms. These firms and, where applicable, their suppliers are subject to inspections by the FDA at any time, and the discovery of violative conditions, including failure to conform to cGMP, could result in enforcement actions that interrupt the operation of any such facilities or the ability to distribute products manufactured, processed or tested by them. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer or holder of an approved NDA, including, among other things, recall or withdrawal of the product from the market.

The FDA also may require post-approval testing, sometimes referred to as Phase 4 testing, REMS and post-marketing surveillance to monitor the effects of an approved product or place conditions on an approval that could restrict the distribution or use of the approved product. Discovery of previously unknown problems with a product or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial or administrative enforcement, untitled or warning letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties, among others. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our products under development.

Other Regulatory Matters

Manufacturing, sales, promotion and other activities following product approval are also subject to regulation by numerous regulatory authorities in addition to the FDA, including, in the United States, the CMS, other Agencies of the Department of Health and Human Services (HHS) (*e.g.*, the Office of Inspector General and Office for Civil Rights), the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency and state and local governments. In the United States, sales, marketing and scientific/educational programs must also comply with federal and state fraud and abuse laws, data privacy and security laws, transparency laws and pricing and reimbursement requirements in connection with governmental payor programs, among others. The handling of any controlled substances must comply with the U.S. Controlled Substances Act and Controlled Substances Import and Export Act. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, sales, promotion and other activities are also potentially subject to federal and state consumer protection and unfair competition laws.

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

The failure to comply with regulatory requirements subjects firms to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in criminal prosecution, fines or other penalties, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of product approvals or refusal to allow a firm to enter into supply contracts, including government contracts. In addition, even if a firm complies with FDA and other requirements, new information regarding the safety or efficacy of a product could lead the FDA to modify or withdraw product approval. Prohibitions or restrictions on sales or withdrawal of future products marketed by us could materially affect our business in an adverse way.

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

505(b)(2) NDAs

The FDA is authorized to approve an alternative type of NDA under Section 505(b)(2) of the FDCA. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference from the data owner. The applicant may rely upon the FDA's findings of safety and efficacy for an approved product that acts as the "listed drug." The FDA may also require 505(b)(2) applicants to perform additional studies or measurements to support the change from the listed drug. The FDA may then approve the

new product for all, or some, of the conditions of use for which the branded reference drug has been approved, or for a new condition of use sought by the 505(b)(2) applicant.

Abbreviated New Drug Applications

The Hatch-Waxman amendments to the FDCA established a statutory procedure for submission and FDA review and approval of abbreviated new drug applications (ANDA) for generic versions of listed drugs. An ANDA is a comprehensive submission that contains, among other things, data and information pertaining to the active pharmaceutical ingredient, drug product formulation, specifications and stability of the generic drug, as well as analytical methods, manufacturing process validation data, and quality control procedures. Premarket applications for generic drugs are termed abbreviated because they generally do not include clinical data to demonstrate safety and effectiveness. However, a generic manufacturer is typically required to conduct bioequivalence studies of its test product against the listed drug. Bioequivalence is established when there is an absence of a significant difference in the rate and extent for absorption of the generic product and the reference listed drug. For some drugs, other means of demonstrating bioequivalence may be required by the FDA, especially where the rate or extent of absorption is difficult or impossible to measure. The FDA will approve an ANDA application if it finds that the generic product does not raise new questions of safety and effectiveness as compared to the reference listed drug. A product is not eligible for ANDA approval if the FDA determines that it is not bioequivalent to the reference listed drug if it is intended for a different use or if it is not subject to, and requires an approved suitability petition.

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 reference drug sponsor's decision to initiate patent litigation. If the drug has new chemical entity (NCE) exclusivity and the ANDA is submitted four years after approval, the 30-month stay is extended so that it expires seven and a half years after approval of the innovator drug, unless the patent expires or there is a decision in the infringement case that is favorable to the ANDA applicant before then.

U.S. Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of the FDA approval of our drug product candidates, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to

five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA plus the time between the submission date of an NDA and the approval of that application, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved drug is eligible for the extension and, among other requirements, the application for the extension must be submitted prior to the expiration of the patent. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may apply for restoration of patent term for our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant NDA.

The Hatch-Waxman Amendments provide a period of five years of non-patent marketing exclusivity for the first approved drug containing an NCE as an active ingredient. An NCE is an active moiety that has not been approved by the FDA in any other NDA. An "active moiety" is defined as the molecule or ion responsible for the drug substance's physiological or pharmacologic action. During the five-year exclusivity period, the FDA cannot accept for filing any ANDA or 505(b)(2) NDA seeking approval of a product that contains the same active moiety, except that the FDA may accept such an application for filing after four years if the application includes a paragraph IV certification to a listed patent. In the case of such applications accepted for filing between four and five years after approval of the reference drug, the 30-month stay of approval triggered by a timely patent infringement lawsuit is extended by the amount of time necessary to extend the stay until 7-1/2 years after the approval of the reference drug NDA. If approved in the United States, as ARD-101 has not been previously approved in the United States for any indication, ARD-101 may be eligible for five years of NCE, which would run concurrently with its seven years of orphan drug exclusivity. Although ARD-101's active moiety has been available as a bittering agent, it has not ever previously been approved by the FDA in an NDA.

Pediatric exclusivity is another type of regulatory market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of the other exclusivity protection or patent term, may be granted based on the voluntary completion and submission of data from of a pediatric trial conducted in accordance with an FDA-issued "Written Request" for such a trial.

Pricing and Reimbursement

United States

Sales of our products will depend, in part, on the extent to which our products, if approved, will be covered and reimbursed by third-party payors, such as government health programs, commercial insurance and managed healthcare organizations. These third-party payors are increasingly reducing reimbursements for medical products and services. The process for determining whether a third-party payor will provide coverage for a drug product typically is separate from the process for setting the price of a drug product or for establishing the reimbursement rate that a payor will pay for the drug product once coverage is approved. Third-party payors may limit coverage to specific drug products on an approved list, also known as a formulary, which might not include all of the approved drugs for a particular indication.

In order to secure coverage and reimbursement for any drug product candidate that might be approved for sale, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the drug product candidate, in addition to the costs required to obtain FDA or other comparable regulatory approvals. Whether or not we conduct such studies, our drug product candidates may not be considered medically necessary or cost-effective. A third-party payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Third party reimbursement may not be sufficient to enable us to maintain price levels high enough to realize an appropriate return on our investment in product development. In the United States, the principal decisions about reimbursement for new drug products are typically made by CMS, an agency within HHS. CMS decides whether and to what extent a new drug product will be covered and reimbursed under Medicare, and private payors tend to follow CMS to a substantial degree. However, no uniform policy of coverage and reimbursement for drug products exists among third-party payors and coverage and reimbursement levels for drug products can differ significantly from payor to payor. Additionally, one third-party payor's decision to cover a particular product or service does not ensure that other payors will also provide coverage for the product or service, and the level of coverage and reimbursement can differ significantly from payor to payor. As a result, the coverage determination process will often require us to provide scientific and clinical support for the use of our products to each payor separately and can be a time-consuming process, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

The containment of healthcare costs has become a priority of federal and state governments, and the prices of drugs, including biologics, have been a focus in this effort. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. In many countries, the prices of drug products are subject to varying price control mechanisms as part

of national health systems. In general, the prices of drug products under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for drug products, but monitor and control company profits. Accordingly, in markets outside the United States, the reimbursement for drug products may be reduced compared with the United States. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. The IRA, for example, includes provisions that impose new manufacturer financial liability on certain drugs under Medicare Part D, allowing the U.S. government to negotiate Medicare Part B and Part D price caps for certain high-cost drugs and biologics without generic or biosimilar competition. Orphan drugs are exempted from the Medicare drug price negotiation program provided that the only approved indications (or indications) is for one or more rare diseases or conditions for which the drug received orphan drug designation by the FDA. Decreases in third-party reimbursement for our drug product candidate or a decision by a third-party payor to not cover our drug product candidate could reduce physician usage of the drug product candidate and have a material adverse effect on our sales, results of operations and financial condition.

Outside of the United States, the pricing of pharmaceutical products is subject to governmental control in many countries. For example, in the European Union, pricing and reimbursement schemes vary widely from country to country. Some countries provide that products may be marketed only after a reimbursement price has been approved. Some countries may require the completion of additional studies that compare the cost effectiveness of a particular therapy to currently available therapies or so-called health technology assessments, in order to obtain reimbursement or pricing approval. Other countries may allow companies to fix their own prices for products, but monitor and control product volumes and issue guidance to physicians to limit prescriptions. Efforts to control prices and utilization of pharmaceutical products will likely continue as countries attempt to manage healthcare expenditures. Historically, products launched in the European Union do not follow price structures of the United States and generally prices tend to be significantly lower.

Other Healthcare Laws and Compliance Requirements

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

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

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

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

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

HIPAA, as amended by HITECH, and its implementing regulations, mandates, among other things, the adoption of uniform standards for the electronic exchange of information in common healthcare transactions, as well as standards relating to the privacy and security of individually identifiable health information, which require the adoption of administrative, physical and technical safeguards to protect such information. Among other things, HITECH makes HIPAA's security standards directly applicable to business associates, defined as independent contractors or agents of covered entities, which include certain health care providers, health plans and healthcare clearinghouses, that create, receive or obtain protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities and business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, certain state laws govern the privacy and security of health information and other personal data in certain circumstances, some of which are more stringent or otherwise different than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and criminal penalties.

Further, the federal Physician Payments Sunshine Act (the Sunshine Act) within the ACA, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) report annually to CMS information related to certain payments or other transfers of value made or distributed to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other licensed health care practitioners and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members. In addition, many states also govern the reporting of payments or other transfers of value, many of which differ from each other in significant ways, are often not pre-empted, and may have a more prohibitive effect than the Sunshine Act, thus further complicating compliance efforts.

We may become subject to federal government price reporting laws, which would require us to calculate and report complex pricing metrics in an accurate and timely manner to government programs, as well as federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

Similar federal, state and foreign fraud and abuse laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services. Such laws are generally broad and are enforced by various state agencies and private actions. Also, many states have similar fraud and abuse statutes or regulations that may be broader in scope and may apply regardless of payor, in addition to items and services reimbursed under Medicaid and other state programs. Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant federal government compliance guidance, and require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures.

In order to distribute products commercially, we must comply with federal and state laws relating to drug supply chain traceability, including those that require the registration of manufacturers and wholesale distributors of drug and biological products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Federal laws require the implementation of systems to provide, capture, and maintain information about transactions involving drug products distributed within the United States and the trading partners who engaged in such transactions. Several states have enacted legislation requiring pharmaceutical and biotechnology companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities and/or register their sales representatives and to prohibit certain other sales and marketing practices. All of our activities are potentially subject to federal and state consumer protection and unfair competition laws.

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

Current and Future Legislation

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

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

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

Since its enactment, there have been executive, judicial and Congressional challenges to certain aspects of the ACA. For example, in June 2021, the U.S. Supreme Court held that Texas and other challengers had no legal standing to challenge the ACA, dismissing the case on procedural grounds without specifically ruling on the constitutionality of the ACA. Thus, while the ACA remains in effect in its current form, it is possible that the ACA will be subject to judicial or Congressional challenges in the future.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted:

- The Budget Control Act of 2011 and subsequent legislation, among other things, created measures for spending reductions by Congress that include aggregate reductions of Medicare payments to providers of 2% per fiscal year, which remain in effect through the first half of 2032. Under the Statutory Pay-As-You-Go Act of 2010, estimated budget deficit increases resulting from the American Rescue Plan Act of 2021 and subsequent legislation would trigger reductions in Medicare payments to providers, but 2025 legislation eliminated the impact of the estimated budget deficit increases by setting the scorecard used to determine the need for such reductions (sequestration) equal to zero.

- American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability.
- On May 30, 2018, the Right to Try Act was signed into law. The law, among other things, provides a federal framework for certain patients to request access to certain IND products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

In addition, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient assistance programs and reform government program reimbursement methodologies for drugs. Previous administrations have issued multiple executive orders seeking to reduce prescription drug costs, and the current Trump administration has signaled that lowering the cost of prescription drugs is a top priority.

The IRA includes several provisions that may impact our business to varying degrees, including provisions that reduce the out-of-pocket spending cap for Medicare Part D beneficiaries from $7,050 to $2,000 starting in 2025, thereby effectively eliminating the coverage gap; impose new manufacturer financial liability on certain drugs under Medicare Part D, allowing the U.S. government to negotiate Medicare Part B and Part D price caps for certain high-cost drugs and biologics without generic or biosimilar competition; require companies to pay rebates to Medicare for certain drug prices that increase faster than inflation; and delay until January 1, 2032 the implementation of the HHS rebate rule that would have limited the fees that pharmacy benefit managers can charge. Various industry stakeholders, including pharmaceutical companies, have lawsuits pending against the federal government asserting that the price negotiation provisions of the IRA are unconstitutional. HHS has generally won the substantive disputes in these cases, but certain of these cases continue to be appealed. Under the Trump Administration, CMS has continued to negotiate drug prices pursuant to the IRA framework. The Trump Administration has also issued public statements about its commitment to lowering the cost of prescription drugs and has sought additional voluntary agreements to reduce drug pricing from certain pharmaceutical manufacturers. The effects of the IRA on our business is not yet known.

Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain drug access, marketing cost disclosure, transparency measures and other measures designed to encourage importation from other countries and bulk purchasing. In January 2024, the FDA authorized Florida's Agency for Health Care Administration's drug importation program, which is the first step toward Florida facilitating importation of certain prescription drugs from Canada. Authorization of other state programs may follow as other states have submitted importation program proposals. The Trump Administration has publicly supported such state-directed importation programs, and the FDA has taken steps to facilitate such states in initiating such programs. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, financial condition, results of operations and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our drugs or put pressure on our drug pricing, which could negatively affect our business, financial condition, results of operations and prospects.

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

The Foreign Corrupt Practices Act

The FCPA prohibits any U.S. individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Additional Regulation

In addition to the foregoing, state and federal laws regarding environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservancy and Recovery Act and the Toxic Substances Control Act, affect our business. These and other laws govern our use, handling and disposal of various biological, chemical and radioactive substances used in, and wastes generated by, our operations. If our operations result in contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and governmental fines. We believe that we are in material compliance with applicable environmental laws and that continued compliance therewith will not have a material adverse effect on our business. We cannot predict, however, how changes in these laws may affect our future operations.

Europe / Rest of World Government Regulation

In addition to regulations in the United States, we may be subject to a variety of regulations in other jurisdictions that we may in the future select, which may govern, among other things, clinical trials and any commercial sales and distribution of our products. Whether or not we obtain FDA approval of a product, we would need to obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application much like the IND prior to the commencement of human clinical trials. In the EU, for example, a clinical trial application must be submitted to each country's national health authority and an independent ethics committee, much like the FDA and IRB, respectively. Once the clinical trial application is approved in accordance with a country's requirements, clinical trial development may proceed.

To obtain a marketing authorization for a product in the EU, an applicant must submit an MAA either under a centralized procedure administered by the European Medicines Agency (EMA) or one of the procedures administered by competent authorities in the EU Member States (decentralized procedure or mutual recognition procedure) for obtaining a marketing authorization in multiple EU Member States. A marketing authorization may be granted only to an applicant established in the European Economic Area (EEA) (which is comprised of the EU Member States plus Norway, Iceland and Liechtenstein).

U.S. Privacy Laws

In addition to HIPAA, we may be subject to other U.S. federal and state privacy laws. For example, failing to take appropriate steps to keep consumers' personal data secure may constitute unfair acts or practices in or affecting commerce in violation of the FTC Act. Additionally, the FTC Health Breach Notification Rule applies to health apps and other similar technologies and expanded breach notification requirements, which adds complexity to compliance obligations. Further, the SEC implemented rules around incident reporting, requiring cybersecurity incidents to be reported four business days after determining that an incident is material.

The U.S. Department of Justice issued a final rule entitled, "Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons," codified at 28 CFR part 202 (the Bulk Transfer Rule). The Bulk Transfer Rule prohibits and restricts bulk transfers of sensitive personal data (including genetic and health data) to countries of concern, such as China, Russia, and Iran to prevent access by foreign adversaries. It restricts our ability to engage in certain cross-border transactions involving genomic or biological samples and related data, which may increase compliance costs, lead to increased regulatory scrutiny or liability, and may require additional contractual negotiations, which may adversely impact our business, financial condition, and operating results.

We may be subject to certain state laws that govern the privacy and security of health-related and other personal information in certain circumstances, some of which may be more stringent, broader in scope or offer greater individual rights with respect to protected health information than HIPAA, many of which may differ from each other, 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. For example, the California Consumer Privacy Act (CCPA), revised and amended by the California Privacy Rights Act (CPRA), created new individual privacy rights for California residents, including the right to opt out of certain disclosures of their data and the right to limit the use and disclosure of sensitive personal information (including health information). While California was the first among the states to adopt comprehensive data privacy legislation similar to the GDPR, many other states are following suit, which could increase our potential liability and adversely affect our business. More than 20 states have adopted statewide comprehensive privacy laws and many other states have privacy legislation that is pending. Many of these new state laws contain some type of exemption for information collected under HIPAA and some data processed in the context of clinical trials, either at the entity level or the data level, so the impact might be limited particularly as it relates to protected health information. Some states also have laws that specifically focus on the processing of personal data related to individuals' health, including California's Confidentiality of Medical Information Act and Washington's My Health My Data Act. Finally, all 50 U.S. states and territories and international jurisdictions have varying breach notification laws that may require us to notify patients, employees or regulators in the event of unauthorized access to or disclosure of personal or confidential data experienced by us or our service providers.

European Union General Data Protection Regulation and Other International Data Protection Laws

In addition to EU regulations related to the approval and commercialization of our products, we may be subject to international laws governing data privacy. For example, the GDPR in the EEA and the GDPR in the United Kingdom (together, the GDPR) impose stringent requirements for controllers and processors of personal data of individuals within the EEA or the United Kingdom. The EU and UK GDPRs impose stringent requirements for controllers and processors of personal data of persons in the EEA and UK, including, for example, more robust disclosures to individuals and a strengthened individual data rights regime, shortened timelines for data breach notifications, limitations on retention of information, increased requirements pertaining to special categories of data, such as health data and additional obligations when we contract with third-party processors in connection with the processing of the personal data. The EU and UK GDPRs also impose strict rules on the transfer of personal data out of the European Union to the United States and other third countries. In addition, the EU and UK GDPRs provide that EU member states may make their own further laws and regulations limiting the processing of personal data, including genetic, biometric or health data.

The GDPR applies extraterritorially, and we may be subject to the GDPR because of our data processing activities that involve the personal data of individuals located in the European Union, such as in connection with our EU clinical trials. Failure to comply with the requirements of the GDPR and the applicable national data protection laws of the EU member states may result in fines of up to €20,000,000 (£17.5 million) or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, and other administrative penalties. EEA and UK GDPR regulations may impose additional responsibility and liability in relation to the personal data that we process, and we may be required to put in place additional mechanisms to ensure compliance with the new data protection rules. Such requirements may be subject to change in the near future as the European Commission announced proposed amendments to the GDPR in November 2025.

In addition, on June 19, 2025, the UK's Data (Use and Access) Act 2025 (the DUAA) was granted Royal Assent, implementing various measures concerning data usage in the UK and reforming data protection laws. The provisions within the DUAA will come into force through 2026, and it remains too soon to tell how the DUAA will be implemented and what impact it will have on our international activities. Further, other EU and member state laws and regulations may impose further obligations or restrictions on processing health information in the EEA, such as the European Health Data Space Regulation. Further, in the EEA, the NIS 2 Directive (NIS 2) is replacing the cybersecurity legal framework under the current NIS framework, aiming to ensure a high level of cybersecurity in the region. NIS 2 brings new medium and large organizations providing services in the EEA within scope of the legal framework. It extends to additional sectors and expands the list of in-scope healthcare organizations, including to certain providers engaged in research and development of medicinal products. The new regime imposes direct obligations on management in respect of an in-scope organization's compliance with NIS 2, requires covered organizations to put in place certain cyber risk management measures, strengthens incident reporting requirements and provides supervisory authorities with greater oversight. To the extent that we become subject to NIS 2 in the future, we may require additional investment of our resources in compliance programs. Under NIS 2, companies may be subject to administrative fines of up to the higher amount of €10 million or 2% of worldwide turnover.

Certain jurisdictions, including the EEA, have enacted laws and regulations governing cross-border personal information transfer and providing for data localization in certain cases. For example, absent appropriate safeguards or other circumstances, the GDPR and laws in Switzerland and the UK generally restrict the transfer of personal information to countries outside the EEA, Switzerland and the UK, such as the United States. Such safeguards include the use of standard contractual clauses approved by the European Commission and the UK and Swiss Data Protection Authorities as well as the EU-U.S. Data Privacy Framework. Additionally, other countries outside of the EU have enacted or are considering enacting similar cross-border data transfer restrictions and laws requiring local data residency, which could increase the cost and complexity of operating our business. The types of challenges we face in the EEA, Switzerland, and the UK will likely also arise in other jurisdictions that adopt laws similar to the GDPR or regulatory frameworks of equivalent complexity.

Employees and Human Capital Resources

As of February 28, 2026, we had 40 employees, all of whom were full-time. Of those, 25 were engaged in research and development activities. All of our employees are located in the United States. We do not have any employees that are represented by a labor union or covered under a collective bargaining agreement. We consider our relationship with our employees to be good.

Our future success depends on our ability to attract, develop and retain key personnel, maintain our culture and ensure diversity and inclusion in our board of directors, management and broader workforce. Our human resources objectives include, among other things, identifying, recruiting, retaining, incentivizing and integrating our existing and prospective employees. The principal purposes of our equity incentive plans are to attract, retain and motivate selected employees, consultants and directors through the granting of stock-based compensation awards. As these areas directly impact our ability to compete and innovate, they are key focus areas for our board of directors and senior executives.

Corporate and Other Information

We were incorporated in Delaware on May 17, 2017. Our principal executive offices are located at 4370 La Jolla Village Drive, Suite 1050, San Diego, CA 92122 and our telephone number is 858-225-7696. We have two wholly-owned subsidiaries, Artisan Therapeutics, Inc., incorporated in Delaware in October 2024, and Ardia Therapeutics, Inc., incorporated in Delaware in February 2026. Our website address is https://aardvarktherapeutics.com. Our investor relations website is located at https://ir.aardvarktherapeutics.com. We make available free of charge on our investor relations website under "Financials—SEC Filings" our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, our directors' and officers' Section 16 reports and any amendments to those reports as soon as reasonably practicable after filing or furnishing such materials to the SEC. They are also available for free on the SEC's website at www.sec.gov.

We use our investor relations website as a means of disclosing material non-public information and for complying with our disclosure obligations under Regulation FD. Investors should monitor such website, in addition to following our press releases, SEC filings and public conference calls and webcasts. Information relating to our corporate governance is also included on our investor relations website. The information in or accessible through the SEC and our website are not incorporated into, and are not considered part of, this filing, and inclusions of our website address in this Annual Report are inactive textual references only.

The Aardvark Therapeutics design logo, "Aardvark Therapeutics," and our other registered or common law trademarks, service marks or tradenames appearing in this Annual Report are our property. Solely for convenience, our trademarks, tradenames and service marks referred to in this Annual Report appear without the ®, TM, and SM symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights to these trademarks, tradenames and service marks. This Annual Report contains additional trademarks, tradenames and service marks of other companies that are the property of their respective owners. We do not intend our use or display of other companies' trademarks, tradenames or service marks to imply relationships with, or endorsement or sponsorship of us by, these other companies.

Item 1A. Risk Factors.

An investment in our common stock involves a high degree of risk. In deciding whether to invest, you should carefully consider and read the following risk factors, as well as the financial and other information contained in this Annual Report, including in Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations", of this Annual Report and in our consolidated financial statements and related notes thereto included elsewhere in this Annual Report. Any of the following risks could have a material adverse effect on our business, financial condition, results of operations or prospects and cause the value of our common stock to decline, which could cause you to lose all or part of your investment. The risks described below are not the only ones facing us. Additional risks and uncertainties of which we are unaware, or that we currently deem immaterial also may become important factors that affect us.

Risk Factor Summary

Below is a summary of material factors that make an investment in our securities speculative or risky. Importantly, this summary does not address all of the risks that we face. Additional discussion of the risks and uncertainties summarized in this risk factor summary, as well as other risks that we face, follows this summary. This summary is qualified in its entirety by that more complete discussion of such risks and uncertainties:

- We are a clinical-stage biopharmaceutical company with a limited operating history and no products approved for commercial sale, which may make it difficult for an investor to evaluate the success of our business to date and to assess our future viability.
- We will require substantial additional financing to achieve our goals, 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 product development programs, commercialization efforts or other operations.
- Our business is heavily dependent on the successful development, regulatory approval and commercialization of our lead product candidate, ARD-101.
- The regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable. If we are not able to obtain required regulatory approval for our product candidates, our business will be substantially harmed.
- Preclinical and clinical drug development involves a lengthy and expensive process, with uncertain timelines and outcomes, and results of earlier studies and trials may not be predictive of future trial results. If development of our

product candidates is unsuccessful or delayed, we may be unable to obtain required regulatory approvals and we may be unable to commercialize our product candidates on a timely basis, if at all.

- Certain disorders we seek to treat, such as PWS, have low prevalence and it may be difficult to identify and enroll patients with these disorders. If we encounter difficulties or delays enrolling subjects in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.
- Our clinical trials may fail to demonstrate safety and efficacy of our product candidates, or serious adverse events or side effects may be identified during the development of our product candidates, which could prevent or delay regulatory approval and commercialization, increase our costs or necessitate the abandonment or limitation of the development of some of our product candidates.
- We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.
- We have relied and expect to continue to rely on third parties to conduct our preclinical studies and clinical trials, as well as investigator-initiated trials. If those third parties do not perform as contractually required, fail to satisfy legal or regulatory requirements, miss expected deadlines or terminate the relationship, our development programs could be delayed, more costly or unsuccessful, and we may never be able to seek or obtain regulatory approval for or commercialize our product candidates.
- We rely completely on third parties to manufacture our clinical drug supplies and we intend to rely on third parties to produce commercial supplies of any approved product candidate, and our commercialization of any of our product candidates could be stopped, delayed or made less profitable if those third parties fail to obtain approval of the FDA or comparable regulatory authorities, fail to provide us with sufficient quantities of drug product or fail to do so at acceptable quality levels or prices.
- If we are unable to obtain, maintain and enforce intellectual property protection directed to our current and any future technologies that we develop, others may be able to make, use or sell product candidates substantially the same as ours, which could adversely affect our ability to compete in the market.
- We face substantial competition, which may result in a smaller than expected commercial opportunity and/or others discovering, developing or commercializing products before or more successfully than we do.

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

We are a clinical-stage biopharmaceutical company with a limited operating history and no products approved for commercial sale, which may make it difficult for an investor to evaluate the success of our business to date and to assess our future viability.

Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We are a clinical-stage biopharmaceutical company with a limited operating history, which may make it difficult to evaluate the success of our business to date and assess our future viability. Since our inception in 2017, we have focused primarily on organizing and staffing our company, business planning, establishing our intellectual property portfolio, raising capital, identifying and developing our product candidates, conducting preclinical studies and, more recently, clinical trials, and providing general and administrative support for these operations. To date, we have not yet demonstrated our ability to successfully obtain regulatory approvals, manufacture a 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 commercialization. Our approach to the discovery and development of product candidates is unproven, and we do not know whether we will be able to develop any products of commercial value. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing products.

We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives. We may also need to transition from a company with a research focus to a company capable of supporting commercial activities. Our inability to adequately address these risks and difficulties or successfully make such a transition could adversely affect our business, financial condition, results of operations and growth prospects.

We have incurred significant losses since our inception and expect to incur losses over the next several years and may never achieve or maintain profitability.

We have no products approved for commercial sale and have not generated any revenue to date, and we continue to incur significant research and development and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred significant losses since our inception and expect to continue to incur significant and increasing operating losses for at least the next several years. For the years ended December 31, 2025 and 2024, we reported a net loss of $57.6 million and $20.6 million,

respectively. As of December 31, 2025, we had an accumulated deficit of $115.9 million. Substantially all of our losses have resulted from expenses incurred in connection with our research and development programs and from general and administrative costs associated with our operations. ARD-101 will require substantial additional development time and resources before we would be able to apply for or receive marketing approvals and begin generating revenue from product sales. We expect to continue to incur losses for the foreseeable future, and we anticipate that our expenses will increase substantially as we:

- conduct our ongoing and planned clinical trials of ARD-101 as well as initiate and complete additional clinical trials for other product candidates and programs;
- complete preclinical studies;
- pursue regulatory approval of our product candidates;
- seek to discover and develop additional clinical and preclinical product candidates;
- scale up our clinical, operational, regulatory and quality assurance capabilities;
- establish a commercialization infrastructure and scale up external manufacturing and distribution capabilities to commercialize any product candidates for which we may obtain regulatory approval;
- adapt our regulatory compliance efforts to incorporate requirements applicable to marketed products;
- maintain, expand and protect our intellectual property portfolio;
- hire additional clinical, manufacturing, regulatory, quality assurance and scientific personnel;
- add operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts; and
- incur additional legal, accounting and other expenses in operating as a public company.

Even if we succeed in developing and obtaining marketing approval for one or more product candidates, we may never generate revenue that is significant enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis and we will continue to incur substantial research, development and other expenditures to develop and market additional product candidates. If we fail to become and remain profitable, it would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our development efforts, obtain product approvals, diversify our offerings or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

We will require substantial additional financing to achieve our goals, 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 product development programs, commercialization efforts or other operations.

The development of biopharmaceutical product candidates is capital-intensive. We expect our expenses to increase substantially in connection with our ongoing and planned activities, particularly as we conduct our ongoing and planned preclinical studies and clinical trials of ARD-101 and our other product candidates and programs, and any future product candidates we may develop. Our expenses will increase substantially if our product candidates successfully complete early clinical and other studies and also could increase beyond expectations if the FDA or comparable foreign regulatory authorities require us to perform studies in addition to those that we currently anticipate. Because the outcome of any clinical trial or preclinical study is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates. In addition, we will incur additional costs associated with operating as a public company. Furthermore, if we obtain marketing approval for our product candidates, we expect to incur significant expenses related to manufacturing, marketing, sales and distribution. 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 could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts.

As of December 31, 2025, we had cash, cash equivalents and short-term investments of approximately $110.0 million. Based on our current operating plan, we believe that our existing cash, cash equivalents and short-term investments will be sufficient to fund our projected operations into the second quarter of 2027. We have based these estimates on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through equity offerings, debt financings or other capital sources, including potential grants, collaborations, licenses and other similar arrangements. Even if we believe we have sufficient capital for our current or future operating plans, we may seek additional capital if market conditions are favorable or if we

have specific strategic considerations. Such financing may result in dilution to our stockholders, imposition of burdensome debt covenants and repayment obligations, or other restrictions that may affect our business.

Our future capital requirements depend on many factors, including:

- the design, timing, costs, progress, and results of our planned and ongoing preclinical studies and clinical trials;
- whether the FDA or comparable foreign regulatory authorities accept our clinical trial designs and development, data from our planned and ongoing preclinical studies and clinical trials and other work as the basis for review and approval of our product candidates;
- the extent to which we develop, in-license or acquire other product candidates and technology;
- the timing, costs and outcome of seeking, obtaining and, if applicable, maintaining, FDA and comparable foreign regulatory approvals;
- the number and characteristics of product candidates that we pursue;
- our efforts to maintain, expand, and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;
- the cost of pre-commercial activities and, if approved, commercialization activities related to our product candidates, including marketing, sales and distribution costs;
- the costs and timing associated with manufacturing our product candidates and establishing commercial supplies and sales, marketing and distribution capabilities;
- the cost of building or contracting a sales force in anticipation of commercialization;
- our ability to establish strategic collaborations, licensing or other arrangements and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty or other payments due under any such agreement;
- our need and ability to identify and retain key management and hire scientific, technical, business, clinical and clinical operations personnel;
- our need to implement additional internal systems and infrastructure, including financial and reporting systems and validate large-scale data and document systems;
- the costs associated with being a public company;
- the timing, receipt and amount of sales of our product candidates, if approved; and
- potential unforeseen liabilities and payment milestones for current and future in-licensed programs.

Any additional capital raising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and, if approved, commercialize our current and any future product candidates. Additional funding may not be available when we need them, on acceptable terms, or at all. If the equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly or more dilutive. If adequate funds are not available to us on a timely basis or on terms we believe are acceptable, we may be required to:

- delay, limit, reduce or terminate preclinical studies, clinical trials or other development activities for our product candidates;
- delay, limit, reduce or terminate our research and development activities; or
- delay, limit, reduce or terminate our efforts to establish manufacturing and sales and marketing capabilities or other activities that may be necessary to commercialize our product candidates, if approved, or reduce our flexibility in developing or maintaining our sales and marketing strategy.

We also could be required to seek funds through arrangements with collaborators or others that may require us to relinquish rights to some of our technologies or product candidates that we would otherwise pursue on our own. To date, we have primarily financed our operations through the sale of equity securities. We will be required to seek additional funding in the future and currently intend to do so through public or private equity offerings or debt financings, credit or loan facilities, collaborations or a combination of one or more of these funding sources. Our ability to raise additional funds will depend on financial, economic and other factors,

many of which are beyond our control. If additional funding is not available when we need it or on acceptable terms, our ability to grow and support our business and to respond to market challenges could be significantly limited, which could have a material adverse effect on our business, financial condition and results of operations.

Risks Related to the Research, Development and Approval of Our Product Candidates

Our business is heavily dependent on the successful development, regulatory approval and commercialization of our lead product candidate, ARD-101.

We currently have no products that are approved for commercial sale. Our lead product candidate, ARD-101, is an oral gut-restricted small-molecule agonist of certain TAS2Rs expressed in the gut lumen for which we have initiated a Phase 3 clinical trial for hyperphagia associated with PWS. In February 2026, we voluntarily paused enrollment and dosing in the HERO trial and the open label extension (OLE) trial based on reversible cardiac observations in a healthy volunteer study. We are conducting a comprehensive review of the data and collaborating with the FDA to determine next steps and expect to provide further guidance in the second quarter of 2026. The success of our business, including our ability to finance our company and generate revenue in the future, will primarily depend on the successful development, regulatory approval and commercialization of our lead product candidate. We cannot be certain that ARD-101 or any other current or future product candidates will receive regulatory approval or be successfully commercialized even if we receive regulatory approval.

We have not previously submitted an NDA to the FDA or any similar approval filing to a comparable foreign regulatory authority, for any product candidate. An NDA or other relevant regulatory filing must include extensive preclinical and clinical data and supporting information to establish that the product candidate is safe and effective for each desired indication. The NDA or other relevant regulatory filing must also include significant information regarding the chemistry, manufacturing and controls for the product. It may also necessitate a successful regulatory inspection of manufacturing facilities and/or clinical sites. We cannot be certain that our current or future product candidates will be successful in clinical trials. Further, even if they are successful in clinical trials, our current or future product candidates may not receive regulatory approval. If we do not receive regulatory approvals for current or future product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approval to market a product candidate, our revenue will depend, in part, upon the size of the markets in the territories for which we gain regulatory approval and have commercial rights, as well as the availability of competitive products, whether there is sufficient third-party reimbursement and adoption by physicians.

We plan to seek regulatory approval to commercialize our product candidates both in the United States and in select foreign countries. While the scope of regulatory approval generally is similar in other countries, in order to obtain separate regulatory approval in other countries, we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy. Other countries also have their own regulations governing, among other things, clinical trials and commercial sales, as well as pricing and distribution of drugs, and we may be required to expend significant resources to obtain regulatory approval and to comply with ongoing regulations in these jurisdictions.

Before we can generate any revenue from sales of our lead product candidate, ARD-101, or any other current or future product candidates, we must undergo additional preclinical and clinical development, regulatory review and approval in one or more jurisdictions. In addition, if one or more of our product candidates are approved, we must ensure access to sufficient commercial manufacturing capacity and conduct significant marketing efforts in connection with any commercial launch. These efforts will require substantial investment, and we may not have the financial resources to continue development of our product candidates. Our ability to generate product revenues, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of our product candidates. The success of our product candidates will depend on several factors, including the following:

- timely and successful completion of our preclinical studies and clinical trials, which may be significantly slower or more costly than we currently anticipate and will depend substantially upon the performance of third-party contractors;
- sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials;
- successful enrollment of subjects in, and completion of, our clinical trials;
- our ability to raise any additional required capital on acceptable terms, or at all;
- our ability to complete and maintain investigational new drug applications (INDs), IND-enabling studies and successfully submit INDs or comparable applications for our product candidates or any future product candidates;
- whether we are required by the FDA or comparable foreign regulatory authorities to conduct additional clinical trials or other studies beyond those planned to support the approval and commercialization of our product candidates or any future product candidates;

- acceptance of our proposed indications and primary endpoint assessments relating to the proposed indications of our product candidates by the FDA and comparable foreign regulatory authorities, including the use of non-invasive or other novel endpoint to initially obtain market authorization for our product candidates or any future product candidates;
- our ability to demonstrate to the satisfaction of the FDA and comparable foreign regulatory authorities the safety, efficacy and acceptable risk to benefit profile of our product candidates or any future product candidates;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements, which may negatively impact the supply chain or cause other disruptions;
- the prevalence, incidence, duration and severity of potential side effects or other safety issues or adverse events experienced with our product candidates or future approved products, if any;
- the timely receipt of necessary marketing approvals from the FDA and comparable foreign regulatory authorities;
- successful completion of required post-marketing approval commitments and requirements, if any, to the FDA and comparable foreign regulatory authorities;
- successful development of, or arrangements made with third party manufacturers, for our commercial manufacturing processes of any of our product candidates or future product candidates that receive regulatory approval;
- achieving and maintaining and, where applicable, ensuring that our third-party contractors achieve and maintain compliance with our contractual obligations and with all regulatory requirements applicable to our product candidates or any future product candidates or approved products, if any;
- the ability of third parties with whom we contract to manufacture adequate clinical trial and commercial supplies of our product candidates or any future product candidates to remain compliant and in good standing with regulatory agencies, develop, validate and maintain commercially viable manufacturing processes that comply with cGMPs;
- our ability to successfully develop a commercial strategy and thereafter commercialize our current or future product candidates in the United States and internationally, if approved for marketing, reimbursement, sale and distribution in such countries and territories, whether alone or in collaboration with others;
- our ability to achieve sufficient market acceptance, coverage and adequate reimbursement from third-party payors and adequate market share and revenue for any approved drugs;
- the convenience of our treatment or dosing regimen and the degree to which physicians can prescribe and patients are able to comply with the recommended treatment regimen;
- acceptance by physicians, payors and patients of the benefits, safety and efficacy of our product candidates or any future product candidates, if approved, including relative to alternative and competing treatments;
- the willingness of physicians, operators of clinics and patients to utilize or adopt any of our product candidates or any future product candidates, if approved;
- patient demand for our product candidates, if approved, including patients' willingness to pay out-of-pocket for any approved products in the absence of coverage and/or adequate reimbursement from third-party payors;
- effectively competing with other products;
- our ability to establish and enforce intellectual property rights in and to our product candidates or any future product candidates;
- our ability to avoid third-party patent interference, intellectual property challenges or intellectual property infringement claims; and
- our ability to build, train and maintain an organization of people who can successfully develop our product candidates.

These factors, many of which are beyond our control, could cause us to experience significant delays or an inability to obtain regulatory approvals or commercialize our product candidates. Even if regulatory approvals are obtained, we may never be able to successfully commercialize any of our product candidates. Accordingly, we cannot provide assurances that we will be able to generate sufficient revenue through the sale of our product candidates or any future product candidates, if approved, to continue our business or achieve profitability.

The regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable. If we are not able to obtain required regulatory approval for our product candidates, our business will be substantially harmed.

The time required to obtain approval or other marketing authorizations by the FDA and comparable foreign regulatory authorities is unpredictable, and it typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, policies, regulations, and the type and amount of clinical data that the regulatory authority views as necessary for approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate, and it is possible that we may never obtain regulatory approval for any product candidate we may seek to develop in the future. Neither we nor any current or future collaborator is permitted to market any product candidate in the United States until the product candidate receives regulatory approval from the FDA.

Prior to obtaining approval to commercialize any product candidate in the United States or abroad, we must demonstrate with sufficient evidence from adequate and well-controlled clinical trials, and to the satisfaction of the FDA or comparable foreign regulatory authorities, that such product candidates are safe and effective for their intended uses. Results from preclinical studies and clinical trials can be interpreted in different ways. Even if we believe the preclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA or comparable foreign regulatory authorities. Our approach is designed to target biological pathways associated with alleviating hunger, specifically by developing selective compounds targeting TAS2Rs, is unproven and may not result in marketable products. Although multiple studies are currently underway, to date, this mechanism has not been definitively proven to successfully treat hunger-associated conditions. Targeting TAS2Rs is a novel approach in a rapidly developing field, and there can be no assurance that we will not experience currently unknown problems or delays in developing our product candidates, that such problems or delays will not result in unanticipated costs, or that any such development problems can be solved. The FDA may also require us to conduct additional preclinical studies, clinical trials or other studies for our product candidates either prior to or after approval, or it may object to elements of our clinical development programs.

Of the large number of products in development globally, only a small percentage successfully complete the FDA or comparable foreign regulatory approval processes and are commercialized. The lengthy approval and marketing authorization process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval and marketing authorization to market our product candidates, which would adversely affect our business, financial condition, results of operations and prospects.

We have invested a significant portion of our time and financial resources in the development of our clinical and preclinical product candidates. Our business is dependent on our ability to successfully complete preclinical and clinical development of, obtain regulatory approval for, and, if approved, successfully commercialize, our current and future product candidates in a timely manner.

Even if we eventually complete clinical testing and receive approval or other marketing authorization from the FDA or comparable foreign regulatory authority, the FDA or the comparable foreign regulatory authority may grant approval or other marketing authorization contingent on the performance of costly additional clinical trials, including post-marketing clinical trials. The FDA or the comparable foreign regulatory authority also may approve or authorize for marketing a product candidate for a more limited indication or patient population than we originally propose, and the FDA or comparable foreign regulatory authority may not approve or authorize the labeling that we believe is necessary or desirable for the successful commercialization of a product candidate. Any delay in obtaining, or inability to obtain, applicable regulatory approval or other marketing authorization would delay or prevent commercialization of that product candidate and would materially and adversely impact our business and prospects.

In addition, the FDA and comparable foreign regulatory authorities may change their policies, issue additional regulations or revise existing regulations, or take other actions, which may prevent or delay approval of our future products under development on a timely basis. There remains substantial uncertainty as to how the current U.S. administration will seek or continue to modify or revise the requirements and policies of the FDA and other regulatory agencies with jurisdiction over our product candidates. State governments may also attempt to address or react to changes at the federal level with changes to their own regulatory frameworks in a manner that is adverse to our operations. This uncertainty could present new challenges or potential opportunities as we navigate the clinical development and approval process for our product candidates. Such policy or regulatory changes through, for example, executive orders or legislation could impose additional requirements upon us that could delay our ability to obtain approvals, increase the costs of compliance or restrict our ability to maintain any marketing authorizations we may have obtained.

Preclinical and clinical drug development involves a lengthy and expensive process, with uncertain timelines and outcomes, and results of earlier studies and trials may not be predictive of future trial results. If development of our product candidates is unsuccessful or delayed, we may be unable to obtain required regulatory approvals and we may be unable to commercialize our product candidates on a timely basis, if at all.

Our product candidates, including ARD-101, are still in clinical development and their risk of failure is high. To obtain the requisite regulatory approvals to commercialize any product candidates, we must demonstrate through extensive preclinical studies and lengthy, complex and expensive clinical trials that our product candidates are safe and effective in humans for the indications for which we intend to commercialize our product candidates. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure or delay can occur at any time during the preclinical or clinical trial process. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will generate the same results or otherwise provide adequate data to demonstrate the safety and effectiveness of a product candidate. Preclinical tests and Phase 1 and Phase 2 clinical trials are primarily designed to test safety, to study pharmacokinetics and pharmacodynamics and to understand the side effects of product candidates at various doses and regimens. Success in preclinical studies and early or Phase 2 clinical trials does not ensure that later large-scale efficacy trials will be successful nor does it predict final results. Our product candidates may fail to show the required safety and effectiveness through clinical trials despite positive results in preclinical studies or having successfully advanced through initial clinical trials, particularly because we are targeting novel pathways that have not yet been tested in later-stage clinical trials.

A number of companies in the pharmaceutical industry, including biotechnology companies, have suffered significant setbacks in clinical trials, even after receiving promising results in earlier non-clinical or clinical trials. These setbacks have been caused by, among other things, non-clinical findings made while clinical trials were underway and safety or efficacy observations made in clinical trials, including previously unreported adverse events. Product candidates in later stages of clinical trials may fail to show the desired safety and effectiveness traits despite having progressed through preclinical and earlier phase clinical trials. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many sponsors that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. Notwithstanding any potential promising results in earlier studies, we cannot be certain that we will not face similar setbacks. Even if our clinical trials are completed, the results may not be sufficient to obtain regulatory approval for our product candidates.

We may incur additional costs and experience delays in ongoing clinical trials for our product candidates, and we do not know whether future clinical trials, if any, will begin on time, need to be redesigned, enroll an adequate number of subjects on time or be completed on schedule, if at all. We may experience numerous unforeseen events during or as a result of clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including:

- regulators or institutional review boards (IRBs) and ethics committees (ECs) may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts for our clinical trial protocols with prospective trial sites or prospective CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical trials of our product candidates may produce negative or inconclusive results, including failure to demonstrate statistical significance, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- we may fail to demonstrate statistical significance in early stage or Phase 2 clinical trials of our product candidates, which may impact the timing and design of late-stage clinical trials for such product candidates;
- the number of subjects required for clinical trials of our product candidates may be larger than we anticipate, we may be required or determine it is appropriate to expand enrollment in clinical trials, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- our product candidates may have undesirable side effects, unforeseen adverse events, or other unexpected characteristics, causing us or our investigators, regulators or IRBs or ECs to suspend or terminate the trials. For example, in February 2026, we voluntarily paused enrollment and dosing in the Phase 3 HERO trial and the OLE trial for ARD-101, and the POWER and STRENGTH clinical trials for ARD-201, based on reversible cardiac observations in a healthy volunteer study of ARD-101;
- we or our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;

- regulators or IRBs and ECs may require that we or our investigators suspend or terminate clinical trials for various reasons, including non-compliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate; and
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs representing the institutions at which such trials are being conducted, by a data monitoring committee for such trial or by the FDA or comparable foreign regulatory authorities. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or comparable foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate candidate product benefit, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

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

If we experience delays in the completion of any clinical trial of our product candidates or terminate any such clinical trial, the commercial prospects of our product candidates may be harmed, and our ability to generate drug revenues from any of these product candidates will be delayed or not realized at all. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may adversely affect our business, operating results, prospects or financial condition. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

Certain disorders we seek to treat, such as PWS, have low prevalence and it may be difficult to identify and enroll patients with these disorders. If we encounter difficulties or delays enrolling subjects in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

We may not be able to initiate or continue our planned clinical trials for our product candidates if we are unable to identify and enroll a sufficient number of eligible subjects to participate in these trials. For example, we are developing ARD-101 for the treatment of hyperphagia associated with PWS. PWS is a rare disease with a limited patient pool from which to draw. In February 2026, we voluntarily paused enrollment and dosing in the HERO trial, the OLE trial, and the POWER and STRENGTH clinical trials for ARD-201 based on reversible cardiac observations in a healthy volunteer study of ARD-101. We are conducting a comprehensive review of the data and collaborating with the FDA to determine next steps and expect to provide further guidance in the second quarter of 2026. There can be no assurance that we will be able to resume enrollment or dosing in these trials on a timely basis, or at all, which could further delay our clinical development timelines. Moreover, there is no guarantee that, if and when we resume any clinical trials, we may encounter further delays or difficulties in resuming enrollment and/or dosing, including due to our announcement of having voluntarily paused our HERO and other clinical trials.

The timely completion of any clinical trial in accordance with its protocol depends, among other things, on our ability to enroll a sufficient number of subjects who remain in the study until its conclusion. We may experience difficulties in subject enrollment in our clinical trials for a variety of reasons. The enrollment of subjects depends on many factors, including:

- the subject eligibility criteria defined in the protocol;
- the size of the patient population required for analysis of the clinical trial's primary endpoints and the process for identifying subjects;
- the proximity of subjects to clinical sites;
- the design of the clinical trial;

- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- the existing body of safety and efficacy data for the product candidates;
- the availability of competing commercially available products and other competing product candidates' clinical trials;
- the efforts to facilitate timely enrollment in clinical trials;
- the ability to monitor subjects adequately during and after treatment;
- clinicians' and subjects' perceptions as to the potential risks and benefits of the product candidate being studied in relation to other available products, including any approved or new products that may be approved for the indications we are investigating;
- other factors outside of our control, such as the effects of global economic and geopolitical conditions;
- our ability to obtain and maintain patient informed consent;
- the risk that subjects enrolled in clinical trials will drop out of the trials before completion; and
- our ability to timely manufacture and supply clinical supplies for our product candidates.

Our Phase 3 HERO trial, evaluating the effect of ARD-101 on hyperphagia-related behavior in PWS, is currently limited to subjects 10 years of age and older after reaching alignment with the FDA in October 2025 on a protocol amendment to change the minimum age of eligibility to participate in the trial from 13 to 10 years of age or older. In December 2025, we submitted an additional protocol amendment seeking to further lower the minimum age of eligibility to participate in the trial to 7 years of age. However, certain factors may preclude us from receiving regulatory approval to treat younger pediatric subjects, including potential disagreements regarding appropriate dose and dose escalation, product presentation for possibly lower doses, validity of patient-reported outcomes in younger, actively growing patients, and avoiding inappropriate hunger suppression in these growing individuals. We can neither predict if the FDA or comparable foreign regulatory authorities will approve the use of our product candidates or programs in younger pediatric subjects, nor provide an estimate for the timing of such approval, if any. Furthermore, if the FDA or comparable foreign regulatory authorities do not approve the use of our product candidates or programs in this population, such product candidates or programs will not be labeled for use in these subjects. Given that the median lifespan of PWS patients is currently 30 years, the size of our market opportunity in this indication will be more limited if ARD-101 is not ultimately approved in pediatric patients and does not result in a significant increase in patient lifespan. Following the voluntary pause of the HERO trial in February 2026, we are reviewing the trial design and protocol in collaboration with the FDA and the previously agreed protocol elements may be revisited.

In addition, our clinical trials may compete for patients that are already taking existing products approved for the indications we are seeking to treat and also compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of subjects available to us, because some subjects who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Furthermore, if subjects drop out of our clinical trials, miss scheduled doses or follow-up visits, or otherwise fail to follow clinical trial protocols, the integrity of data from our clinical trials may be compromised or not accepted by the FDA or comparable foreign regulatory authorities, which would represent a significant setback for the applicable program. In addition, we may rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and we will have limited influence over their performance.

As a result, delays in subject enrollment or inability to identify and enroll a sufficient number of eligible subjects may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates.

Interim "topline" and preliminary results from our clinical trials and preclinical 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 publish interim topline or preliminary results from our preclinical studies and clinical trials, which are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following the availability of more data or following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, interim results from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or topline results also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data

should be viewed with caution until the final data are available. Differences between preliminary or interim data and final data could adversely affect our business prospects and may cause the trading price of our common stock to fluctuate significantly.

Further, others, including regulatory agencies, 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. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and investors 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 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, our product candidates may be harmed, which could adversely affect our business, operating results, prospects or financial condition.

Our clinical trials may fail to demonstrate safety and efficacy of our product candidates, or serious adverse events or side effects may be identified during the development of our product candidates, which could prevent or delay regulatory approval and commercialization, increase our costs or necessitate the abandonment or limitation of the development of some of our product candidates.

Unforeseen adverse events or undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. Before obtaining regulatory approvals for the commercial sale of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product candidates are safe and effective for use in each target indication, and failures can occur at any stage of testing. Clinical trials often fail to demonstrate safety or efficacy of the product candidate studied for the target indication. Our clinical trials of ARD-101 for the treatment of hyperphagia associated with PWS rely on measurement of reduction of hyperphagia behavior based on HQ-CT scores, which are typically caregiver reported questionnaires. Because these questionnaires rely on subjective caregiver feedback, responses can be influenced by factors outside of our control, and can vary widely from day to day for a particular patient/caregiver, and from patient to patient and site to site within a clinical trial.

If our product candidates are associated with adverse events in clinical trials or have side effects or other characteristics that are serious or unexpected, we may need to abandon their development or limit development to more narrow uses in which the adverse events, side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. We may also be required to modify our trial plans based on findings in our ongoing clinical trials. The FDA may also require that we conduct additional studies regarding the safety and efficacy of our product candidates which we have not planned or anticipated. Such findings could further result in regulatory authorities failing to provide marketing authorization for our product candidates or limiting the scope of the approved indication, if approved. Many product candidates that initially showed promise in early stage testing have later been found to cause side effects that prevented further development of such product candidates.

Treatment-related side effects could also affect subject recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. Furthermore, we may be required to expend time and incur costs to train medical personnel using our product candidates to understand the side effect profiles for our clinical trials and upon any commercialization of any of our product candidates. Any of these occurrences may adversely affect our business, operating results, prospects or financial condition. Moreover, if any serious side effects or other adverse events were to occur in any of our clinical programs, we could be subject to negative publicity and our company and reputation may be harmed.

Additionally, if one or more of our product candidates receives marketing approval, and we or others identify adverse events or undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- we may discontinue marketing of the product candidate, or decide to remove the product candidate from the marketplace, if approved;
- regulatory authorities may withdraw or change their approvals of that product candidate;
- regulatory authorities may require additional warnings on the label or limit access of that product candidate to selective specialized centers with additional safety reporting and with requirements that subjects be geographically close to these centers for all or part of their treatment;

- we may be required to send "dear doctor" letters to treatment providers or disseminate a medication guide outlining the risks of the product candidate for subjects, or to conduct post-marketing studies;
- we may be required to change the way the product candidate is administered;
- we may need to conduct a recall;
- 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;
- we may not be able to achieve or maintain third-party payor coverage and adequate reimbursement; and
- the product candidate may become less competitive, and our reputation and physician or patient acceptance of our products may suffer.

There can be no assurance that we will resolve any issues related to any product-related adverse events to the satisfaction of the FDA or comparable foreign regulatory authorities in a timely manner or at all. Moreover, any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could adversely affect our business, operating results, prospects or financial condition. For example, in February 2026, we voluntarily paused enrollment and dosing in the HERO trial following reversible cardiac observations identified in a healthy volunteer study of ARD-101. While these observations were not reported as serious adverse events and were not observed at the target therapeutic dose used in our clinical trials, they may nevertheless lead to additional regulatory scrutiny or changes to our development program.

As an organization, we have not previously conducted pivotal clinical trials, and we may be unable to do so successfully for any product candidates we may develop.

We will need to successfully complete pivotal clinical trials in order to obtain product approval from the FDA or comparable foreign regulatory authorities to market ARD-101 or any other current or future product candidate. Carrying out pivotal clinical trials is a complicated process. We initiated a Phase 3 HERO clinical trial in hyperphagia associated with PWS in December 2024. In February 2026, we voluntarily paused enrollment and dosing in the HERO trial based on reversible cardiac observations in a healthy volunteer study. We are conducting a comprehensive review of the data and collaborating with the FDA to determine next steps. If the FDA determines that additional nonclinical studies, dose modifications, enhanced monitoring or other protocol changes are required, our clinical development timelines could be significantly delayed. We no longer anticipate topline data from the HERO trial in the third quarter of 2026, and the timing of additional staffing and operational expansion may be delayed as we evaluate next steps following the voluntary pause of the HERO trial and related clinical programs. We expect to provide further guidance in the second quarter of 2026. Additionally, because ARD-201 contains ARD-101 as a component, we have also voluntarily paused the POWER and STRENGTH clinical trials for ARD-201. As an organization, we have not previously successfully conducted any later stage or pivotal clinical trials. In order to do so, we have expanded our clinical management and regulatory capabilities, including hiring clinical, regulatory and quality personnel, and we expect to potentially need to expand our clinical management and regulatory capabilities, but may be unable to recruit and train qualified personnel. We also expect to continue to rely on third parties to conduct our later stage or pivotal clinical trials. See the subsection titled "—Risks Related to Our Dependence on Third Parties—We have relied and expect to continue to rely on third parties to conduct our preclinical studies and clinical trials, as well as investigator-initiated trials. If those third parties do not perform as contractually required, fail to satisfy legal or regulatory requirements, miss expected deadlines or terminate the relationship, our development programs could be delayed, more costly or unsuccessful, and we may never be able to seek or obtain regulatory approval for or commercialize our product candidates." Consequently, we may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that leads to submission of an NDA and approval of ARD-101 or any other current or future product candidates. In addition, no product candidate can receive FDA approval unless clinical trials show both safety and efficacy for each target indication in accordance with FDA or foreign country standards. We plan to conduct a number of clinical trials for multiple product candidates in parallel over the next several years depending on the outcome of our ongoing evaluation of the voluntary pause of our HERO trial and related clinical programs. This may be a difficult process to manage with our limited resources and may divert the attention of management. 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 commercializing our product candidates, which could adversely affect our business, operating results, prospects or financial condition.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and management resources, we focus on development programs and product candidates that we identify for specific indications. As such, we are currently primarily focused on the development of ARD-101 for the treatment of hyperphagia associated with PWS. As a result, we may forgo or delay pursuit of opportunities with other product candidates or for

other indications for our product candidates that later prove to have greater commercial potential. Moreover, in February 2026, we voluntarily paused enrollment and dosing in the Phase 3 HERO trial and the OLE trial for ARD-101, and the POWER and STRENGTH clinical trials for ARD-201, based on reversible cardiac observations in a healthy volunteer study of ARD-101. We are conducting a comprehensive review of the data and collaborating with the FDA to determine next steps and expect to provide further guidance in the second quarter of 2026. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future development programs and product candidates for specific indications may not yield any commercially viable products. We must continually assess the potential commercial viability of our research programs and product candidates, and we may decide to pause, discontinue or deprioritize development of any of our product candidates based upon such assessments, even if we obtain positive data from our product candidates in preclinical studies and clinical trials. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

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

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the regulatory submission, preclinical studies, clinical trials, manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our drugs is also subject to approval.

Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our drugs in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed, which would adversely affect our business, prospects, financial condition and results of operations.

We are conducting and plan to conduct certain clinical trials for our product candidates outside the United States, and the FDA and comparable foreign regulatory authorities may not accept data from such trials.

We are conducting and plan to conduct certain clinical trials of ARD-101 outside the United States, including, but not limited to, in the United Kingdom, South Korea, Canada and Australia. 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. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence; and (iii) the data may be considered valid without the need for an on-site inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical power, must be met. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, we would need to conduct additional trials, which could be costly and time-consuming.

Even if we receive regulatory approval of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions on marketing or withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our product candidates, when and if any of them are approved.

Any product candidate for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, packaging, distribution, adverse event reporting, storage, recordkeeping, export, import, and advertising and

promotional activities for such product, among other things, will be subject to extensive and ongoing requirements of and review by the FDA and other comparable foreign regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, establishment registration and drug listing requirements, continued compliance with cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, product tracking and tracing requirements, requirements regarding the distribution of samples to physicians and recordkeeping and GCP requirements for any clinical trials that we conduct post-approval.

Even if we receive approval for our product candidates, they may be subject to limitations on the approved indicated uses for which the drug may be marketed or the conditions of approval, or contain requirements for potentially costly post-market testing and surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require us to adopt a Risk Evaluation and Mitigation Strategy (REMS) to ensure that the benefits of treatment with such product candidate outweigh the risks for each potential subject, which may include, among other things, a communication plan to health care practitioners, patient education, extensive subject monitoring or distribution systems and processes that are highly controlled, restrictive and more costly than what is typical for the industry. We or our collaborators may also be required to adopt a REMS or engage in similar actions, if we or others later identify undesirable side effects caused by any drug that we develop alone or with collaborators.

Later discovery of previously unknown problems with a product candidate, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things, the following actions by regulators:

- the FDA issuing warning letters or untitled letters;
- mandating modifications to promotional materials or requiring us to provide corrective information to healthcare practitioners, or requiring other restrictions on the labeling or marketing of such product;
- requiring us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for non-compliance;
- seeking an injunction or imposing civil or criminal penalties or monetary fines;
- being sued and held liable for harm caused to subjects or patients;
- suspending, withdrawing or modifying regulatory approval;
- suspending or modifying any ongoing clinical trials or requirement to conduct additional clinical trials;
- refusing to act on pending applications, supplements to applications or comparable foreign applications filed by us;
- suspending or imposing restrictions on operations, including costly new manufacturing requirements; or
- seizing or detaining products, refusing to permit the import or export of products or requiring us to initiate a product recall.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response, and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected.

Advertising and promotion of any product candidate that obtains approval in the United States will be heavily scrutinized by the FDA, the U.S. Federal Trade Commission (the FTC), the Department of Justice, the U.S. Department of Health and Human Services Office of Inspector General, state attorneys general, members of the U.S. Congress and the public. The FDA strictly regulates the promotional claims that may be made about drug products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. If we receive marketing approval for a product candidate, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability.

Additionally, advertising and promotion of any product candidate that obtains approval outside of the United States will be heavily scrutinized by comparable foreign entities and stakeholders. Violations, including actual or alleged promotion of our drugs for unapproved or off-label uses, are subject to enforcement letters, inquiries and investigations, and civil and criminal sanctions by the FDA or comparable foreign bodies. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The government has also required companies to enter into consent decrees and/or imposed permanent injunctions under which specified promotional conduct is changed or curtailed. Any actual or alleged failure to comply with labeling and promotion requirements may result in fines, warning letters, mandates to corrective information to healthcare practitioners, injunctions or civil or criminal penalties.

The FDA's and comparable foreign regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. For example, the U.S. Supreme Court's June 2024 decision in Loper Bright Enterprises v. Raimondo overturned the longstanding Chevron doctrine, under which courts were required to give deference to regulatory agencies' reasonable interpretations of ambiguous federal statutes. The Loper decision could result in additional legal challenges to regulations and guidance issues by federal agencies, including the FDA, on which we rely. Any such legal challenges, if successful, could have a material impact on our business. The Loper decision also may result in increased regulatory uncertainty, inconsistent judicial interpretations, and other impacts to the agency rulemaking process, any of which could adversely impact our business and operations. We 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 lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which could adversely affect business, operating results, prospects or financial condition.

Disruptions at the FDA, the SEC and other government agencies caused by funding shortages, government shutdowns or global health concerns could negatively impact our business operations, regulatory interactions and access to capital.

Significant disruptions to the operations of government agencies, including from prolonged or repeated shutdown of the federal government, could adversely affect our business, financial condition and results of operations. For example, on October 1, 2025, the U.S. government shut down for 43 days, during which time certain regulatory agencies, such as the FDA and the SEC, furloughed certain employees and stopped critical activities. On October 10, 2025, the U.S. government implemented substantial layoffs and workforce reductions in connection with the federal government shutdown, which resulted in the suspension or delay of various government-funded programs. The ability of the FDA to review and approve new products, to provide feedback on clinical trials and development programs, to meet with sponsors and to otherwise review regulatory submissions can be affected by a variety of factors, including government budget and funding levels, reductions in workforce, ability to hire and retain key personnel and accept the payment of user fees, substantial changes in leadership and shifting policy priorities as a result of changes in the presidential administration and its appointees tasked to oversee the agency, and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result and may continue in the future. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies, including as a result of reductions in force, significant organizational changes, substantial leadership departures, and policy changes, may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, the current U.S. administration has discussed several changes to the reach and oversight of the FDA, which could affect its relationship with the pharmaceutical industry, transparency in decision making and ultimately the cost and availability of prescription drugs. Additionally, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough certain employees and stop certain critical activities. The current U.S. administration also has taken steps to reduce the number of federal employees by establishing voluntary termination programs, by position eliminations or by involuntary terminations. If funding for the FDA is reduced, if the FDA workforce is reduced, or if government shutdowns reoccur, any of these factors could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Further, a future shutdown of the U.S. federal government could materially impact the operations of the SEC. For example, during the most recent U.S. federal government shutdown, the SEC announced that it would not declare registration statements effective. In the event of a future shutdown, the SEC may operate with limited staff or suspend certain functions altogether, which could delay the review or effectiveness of our filings, including registration statements or other financing-related disclosures. Such delays could adversely affect our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue to fund our operations.

In addition, future government shutdowns or funding freezes could negatively affect broader business operations and economic conditions and cause delays in or suspension of manufacturing facility and shipping operations, which could adversely affect our clinical trials and supply of product candidates. If these disruptions reoccur or worsen, our business, financial condition, results of operations and ability to execute our strategic plans could be materially and adversely affected.

The FDA or comparable foreign regulatory authorities may also face delays or resource constraints relating to foreign inspections, such as those that occurred during the COVID-19 pandemic. In response, such agencies may shift inspection priorities, may turn to remote regulatory assessments, or may issue other policies that could affect product approval timelines, which could have a material adverse effect on our business. A U.S. government shutdown or reduction in FDA funding or workforce may also affect inspection-related activities.

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

As product candidates proceed through preclinical studies to late-stage clinical trials towards regulatory application submission, potential approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize processes and product characteristics. Such changes carry the risk that they will not achieve their 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. Such changes may also require additional testing, FDA notification or FDA agreement. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commence sales and generate revenue.

We may not be successful in our efforts to identify or discover additional product candidates in the future.

Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for a number of reasons, including:

- our inability to design such product candidates with the pharmacological properties that we desire or attractive pharmacokinetics; or
- potential product candidates may, on further study, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be medicines that will receive marketing approval and achieve market acceptance.

Research programs to identify new product candidates require substantial technical, financial and human resources. If we are unable to identify suitable compounds for preclinical and clinical development, we will not be able obtain product revenue in future periods for such programs.

We have received Orphan Drug Designation and Rare Pediatric Disease Designation for ARD-101 for the treatment of PWS, and we may seek Orphan Drug Designation and/or Rare Pediatric Disease Designation for some or all of our other product candidates. However, we may not receive either such designation, and we may not be able to maintain Orphan Drug Designation or Rare Pediatric Disease Designation or obtain a Rare Pediatric Disease priority review voucher or orphan drug exclusivity for ARD-101, which could limit the potential profitability of our product candidates.

Regulatory authorities in some jurisdictions, including the United States, may designate drugs intended to treat relatively small patient populations as orphan drug products. Under the Orphan Drug Act, the FDA may designate a product candidate as an orphan drug if it is intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States.

In the United States, Orphan Drug Designation entitles a party to financial incentives such as opportunities for granting funding towards clinical trial costs, tax advantages and application fee waivers. If a drug or biologic with an Orphan Drug Designation subsequently receives marketing approval for the indication for which it has such designation, the product may be entitled to an expanded period of marketing exclusivity, which precludes the FDA from approving another marketing application for the same drug and indication for that time period, except in limited circumstances. The applicable period is seven years in the United States. An orphan drug benefiting pediatric patients can qualify as a drug for a Rare Pediatric Disease Designation as well. If so designated, the sponsor of the Rare Pediatric Disease designated product may be eligible for a rare pediatric disease priority review voucher, which would be issued in connection with FDA approval for the designated product. Under the Federal Food, Drug, and Cosmetic Act (the FDCA), a rare pediatric disease product application may be eligible for a rare pediatric disease priority review voucher if the drug receives marketing approval before September 30, 2029.

The FDA granted us an Orphan Drug Designation and a Rare Pediatric Disease Designation for the use of ARD-101 in PWS in August 2023, and we may also seek Orphan Drug Designation for some or all of our other product candidates. However, we may be unsuccessful in obtaining Orphan Drug Designation and/or Rare Pediatric Disease Designation for other product candidates, and we may be unable to obtain or maintain the benefits associated with Orphan Drug Designation or Rare Pediatric Disease Designation for ARD-101 or other product candidates for which we may receive such designations. The exclusivity granted under the Orphan Drug Designation may not effectively protect ARD-101 from competition because different drugs can be approved for the same condition, and orphan drug exclusivity does not prevent the FDA from approving the same or a different drug for another indication. The FDA may be able to subsequently approve a later application for the same drug for the same condition before the expiration of the seven-year exclusivity period if the FDA concludes that the later drug is clinically superior in that it is shown to be safer in a substantial portion of the target populations, more effective or makes a major contribution to patient care. In addition, a designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan

designation. Moreover, orphan-drug-exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to manufacture sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Neither Orphan Drug Designation nor Rare Pediatric Disease Designation shortens the development time or regulatory review time of a drug and does not give the drug any advantage in the regulatory review or approval process. Additionally, even if we obtain orphan drug designation for a product candidate, we may not be able to obtain orphan drug exclusivity for that product candidate. Similarly, we may not be able to obtain a rare pediatric disease priority review voucher for any product candidate for which we receive a Rare Pediatric Disease Designation, particularly if such product candidate does not receive marketing approval before September 30, 2029 and the program is not further extended.

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

We may apply for a Breakthrough Therapy designation for ARD-101 and any other current or future product candidates for one or more indications when we have placebo-controlled data and we believe that the clinical data may support such a designation for one or more product candidates. A Breakthrough Therapy is defined as a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition with unmet medical need, and preliminary clinical evidence indicates that the drug, or biologic, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For product candidates that have been designated as Breakthrough Therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs and biologics designated as Breakthrough Therapies by the FDA may also be eligible for rolling review (submissions of portions of an application before the complete marketing application is submitted) and priority review.

Designation as a Breakthrough Therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a Breakthrough Therapy, the FDA may disagree and determine not to make such designation. For example, we previously applied for Breakthrough Therapy designation for ARD-101 for the treatment of hyperphagia associated with PWS; however, the FDA noted that we would need to provide additional information in order to support such a Breakthrough Therapy designation. We may determine to submit a new request for Breakthrough Therapy designation for ARD-101 for the treatment of hyperphagia associated with PWS that includes the additional information requested by the FDA when available. However, there can be no assurances that the FDA would consider any such additional information to be sufficient or otherwise determine to grant a Breakthrough Therapy designation for ARD-101 for the treatment of hyperphagia associated with PWS. In any event, the receipt of a Breakthrough Therapy designation for a product candidate may not result in a faster development process, review or approval compared to drugs considered for approval under non-expedited FDA review procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as Breakthrough Therapies, the FDA may later decide that the product no longer meets the conditions for such qualification.

We may not be successful in pursuing or maintaining fast track or other expedited regulatory designations for our product candidates, and such designations may not actually lead to a faster development or regulatory approval process.

We may apply for fast track designation, priority review or accelerated approval status for ARD-101 or any other current or future product candidates. However, even if we receive fast track designation, priority review or accelerated approval status or other accelerated review designation for one or more of our product candidates, these designations do not assure that we will experience a faster development process, regulatory review or regulatory approval process compared to conventional FDA procedures. In addition, the FDA may withdraw a fast track, priority review, accelerated approval status or other accelerated review designation if it believes that the status or designation is no longer supported by data from our clinical development program. Additionally, qualification for any expedited review procedure does not ensure that we will ultimately obtain regulatory approval for such product candidate. Access to an expedited program may expedite the development or approval process, but it does not change the standards for approval.

Furthermore, although we may pursue additional opportunities to accelerate the development of certain of our product candidates through one or more of the FDA's expedited program designations, we cannot be assured that any of our product candidates will qualify for such programs. The FDA may determine that our proposed target indication or other aspects of our clinical development plans do not qualify for such expedited program.

Risks Related to Our Dependence on Third Parties

We have relied and expect to continue to rely on third parties to conduct our preclinical studies and clinical trials, as well as investigator-initiated trials. If those third parties do not perform as contractually required, fail to satisfy legal or regulatory requirements, miss expected deadlines or terminate the relationship, our development programs could be delayed, more costly or unsuccessful, and we may never be able to seek or obtain regulatory approval for or commercialize our product candidates.

We rely and intend to rely in the future on third-party clinical investigators, CROs, and clinical data management organizations to conduct, supervise and monitor preclinical studies and clinical trials of our current or future product candidates. In addition, third parties are conducting and we expect will continue to conduct investigator-initiated trials with our product candidates. Because we currently rely and intend to continue to rely on these third parties, we will have less control over the timing, quality and other aspects of preclinical studies and clinical trials than we would have had we conducted them independently. These parties are not, and will not be, our employees and we will have limited control over the amount of time and resources that they dedicate to our programs. Additionally, such parties may have contractual relationships with other entities, some of which may be our competitors, for whom they may also be conducting clinical trials or other drug development activities that could harm our competitive position.

Large-scale clinical trials require significant financial and management resources, and reliance on third-party clinical investigators, CROs, partners or consultants. Relying on third-party clinical investigators or CROs may force us to encounter delays and challenges that are outside of our control. We may not be able to demonstrate sufficient comparability between products manufactured at different facilities to allow for inclusion of the clinical results from participants treated with products from these different facilities, in our product registrations. Further, our third-party clinical manufacturers may not be able to manufacture our product candidates or otherwise fulfill their obligations to us because of interruptions to their business, including the loss of their key staff or interruptions to their raw material supply.

Our reliance on these third parties for development activities will reduce our control over these activities. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable trial protocol and legal, regulatory and scientific standards, and our reliance on the CROs, clinical trial sites, and other third parties does not relieve us of these responsibilities. For example, we will remain responsible for ensuring that each of our preclinical studies is conducted in accordance with GLPs, and clinical trials are conducted in accordance with GCPs. Moreover, the FDA and comparable foreign regulatory authorities require us to comply with GCPs for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Regulatory authorities enforce these requirements through periodic inspections (including pre-approval inspections once an NDA or biologics license application is submitted to the FDA) of trial sponsors, clinical investigators, trial sites and certain third parties including CROs. If we, our CROs, clinical trial sites, or other third parties fail to comply with applicable GCP or other regulatory requirements, we or they may be subject to enforcement or other legal actions, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials complies with GCP regulations. Moreover, our business may be significantly impacted if our CROs, clinical investigators or other third parties violate federal or state healthcare fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

In the event we need to repeat, extend, delay or terminate our clinical trials because these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, our clinical trials may need to be repeated, extended, delayed or terminated and we may not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates, and we will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates or we or they may be subject to regulatory enforcement actions. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed. To the extent we are unable to successfully identify and manage the performance of third-party service providers in the future, our business may be materially and adversely affected.

If any of our relationships with these third parties terminate, we may not be able to enter into alternative arrangements or do so on commercially reasonable terms. Switching or adding additional contractors involves additional cost and time and requires management's time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays could occur, which could compromise our ability to meet our desired development timelines. In addition, if an agreement with any of our collaborators terminates, our access to technology and intellectual property licensed to us by that collaborator may be restricted or terminate entirely, which may delay our continued development of our product candidates utilizing the collaborator’s technology or intellectual property or require us to stop development of those product candidates completely.

We also expect to rely on other third parties to store and distribute product supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our product candidates or commercialization of our products, producing additional losses and depriving us of potential revenue.

We rely completely on third parties to manufacture our clinical drug supplies and we intend to rely on third parties to produce commercial supplies of any approved product candidate, and our commercialization of any of our product candidates could be stopped, delayed or made less profitable if those third parties fail to obtain approval of the FDA or comparable regulatory authorities, fail to provide us with sufficient quantities of drug product or fail to do so at acceptable quality levels or prices.

We do not currently have nor do we plan to acquire the infrastructure or internal capability to manufacture our clinical drug supplies for use in the conduct of our clinical trials, and we lack the internal resources and the capability to manufacture any of our product candidates on a clinical or commercial scale. The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit our NDA to the FDA. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

Any replacement of our manufacturers could require significant effort and expertise because there may be a limited number of qualified replacements. In some cases, the technology required to manufacture our product candidates may be unique to the original manufacturer and we may have difficulty transferring such skills or technology to another third party. The process of changing manufacturers is extensive and time-consuming and could cause delays or interruptions in our product candidate supply. Further, if we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with all applicable regulations and guidelines, including cGMPs, and that the post-change material is comparable to pre-change. The delays associated with the verification of a new manufacturer could negatively affect our ability to develop product candidates in a timely manner or within budget.

We rely on our manufacturers to purchase from third-party suppliers the materials necessary to produce our product candidates for our clinical trials. There are a limited number of suppliers for raw materials that we use to manufacture our product candidates and there may be a need to assess alternate suppliers to prevent a possible disruption of the manufacture of the materials necessary to produce our product candidates for our clinical trials, and if approved, ultimately for commercial sale. We do not have control over the process or timing of the acquisition of these raw materials by our manufacturers. Moreover, we currently do not have any agreements for the commercial production of these raw materials. Although we generally do not begin a clinical trial unless we believe we have a sufficient supply of a product candidate to complete the clinical trial, any significant delay in the supply of a product candidate, or the raw material components thereof, for an ongoing clinical trial due to the need to replace a third-party manufacturer could considerably delay completion of our clinical trials, product testing and potential regulatory approval of our product candidates. If our manufacturers or we are unable to purchase these raw materials after regulatory approval has been obtained for our product candidates, the commercial launch of our product candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenues from the sale of our product candidates.

We, or our manufacturing partners, may be unable to successfully increase the manufacturing capacity for any of our product candidates in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up activities. If we or our manufacturing partners are unable to successfully scale up the manufacture of our product candidates in sufficient quality and quantity, the development, testing and clinical trials of that product candidate may be delayed or become infeasible, and marketing approval or commercial launch of any resulting product may be delayed or not obtained, which could adversely affect our business, operating results, prospects or financial condition.

We expect to continue to depend on third-party contract manufacturers for the foreseeable future. We have not entered into long-term agreements with our current contract manufacturers or with any alternate fill/finish suppliers, and though we intend to do so prior to commercial launch in order to ensure that we maintain adequate supplies of finished drug products, we may be unable to enter into such an agreement or do so on commercially reasonable terms, which could have a material adverse impact upon our business. Our product candidates, and any drugs that we may develop, may compete with other product candidates and drugs for access to manufacturing facilities. Qualifying and validating such manufacturers may take a significant period of time and reliance on third-party manufacturers 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 misappropriation of our proprietary information, including our trade secrets and know-how;
- the possible increase in costs for the raw materials for our product candidates; and
- the possible termination or nonrenewal of any agreement by any third party at a time that is costly or inconvenient for us.

Under recent legislation, certain third-party manufacturers and other third parties (frequently China-based companies) may be considered a "biotechnology company of concern." If a third-party manufacturer receives such a designation, it may restrict the ability of U.S. companies like us to purchase services or products from, collaborate with, or otherwise work with such manufacturers. For example, it may delay the procurement or supply of such material or have an adverse effect on our ability to secure significant commitments from governments to purchase our potential therapies. Such disruption could have adverse effects on the development of our product candidates.

Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supply of our products.

We have entered into collaborations with third parties for the development of certain potential product candidates, and we may seek additional collaborations in the future for the development and commercialization of these or other potential candidates. If our collaborations are not successful, our ability to develop and commercialize our product candidates could be adversely affected.

We currently have collaborations with third parties to develop certain of our potential product candidates, although none of these collaborations relate to ARD-101. In the future, we may seek collaboration arrangements for the commercialization, or potentially for the development, of other product candidates depending on the merits of retaining commercialization rights for ourselves as compared to entering into collaboration arrangements. For example, certain disease areas that we believe our product candidates address require large, costly and later-stage clinical trials, which a collaboration partner may be better positioned to finance and/or conduct.

If we enter into any additional such arrangements with any third parties, we will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenue from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements.

Collaborations involving our product candidates would pose the following risks to us:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or drugs, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- collaborators may seek to amend or modify the terms of any collaboration;
- collaborators may fail to comply with applicable regulatory requirements regarding the development, manufacture, distribution or marketing of a product candidate or product;
- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such products;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product

candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;

- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators may own or co-own intellectual property covering product candidates and other research that result from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property and may not be able to commercialize such intellectual property without their consent;
- collaborators may not properly maintain or defend our or their intellectual property rights or may use our or their proprietary information in such a way as to invite litigation that could jeopardize or invalidate such intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. If any future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program could be delayed, diminished or terminated.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for any 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 design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to subjects in our clinical trials, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

We may not be able to negotiate additional 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 such product candidate, 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. 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 revenue.

If conflicts arise between us and our collaborators or strategic partners, these parties may act in a manner adverse to us and could limit our ability to implement our strategies.

If conflicts arise between our collaborators or strategic partners and us, the other party may act in a manner adverse to us and could limit our ability to implement our strategies. Current or future collaborators or strategic partners may develop, either alone or with others, products in related fields that are competitive with the products or potential products that are the subject of these collaborations.

Our current or future collaborators or strategic partners may preclude us from entering into collaborations with their competitors, fail to obtain timely regulatory approvals, terminate their agreements with us prematurely or fail to devote sufficient resources to the development and commercialization of products. Furthermore, competing products, either developed by our current or future collaborators or strategic partners or to which our collaborators or strategic partners may have rights, may result in the withdrawal of partner support for our product candidates. Any of these developments could harm our product development efforts, which could adversely affect our business, operating results, prospects or financial condition.

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

Reliance on third parties to manufacture or commercialize our current or any future product candidates, and on collaborations with additional third parties for the development of our current or any future product candidates, requires us to share trade secrets with these third parties. We may also conduct joint research and development programs that may require us to share trade secrets under the terms of our research and development partnerships or similar agreements. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, services agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors 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, including our trade secrets. 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, are 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, a competitor's discovery of our trade secrets or other unauthorized use or disclosure could have an adverse effect on our business and results of operations.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any third-party collaborators. A competitor's discovery of our trade secrets could adversely affect our business, operating results, prospects or financial condition.

Confidentiality agreements with employees and third parties may not prevent unauthorized disclosure of trade secrets and other proprietary information.

In addition to the protection afforded by patents, we seek to rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce, and any other elements of our product candidates, technology and product discovery and development processes that involve proprietary know-how, information, or technology that is not covered by patents. Any disclosure, either intentional or unintentional, by our employees, the employees of third parties with whom we share our facilities or third-party consultants and vendors that we engage to perform research, clinical trials or manufacturing activities, or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market.

Trade secrets and confidential information, however, may be difficult to protect. We seek to protect our trade secrets, know-how and confidential information, including our proprietary processes, in part, by entering into confidentiality agreements with our employees, consultants, outside scientific advisors, contractors, and collaborators. With our consultants, contractors, and outside scientific collaborators, these agreements typically include invention assignment obligations. Despite these efforts, we cannot provide any assurances that all such agreements have been duly executed, and any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. In addition to contractual measures, we try to protect the confidential nature of our proprietary information using commonly accepted physical and technological security measures. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, outside scientific advisors, contractors, and collaborators might intentionally or inadvertently disclose our trade secret information, including to competitors. In addition, competitors or other third-parties may otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Despite our 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. Recourse we take against such misconduct may not provide an adequate remedy to fully protect our interests. 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. Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our product candidates that we consider proprietary. Trade secrets will over time be disseminated within the industry through independent development, the publication of journal articles and the movement of personnel skilled in the art from company to company or academic to industry scientific positions.

Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. 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, which could harm our competitive position.

Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property

both in the United States and abroad. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, or misappropriation of our intellectual property by third parties, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, operating results and financial condition.

The operations of our suppliers, some of which may source raw materials and other supplies outside of the United States, are subject to additional risks that are beyond our control and that could adversely affect our business, financial condition, results of operations and prospects.

Currently, some of our suppliers may source raw materials and other supplies outside of the United States. As a result, we may be subject to risks associated with doing business abroad, including:

- political unrest, terrorism, labor disputes, and economic instability resulting in the disruption of trade from foreign countries in which our products are manufactured;
- the imposition of new laws and regulations, including those relating to labor conditions, quality and safety standards, imports, duties, taxes, and other charges on imports, as well as trade restrictions and restrictions on currency exchange or the transfer of funds, particularly new or increased tariffs imposed on imports from countries where our suppliers operate;
- greater challenges and increased costs with enforcing and periodically auditing or reviewing our suppliers' and manufacturers' compliance with cGMPs or status acceptable to the FDA or comparable foreign regulatory authorities;
- reduced protection for intellectual property rights, including trademark protection, in some countries;
- disruptions in operations due to global, regional, or local public health crises or other emergencies or natural disasters;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements, which may negatively impact the supply chain or cause other disruptions;
- disruptions or delays in shipments; and
- changes in local economic conditions in countries where our manufacturers or suppliers are located.

These and other factors beyond our control could interrupt our suppliers' production, influence the ability of our suppliers to export our clinical supplies cost-effectively or at all, and inhibit our suppliers' ability to procure certain materials, any of which could adversely affect our business, operating results, prospects or financial condition.

Risks Related to Our Intellectual Property

If we are unable to obtain, maintain and enforce intellectual property protection directed to our current and any future technologies that we develop, others may be able to make, use or sell product candidates substantially the same as ours, which could adversely affect our ability to compete in the market.

The market for pharmaceuticals and biopharmaceuticals is highly competitive and subject to rapid technological change. Our success depends, in part, upon our ability to maintain a competitive position in the development and protection of technologies and any future product candidates for use in these fields and upon our ability to obtain, maintain and enforce our intellectual property rights. We seek to obtain and maintain patents and other intellectual property rights to restrict the ability of others to market products that misappropriate our technology and/or infringe our intellectual property to unfairly and illegally compete with any of our product candidates. Given the amount of time required for the development, testing and regulatory review of new planned products, patents protecting such products might expire before or shortly after such products are commercialized. If we are unable to protect our intellectual property and proprietary rights, our competitive position and our business could be harmed, as third parties may be able to make, use or sell products that are substantially the same as any product candidates we may sell without incurring the sizeable development and licensing costs that we have incurred, which would adversely affect our ability to compete in the market. We use a combination of patents, trademarks, know-how, confidentiality procedures and contractual provisions to protect our proprietary technology and that of our licensors. However, these protections may not be adequate and may not provide us with any competitive advantage. For example, patents may not issue from any of our or our licensors' currently pending or any future patent applications, and our or our licensors' issued patents and any future patents that may issue may not survive legal challenges to their scope, validity or enforceability or provide significant protection for us.

To protect our proprietary position, we file patent applications in the United States and abroad related to our product candidates that we consider important to our business. The patent application and approval process is expensive, time-consuming and complex. We may not be able to file, prosecute and maintain all necessary or desirable patent applications at a reasonable cost or in a timely manner or in all jurisdictions. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, depending on the terms of any future license or collaboration agreements to

which we may become a party, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology licensed from third parties. Therefore, these patents and patent applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

Furthermore, the patent position of biotechnology and pharmaceutical companies generally is highly uncertain. No consistent policy regarding the breadth of claims allowed in biotechnology and pharmaceutical patents has emerged to date in the United States or in many foreign jurisdictions. The standards applied by the USPTO and foreign patent offices in granting patents are not always applied uniformly or predictably. In addition, the determination of patent rights with respect to biological and pharmaceutical products commonly involves complex legal and factual questions, which have in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Thus, we cannot offer any assurances about which, if any, patents will issue, the breadth of any such patents, whether any issued patents will be found invalid and unenforceable or will be threatened by third parties or whether any issued patents will effectively prevent others from commercializing competing technologies and product candidates.

The USPTO, international patent offices or judicial bodies may deny or significantly narrow claims made under our patent applications, and our issued patents may be successfully challenged, may be designed around or may otherwise be of insufficient scope to provide us with protection for our drugs or combination therapies.

Further, the USPTO, international trademark offices or judicial bodies may deny our trademark applications and, even if published or registered, these trademarks may not effectively protect our brand and goodwill. Like patents, trademarks also may be successfully opposed or challenged.

We cannot be certain that the steps we have taken will prevent unauthorized use or unauthorized reverse engineering of our technology. Moreover, third parties may independently develop technologies that are competitive with ours and such competitive technologies may or may not infringe our intellectual property. The enforcement of our intellectual property rights also depends on the success of any legal actions we may take against these infringers in the respective country or forum, but these actions may not be successful. As with all granted intellectual property, such intellectual property may be challenged, invalidated or circumvented, may not provide protection and/or may not prove to be enforceable in actions against specific alleged infringers.

Even if our patents are determined by a court to be valid and enforceable, they may not be interpreted sufficiently broadly to prevent others from marketing products similar to ours or designing around our patents. For example, third parties may be able to make products that are similar to ours but that are not covered by the claims of our patents. Third parties may assert that we or our licensors were not the first to make the inventions covered by our issued patents or pending patent applications. The claims of our or our licensors' issued patents or patent applications when issued may not cover our product candidates or any future product candidates that we develop. We may not have freedom to commercialize unimpeded by the patent rights of others. Third parties may have patents that dominate, block or are otherwise relevant to our technology. In addition, there may be prior public disclosures or other art that could be deemed to invalidate one or more of our patent claims. We may not develop additional proprietary technologies in the future, and, if we do, they may not be patentable.

We may not be able to correctly estimate or control our future operating expenses in relation to obtaining intellectual property, enforcing intellectual property and/or defending intellectual property, which could affect operating expenses. Our operating expenses may fluctuate significantly in the future as a result of a variety of factors, including the costs of preparing, filing, prosecuting, defending and enforcing patent and trademark claims and other intellectual property-related costs, including adverse proceedings and litigation costs.

Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could have a negative impact on the success of our business.

Our commercial success depends, in part, upon our ability and the ability of our current or future collaborators to develop, manufacture, market and sell our current and any future product candidates and use our proprietary technologies without infringing the proprietary rights and intellectual property of third parties. The biotechnology and pharmaceutical industries are characterized by extensive and complex litigation regarding patents and other intellectual property rights. Because the intellectual property landscape in the industry in which we participate is rapidly evolving and interdisciplinary, it is difficult to conclusively assess our freedom to operate without infringing on third-party rights. U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields relating to our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that others may assert our product candidates infringe the patent rights of others. Moreover, it is not always clear to industry participants, including us, which patents cover various types of drugs, products or their methods of

use or manufacture. Thus, because of the large number of patents issued and patent applications filed in our fields, there may be a risk that third parties may allege they have patent rights encompassing our product candidates, technologies or methods.

Our product candidates and other proprietary technologies we may develop may infringe existing or future patents owned by third parties. We may in the future become party to, or be threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our current and any future product candidates and technologies, including interference or derivation, post-grant review (PGR) and inter partes review (IPR) proceedings before the USPTO. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of their merit. There is a risk that third parties may choose to engage in litigation with us to enforce or to otherwise assert their patent rights against us. Even if we believe such claims are without merit, a court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, which could have a negative impact on our ability to commercialize our current and any future product candidates. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, a court of competent jurisdiction may not invalidate the claims of any such U.S. patent. If we are found to infringe a third party's valid and enforceable intellectual property rights, we could be required to obtain a license from such third party to continue developing, manufacturing and marketing our product candidate(s) and technologies. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. We could be forced, including by court order, to cease developing, manufacturing and commercializing the infringing technologies or product candidate, or redesign our product candidates or processes so they do not infringe, which may not be possible or may require substantial monetary expenditures and time. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent or other intellectual property right. A finding of infringement could prevent us from manufacturing and commercializing our current or any future product candidates or force us to cease some or all of our business operations, which could adversely affect our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business, financial condition, results of operations and prospects.

Third parties asserting their patent or other intellectual property rights against us may also seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates or force us to cease some of our business operations. Defense of these 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, cause development delays, and may impact our reputation.

Many of our employees were employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees 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 employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer.

In addition, if our product candidates are found to infringe the intellectual property rights of third parties, these third parties may assert infringement claims against our licensees and other parties with whom we have business relationships, and we may be required to indemnify those parties for any damages they suffer as a result of these claims. The claims may require us to initiate or defend protracted and costly litigation on behalf of licensees and other parties regardless of the merits of these claims. If any of these claims succeed, we may be forced to pay damages on behalf of those parties or may be required to obtain licenses for the products they use.

Such litigation or proceedings could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

Additionally, during the course of any intellectual property litigation, there could be public announcements of the initiation of the litigation as well as results of hearings, rulings on motions and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our existing product candidates, programs or intellectual property could be diminished. Accordingly, the market price of our common stock may decline. Such announcements could also harm our reputation or the market for our future products, which could have a material adverse effect on our business.

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

We may be subject to claims that former employees, collaborators, or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. The failure to name the proper inventors on a patent application can result in the patents issuing thereon 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. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. Litigation may be necessary to defend against these and other claims challenging inventorship. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. 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 management and other employees.

We or our licensors may in the future rely on third-party consultants or collaborators or on funds from third parties, such as the U.S. government, such that we or our licensors are not the sole and exclusive owners of the patents we in-licensed. If other third parties have ownership rights or other rights to our patents, including in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

We may be subject to claims that we have wrongfully hired an employee from a competitor or that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets of their former employers.

As is common in the pharmaceutical and biotechnology industries, in addition to our employees, we engage the services of consultants to assist us in the development of our product candidates. Many of these consultants, and many of our employees, were previously employed at, or may have previously provided or may be currently providing consulting services to, universities or other pharmaceutical or biotechnology companies including our competitors or potential competitors. These employees and consultants may have executed proprietary rights, non-disclosure and non-competition agreements, or similar agreements, in connection with such other current or previous employment. Although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may become subject to claims that we, our employees or a consultant inadvertently or otherwise used or disclosed trade secrets or other information proprietary to their former employers or their former or current clients. 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, which could adversely affect our business. Such intellectual property could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or drugs and combination therapies. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team. Any of the foregoing would have a material adverse effect on our business, financial condition, results of operations and prospects.

We may be unsuccessful in licensing or acquiring intellectual property from third parties that may be required to develop and commercialize our current or future product candidates.

A third party may hold intellectual property, including patent rights that are important or necessary to the development and commercialization of our current or future product candidates. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our product candidates, in which case we would be required to acquire or obtain a license to such intellectual property from these third parties, and we may be unable to do so on commercially reasonable terms or at all. We may need to cease use of the compositions or methods covered by such third-party intellectual property rights, and may need to seek to develop alternative approaches that do not infringe on such intellectual property rights which may entail additional costs and expenses and development delays, even if we were able to develop such alternatives, which may not be feasible.

The licensing or acquisition of third-party intellectual property rights is a highly competitive area, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and 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. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or product candidate, which could have a material adverse effect on our business.

We license or otherwise have access to patent rights from third-party owners. Such licenses or other arrangements may be subject to early termination if we fail to comply with our obligations in our agreements with third parties, which could result in the loss of rights or technology that are material to our business.

We are and may become a party to licenses and other agreements that give us rights to third-party intellectual property that are necessary or valuable for our business, and we may enter into additional licenses or other agreements in the future. Under these agreements, we are or may be obligated to pay the counterparties' fees, which may include annual license fees, milestone payments, royalties, a percentage of revenues associated with the applicable technology and a percentage of sublicensing revenue. In addition, under certain of such agreements, we are or may be required to diligently pursue the development of products using the applicable technology. If we fail to comply with these obligations and fail to cure our breach within a specified period of time, the counterparty may have the right to terminate the applicable agreement. Termination of this agreement, or reduction or elimination of our rights under it or any other agreement, may result in our having to negotiate new or reinstated arrangements on less favorable terms, or our not having sufficient intellectual property rights to operate our business. The occurrence of such events could adversely affect our business, operating results, prospects or financial condition.

We may rely on third parties from whom we license proprietary technology to file and prosecute patent applications and maintain patents and otherwise protect the intellectual property we license from them. We may have limited control over these activities or any other intellectual property that may be related to our in-licensed intellectual property. For example, we cannot be certain that such activities by these licensors will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. We may have limited control over the manner in which our licensors initiate an infringement proceeding against a third-party infringer of the intellectual property rights, or defend certain of the intellectual property that may be licensed to us. It is possible that the licensors' infringement proceeding or defense activities may be less vigorous than if we conduct them ourselves.

The risks described elsewhere pertaining to our intellectual property rights also apply to any intellectual property rights that we may license, and any failure by us or any future licensor to obtain, maintain, defend and enforce these rights could have a material adverse effect on our business.

Our intellectual property agreements with third parties may be subject to disagreements over contract interpretation, which could narrow the scope of our rights to the relevant intellectual property or technology or increase our financial or other obligations to our licensors.

Certain provisions in our intellectual property agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could affect the scope of our rights to the relevant intellectual property or technology, or affect financial or other obligations under the relevant agreement, any of which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Our intellectual property licensed from third parties may be subject to retained rights.

Our future licensors may retain certain rights under their agreements with us, including the right to use the underlying technology for non-commercial academic and research use, to publish general scientific findings from research related to the technology, and to make customary scientific and scholarly disclosures of information relating to the technology. It is difficult to monitor whether our licensors limit their use of the technology to these uses, and we could incur substantial expenses to enforce our rights to our licensed technology in the event of misuse.

Government agencies may provide funding, facilities, personnel or other assistance in connection with the development of the intellectual property rights owned by or licensed to us. Such government agencies may have retained rights in such intellectual property. The U.S. federal government retains certain rights in inventions produced with its financial assistance under the Patent and Trademark Law Amendments Act (the Bayh-Dole Act); these include the right to grant or require us to grant mandatory licenses or sublicenses to such intellectual property to third parties under certain specified circumstances, including if it is necessary to meet health and safety needs that we are not reasonably satisfying or if it is necessary to meet requirements for public use specified by federal regulations, or to manufacture products in the United States. Any exercise of such rights, including with respect to any such required sublicense of these licenses could result in the loss of significant rights and could harm our ability to commercialize licensed products. While it is our policy to avoid engaging our university partners in projects in which there is a risk that federal funds may be commingled, we cannot be sure that any co-developed intellectual property will be free from government rights pursuant to the Bayh-Dole Act. If, in the future, we co-own or license in technology which is critical to our business that is developed in whole or in part with federal funds subject to the Bayh-Dole Act, our ability to enforce or otherwise exploit patents covering such technology may be adversely affected.

If the scope of any patent protection we obtain is not sufficiently broad, or if we lose any of our patent protection, our ability to prevent our competitors from commercializing similar or identical product candidates would be adversely affected.

The patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation, resulting in court decisions, including U.S. Supreme Court decisions, that have increased uncertainties as to the ability to enforce patent rights in the future. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States, or vice versa.

Further, we may not be aware of all third-party intellectual property rights potentially relating to our research programs and product candidates, or their intended uses, and as a result the potential impact of such third-party intellectual property rights upon the patentability of our own patents and patent applications, as well as the potential impact of such third-party intellectual property upon our freedom to operate, is highly uncertain. While we are not aware of third-party patents and patent filings that would block commercialization of our product candidates, we have not conducted a freedom-to-operate search or analysis for any of our current product candidates, and we may not be aware of patents or pending or future patent applications that, if issued, would block us from commercializing our product candidates. Thus, we cannot guarantee that our current product candidates, or our commercialization thereof, do not and will not infringe any third party's intellectual property. Because patent applications are maintained as confidential for a certain period of time (for example, 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), until the relevant application is published, we may be unaware of third-party patents that may be infringed by commercialization of any of our product candidates, and we cannot be certain that we were the first to file a patent application related to a product candidate or technology. Moreover, because patent applications can take many years to issue, there may be currently-pending patent applications that may later result in issued patents that our product candidates may infringe. There is also no assurance that there is not prior art of which we are aware, but which we do not believe is relevant to our business, which may, nonetheless, ultimately be found to limit our ability to make, use, sell, offer for sale or import our products that may be approved in the future, or impair our competitive position. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. We have pending U.S. and foreign patent applications in our portfolio; however, we cannot predict:

- if and when patents may issue based on our patent applications;
- the scope of protection of any patent issuing based on our patent applications;
- whether the claims of any patent issuing based on our patent applications will provide protection against competitors;
- whether or not third parties will find ways to invalidate or circumvent our patent rights;
- whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications;
- whether we will need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose;
- whether the patent applications that we own or in-license will result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries; and/or
- whether we may experience patent office interruption or delays to our ability to timely secure patent coverage to our product candidates.

Our patents or pending patent applications may be challenged in the courts or patent offices in the United States and other foreign jurisdictions. For example, we may be subject to a third-party pre-issuance submission of prior art to the USPTO or become involved in PGR procedures, derivations, reexaminations, or inter parties review proceedings, in the United States or oppositions or similar proceedings in foreign jurisdictions, challenging our patent rights. The legal threshold for initiating such proceedings may be low, so that even proceedings with a low probability of success might be initiated. An adverse determination in any such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated, or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products.

Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. In addition, we may rely on more than one patent to provide multiple layers of patent protection for our product candidates. If the latest-expiring patent is invalidated or held unenforceable, in whole or in part, the overall protection for the product candidate may be adversely affected. For example, if the latest-expiring patent is invalidated, the overall patent term for our product candidate could be adversely affected.

As a result, only limited protection may be available, and our patent portfolio may not provide us with sufficient rights or permit us to gain or keep any competitive advantage. Any failure to obtain or maintain patent protection with respect to our product candidates or their uses could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time-consuming, and unsuccessful. Further, our issued patents could be found invalid or unenforceable if challenged in court.

Competitors may infringe our intellectual property rights or those of our licensors. To prevent infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in a patent infringement proceeding, a court may decide that one or more patent of ours or any of our current licensors or future licensors is not valid or is unenforceable, in whole or in part, or may refuse to stop the other party from using the technology at issue on the grounds that our or our licensors' patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our or our licensors' patents at risk of being invalidated or interpreted narrowly, which may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products, and could put our or our licensors' patent applications at risk of not issuing. If we or any of our potential future collaborators were to initiate legal proceedings against a third party to enforce a patent directed at our products, the defendant could counterclaim that our or our licensors' patent is invalid and/or unenforceable in whole or in part. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could also include an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution.

If a defendant were to prevail on a legal assertion of invalidity or unenforceability of our or our licensors' patents covering one of our product candidates, we could lose a part, and perhaps all, of the patent protection covering such candidate. Competing products may also be sold in other countries in which our patent coverage might not exist or be as strong. If we lose a foreign patent lawsuit, alleging our infringement of a competitor's patents, we could be prevented from marketing our products in one or more foreign countries. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock.

We may not be able to prevent, alone or with our potential licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms or at all, or if a non-exclusive license is offered and our competitors gain access to the same technology. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties or enter into development or manufacturing partnerships that would help us bring our products to market.

Because of the expense and uncertainty of litigation, we may not be in a position to enforce our intellectual property rights against third parties.

Because of the expense and uncertainty of litigation, we may conclude that even if a third-party is infringing our issued patent, any patents that may be issued as a result of our pending or future patent applications or other intellectual property rights, the risk-adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of our company or our stockholders, or it may be otherwise impractical or undesirable to enforce our intellectual property against some third parties. Our competitors or other third parties may be able to sustain the costs of complex patent litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution. In addition, the uncertainties associated with litigation could compromise our ability to raise the funds necessary to continue

our clinical trials, continue our internal research programs, in-license needed technologies or other product candidates, or enter into development partnerships that would help us bring our product candidates to market.

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

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and/or applications. We employ reputable professionals and rely on such third parties to help us comply with these requirements and effect payment of these fees with respect to the patents and patent applications that we own, and we may have to rely upon our licensors to comply with these requirements and effect payment of these fees with respect to any patents and patent applications that we license. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which non-compliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to use our technologies and this circumstance would have a material adverse effect on our business.

Patent terms may be inadequate to establish our competitive position on our product candidates for an adequate amount of time. If we do not obtain patent term extension for our product candidates, our business may be materially harmed.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Patent terms may be shortened or lengthened by, for example, terminal disclaimers, patent term adjustments, supplemental protection certificates and patent term extensions, but the life of a patent, and the protection it affords, is limited. Non-payment or delay in payment of patent fees, maintenance fees or annuities, delay in patent filings or delay in extension filings (including any patent term extension or adjustment filings), whether intentional or unintentional, may result in the loss of patent rights important to our business. Even if patents covering our product candidates are obtained, once the patent life has expired for a product candidate, we may be open to competition from competitive medications, including generic versions. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents directed towards such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing product candidates similar or identical to ours for a meaningful amount of time, or at all.

Depending upon the timing, duration and conditions of any FDA marketing approval of our product candidates, one or more of our owned or licensed U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act) and similar legislation in the EU and certain other jurisdictions. The Hatch-Waxman Act permits, in certain cases, a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. However, we may not receive an extension if we fail to exercise due diligence during the testing phase or regulatory review process, fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. Only one patent per approved product can be extended, the extension cannot extend the total patent term beyond 14 years from approval and the amount of available extension to any extension-eligible patent which claims a product, a method of using a product or a method of manufacturing a product, depends on a variety of factors, including the date on which the patent issues and certain dates related to the regulatory review period. 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 can enforce our patent rights for the applicable product candidate will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and non-clinical data and launch their product earlier than might otherwise be the case, and our competitive position, business, financial condition, results of operations and prospects could be materially harmed.

We expect to receive five years of new chemical entity exclusivity under the Hatch-Waxman Act; however, because the denatonium active moiety is off-patent, a third party could obtain NDA approval for a denatonium drug prior to our NDA approval. In this case, we would not receive five years of exclusivity.

Further, there are detailed rules and requirements regarding the patents that may be submitted to the FDA for listing in the Orange Book. We may be unable to obtain patents covering our product candidates that contain one or more claims that satisfy the requirements for listing in the Orange Book. Even if we submit a patent for listing in the Orange Book, the FDA may decline to list

the patent, or a manufacturer of generic drugs may challenge the listing. If one of our product candidates is approved and a patent covering that product candidate is not listed in the Orange Book, a manufacturer of generic drugs would not have to provide advance notice to us of any abbreviated new drug application filed with the FDA to obtain permission to sell a generic version of such product candidate. Any of the foregoing could harm our competitive position, business, financial condition, results of operations and prospects.

Changes in patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining, defending, maintaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time-consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents, and may diminish our ability to protect our inventions, obtain, maintain, enforce and protect our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our future owned and licensed patents. Patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act (the AIA), could increase those uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our future issued patents. The AIA includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, re-define prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, PGR, IPR and derivation proceedings.

In addition, the patent positions of companies in the development and commercialization of pharmaceuticals are particularly uncertain. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our or our licensors' ability to obtain new patents and patents that we or our licensors might obtain in the future. We cannot predict how future decisions by the courts, the U.S. Congress or the USPTO may impact the value of our patents. Any similar adverse change in the patent laws of other jurisdictions could also adversely affect our business, financial condition, results of operations and prospects.

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 licensed or that we may obtain in the future. For example, the complexity and uncertainty of European patent laws have also increased in recent years. In Europe, in June 2023, a new unitary patent system was introduced. Under the unitary patent system, after a European patent is granted, the patent proprietor can request unitary effect, thereby getting a European patent with unitary effect (the Unitary Patent). Each Unitary Patent is subject to the jurisdiction of the Unitary Patent Court (the UPC). As the UPC is a relatively new court system, there is little precedent for the court, increasing the uncertainty of any litigation. Patents granted before the implementation of the UPC will have the option of opting out of the jurisdiction of the UPC and remaining as national patents in the UPC countries. Patents that remain under the jurisdiction of the UPC may be potentially vulnerable to a single UPC-based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. We cannot predict with certainty the long-term effects of the unitary patent system.

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 current or future trademarks or trade names may be challenged, infringed, circumvented, declared generic or descriptive, or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. During trademark registration proceedings, we may receive rejections. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected. We may license our trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names.

Moreover, any name we have proposed to use with our 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 a comparable foreign regulatory authority objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. If we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

We may enjoy only limited geographical protection with respect to certain patents and we may not be able to protect our intellectual property rights throughout the world.

Filing and prosecuting patent applications and defending patents covering our product candidates in all countries throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement rights are not as strong as that in the United States or Europe. These products may compete with our product candidates, and our future patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

In addition, we may decide to abandon national and regional patent applications before they are granted. The examination of each national or regional patent application is an independent proceeding. As a result, patent applications in the same family may issue as patents in some jurisdictions, such as in the United States, but may issue as patents with claims of different scope or may even be refused in other jurisdictions. It is also quite common that depending on the country, the scope of patent protection may vary for the same product candidate or technology.

While we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our product candidates. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate, which may have an adverse effect on our ability to successfully commercialize our product candidates in all of our expected significant foreign markets. If we encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished, and we may face additional competition from others in those jurisdictions.

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

Some countries also have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors. In those countries, the patent owner may have limited remedies, which could materially diminish the value of such patents. 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.

Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that

we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

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

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 product candidates that are similar to ours but that are not covered by the claims of the patents that we own or have exclusively licensed;
- we or our licensors or future collaborators might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own or have exclusively licensed;
- we or our licensors or future collaborators might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our owned or licensed pending patent applications will not lead to issued patents;
- issued patents that we own or have exclusively licensed may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- we cannot predict the scope of protection of any patent issuing based on our owned or licensed patent applications, including whether the patent applications that we own or in-license will result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries;
- the claims of any patent issuing based on our owned or licensed patent applications may not provide protection against competitors or any competitive advantages, or may be challenged by third parties;
- if enforced, a court may not hold that our owned or licensed patents are valid, enforceable and infringed;
- we may need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose;
- we may be required to coordinate with licensors on enforcement of our patents;
- we may choose not to file a patent application in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent application and secure an issued patent covering such intellectual property; and
- the patents of others may have an adverse effect on our business, including if others obtain patents claiming subject matter similar to or improving that covered by our patents and patent applications.

Should any of these events occur, they could adversely affect our business, operating results, prospects or financial condition.

Risks Related to Legal and Regulatory Compliance Matters

Our relationships with customers, physicians, and third-party payors may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, other healthcare laws and regulations and health data privacy and security laws and regulations, contractual obligations and self-regulatory schemes. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Healthcare providers, physicians and third-party payors in the United States and elsewhere play a primary role in the recommendation and prescription of pharmaceutical products. Our current and future arrangements with healthcare providers, third-party payors and customers can expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, which may constrain the business or financial arrangements and relationships through which we research and, if approved, sell, market and distribute our products. In particular, the research of our product candidates, as well as the promotion, sales, marketing and business

arrangements of our product candidates, is subject to extensive laws designed to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials, which could result in regulatory sanctions and serious harm to our reputation. The applicable federal, state and foreign healthcare laws and regulations laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation 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 the Medicare and Medicaid programs. A person or entity can be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. The federal Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other;
- the federal civil and criminal false claims laws, including the federal False Claims Act, or FCA, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment to, or approval by, Medicare, Medicaid, or other federal healthcare programs, knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim or an obligation to pay or transmit money to the federal government, or knowingly and improperly avoiding or decreasing or concealing an obligation to pay money to the federal government. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government healthcare programs if they are deemed to "cause" the submission of false or fraudulent claims. In addition, 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 FCA. The FCA also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery;
- the Health Insurance Portability and Accountability Act of 1996 (HIPAA), which created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private), and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating the healthcare fraud statute under HIPAA without actual knowledge of the statute or specific intent to violate it;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH), and its implementing regulations, mandates, among other things, the adoption of uniform standards for the electronic exchange of information in common healthcare transactions, as well as standards relating to the privacy and security of protected health information (PHI), including individually identifiable health information, as defined under HIPAA, which require the adoption of administrative, physical and technical safeguards to protect such information. Among other things, HITECH makes HIPAA's security standards directly applicable to business associates, defined as independent contractors or agents of covered entities, which include certain health care providers, health plans and healthcare clearinghouses, that create, receive or obtain protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities and business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, certain state laws govern the privacy and security of health information and other personal data in certain circumstances, some of which are more stringent or otherwise different than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and criminal penalties;
- the federal Physician Payments Sunshine Act and its implementing regulations, which require some manufacturers of drugs, devices, biologicals 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 U.S. Department of Health and Human Services, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician practitioners (such as physician assistants and nurse practitioners), and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and may be broader in scope than their federal equivalents; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and local laws that require the registration of pharmaceutical sales representatives.

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

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. Federal, state and foreign enforcement bodies regularly scrutinize interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions, significant fines and penalties and settlements in the healthcare industry. Ensuring that business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and may divert our management's attention from the operation of our business.

It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant penalties, including, without limitation, civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participating in federal and state funded healthcare programs, such as Medicare and Medicaid, 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, contractual damages, diminished profits and future earnings, reputational harm and the curtailment or restructuring of our operations, any of which could adversely affect our business, operating results, prospects or financial condition.

The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and/or reporting requirements increase the possibility that a healthcare company may run afoul of one or more of the requirements.

Recently enacted legislation, future legislation and other healthcare reform measures may increase the difficulty and cost for us to obtain marketing approval for and commercialize our product candidates and may 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 product candidates for which we obtain marketing 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 March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, (collectively, the ACA), was enacted in the United States, which substantially changed the way healthcare is financed by both governmental and private insurers in the United States and significantly affected the pharmaceutical industry. The ACA, among other things, subjected biologic products to potential competition by lower-cost biosimilars, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program (the MDRP) are calculated for drugs and biologics that are inhaled, infused, instilled, implanted or injected, increased the minimum Medicaid rebates owed by manufacturers under the MDRP, extended manufacturer Medicaid rebate obligations to utilization by individuals enrolled in Medicaid managed care organizations, established annual fees and taxes on manufacturers of certain branded prescription drugs and biologics, and established a new Medicare Part D coverage gap discount program. Since its enactment, there have been judicial, congressional, and executive branch challenges to the ACA, which have resulted in delays in the implementation of, and action taken to repeal or

replace, certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress.

In addition, there have been a number of health reform initiatives that have impacted the ACA. For example, on August 16, 2022, the Inflation Reduction Act (the IRA) became law, which, among other things, extended enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminated the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and through a newly established manufacturer discount program. In addition, the IRA imposes new manufacturer financial liability on certain drugs under Medicare Part D, allowing the U.S. government to negotiate Medicare Part B and Part D price caps for certain high-cost drugs and biologics without generic or biosimilar competition, subject to certain exemptions applicable to orphan drugs. It is possible that the ACA will be subject to judicial or congressional challenges or legislative modifications in the future. It is unclear how such challenges or modifications, and the healthcare reform measures of the current administration, will impact the ACA and our business.

For example, on November 27, 2024, the Biden administration issued a proposed rule entitled *Medicare and Medicaid Programs; Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly.* The Centers for Medicare & Medicaid Services (CMS) proposed that anti-obesity medications (AOMs), when used for weight loss or chronic weight management for the treatment of obesity, would no longer be excluded from Part D coverage. The aforementioned proposal would also apply to the Medicaid program. The Trump Administration did not finalize the proposal; however, we cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action.

Other legislative changes have been proposed and adopted since the ACA was enacted. For example, on August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, resulted in reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013, and, due to subsequent legislative amendments to the statute, will remain in effect through 2032 unless additional Congressional action is taken. In certain countries outside the United States, reimbursement for products that have not yet received marketing authorization may be provided through national managed access programs.

On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of march-in rights, which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain whether that will continue under the new framework. It is unclear whether or how much such rights may be exercised.

There has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. presidential executive orders, congressional inquiries, and proposed and enacted legislation designed, among other things, to bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for pharmaceutical products. The IRA, among other things, (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. On August 15, 2024, HHS announced the agreed-upon reimbursement prices of the first ten drugs that were subject to price negotiations. The prices of these ten drugs became effective January 1, 2026. On January 17, 2025, HHS announced its selection of 15 additional drugs covered by Part D for the second cycle of negotiations by February 1, 2025. Weight loss drugs, including Ozempic, Rybelsus, and Wegovy, were chosen for the drug price negotiation. Negotiated prices for this second set of drugs will be effective starting January 1, 2027. Each year thereafter more Part B and Part D products will become subject to the Medicare Drug Price Negotiation Program.

The Trump Administration has stated that lowering the cost of prescription drugs for Americans is a top priority and it will continue to pursue drug price negotiations. There may be a significant impact on reimbursement for particular Part D drugs, including AOMs. We cannot predict how this might change or how any changes might impact our business.

Several pharmaceutical companies, as well as the U.S. Chamber of Commerce, and the Pharmaceutical Research and Manufacturers of America have filed lawsuits against HHS and CMS, asserting that, among other things, the IRA's drug price negotiation program for Medicare constitutes an uncompensated taking in violation of the Fifth Amendment of the U.S. Constitution and is otherwise unlawful. HHS has generally won the substantive disputes in these cases, and several federal district court judges have expressed skepticism regarding the merits of the legal arguments being pursued by the pharmaceutical industry. HHS has generally continued to win the substantive disputes in appeals, although certain cases continue to seek appellate review.

We expect that the ACA, the IRA, and any other healthcare reform measures that may be adopted in the future may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, 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. 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 current Trump administration is pursuing policies to reduce regulations and expenditures across government including at HHS, the FDA, CMS and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. These actions and proposals may, for example, include directives: (1) reducing agency workforce and cutting programs; (2) rescinding a Biden administration executive order tasking the Center for Medicare and Medicaid Innovation, or CMNI, to consider new payment and healthcare models to limit drug spending; (3) eliminating the Biden administration's executive order that directed HHS to establishing an AI task force and developing a strategic plan; (4) directing HHS and other agencies to lower prescription drug costs through a variety of initiatives, including by improving upon the Medicare Drug Price Negotiation Program and establishing Most-Favored-Nation pricing for pharmaceutical products; (5) imposing tariffs on imported pharmaceutical products; and (6) directing certain federal agencies to enforce existing law regarding hospital and plan price transparency and by standardizing prices across hospitals and health plans. Congress may introduce and ultimately pass health care related legislation that could impact the drug approval process and make changes to the Medicare Drug Price Negotiation Program created under the IRA. This could lower the price that we receive for any approved product. Any denial in coverage or reduction in reimbursement from Medicare or other government-funded programs may result in a similar denial or reduction in payments from private payors, which may prevent us from being able to generate sufficient revenue, attain profitability or commercialize our product candidates, if approved. Furthermore, on July 4, 2025, legislation commonly referred to as the One Big Beautiful Bill Act was signed into law, which reduced funding to federal healthcare programs and imposed additional requirements to be eligible for healthcare, which may result in decreased access to healthcare, particularly in Medicaid programs.

Further, changes in regulatory requirements and guidance may occur and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for re-examination, which may impact the costs, timing or successful completion of a clinical trial. In light of widely publicized events concerning the safety risk of certain drug products, regulatory authorities, members of Congress, the Governmental Accounting Office, medical professionals and the general public have raised concerns about potential drug safety issues. These events have resulted in the recall and withdrawal of drug products, revisions to drug labeling that further limit use of the drug products and establishment of risk management programs that may, for instance, restrict distribution of drug products or require safety surveillance or patient education. The increased attention to drug safety issues may result in a more cautious approach by the FDA to clinical trials and the drug approval process. Data from clinical trials may receive greater scrutiny with respect to safety, which may make the FDA or comparable foreign regulatory authorities more likely to terminate or suspend clinical trials before completion or require longer or additional clinical trials that may result in substantial additional expense and a delay or failure in obtaining approval or approval for a more limited indication than originally sought.

Changing regulatory environments could negatively impact our business.

Third-party payors, whether domestic or foreign, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product for which we obtain marketing approval.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products. Such reforms could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates.

Many European Economic Area (EEA) Member States periodically review their reimbursement procedures for medicinal products, which could have an adverse impact on reimbursement status. We expect that legislators, policymakers and healthcare insurance funds in the EEA Member States will continue to propose and implement cost-containing measures, such as lower maximum prices, lower or lack of reimbursement coverage and incentives to use cheaper, usually generic, products as an alternative to branded products, and/or branded products available through parallel import to keep healthcare costs down. Moreover, in order to obtain reimbursement for our products in some European countries, including some EEA Member States, we may be required to

compile additional data comparing the cost-effectiveness of our products to other available therapies. Health Technology Assessment (HTA) of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EEA Member States, including those representing the larger markets. The HTA process is the procedure to assess the therapeutic, economic and societal impact of a given medicinal product in the national healthcare systems of the individual country. The outcome of an HTA will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EEA Member States. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product currently varies between EU Member States.

In December 2021, Regulation No. 2021/2282 on HTA, amending Directive 2011/24/EU, was adopted in the European Union. This Regulation, which entered into force in January 2022 and went into effect in January 2025, is intended to boost cooperation among EEA Member States in assessing health technologies, including new medicinal products, and providing the basis for cooperation at European Union level for joint clinical assessments in these areas. The Regulation permits EEA Member States to use common HTA tools, methodologies, and procedures across the European Union, working together in four main areas, including joint clinical assessment of the innovative health technologies with the most 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 EEA Member States will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technologies, and making decisions on pricing and reimbursement. If we are unable to maintain favorable pricing and reimbursement status in EEA Member States for product candidates that we may successfully develop and for which we may obtain regulatory approval, any anticipated revenue from and growth prospects for those products in the European Union could be negatively affected.

Legislators, policymakers and healthcare insurance funds in the European Union may continue to propose and implement cost-containing measures to keep healthcare costs down. These measures could include limitations on the prices we would be able to charge for product candidates that we may successfully develop and for which we may obtain regulatory approval or the level of reimbursement available for these products from governmental authorities or third-party payors. Further, an increasing number of European Union and other foreign countries use prices for medicinal products established in other countries as "reference prices" to help determine the price of the product in their own territory. Consequently, a downward trend in prices of medicinal products in some countries could contribute to similar downward trends elsewhere.

We are subject to certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations. We can face serious consequences for violations.

Among other matters, U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations, which are collectively referred to as Trade Laws, prohibit companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors, and other partners from authorizing, promising, offering, providing, soliciting, or receiving, directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. We have direct or indirect interactions with officials and employees of government authorities or government-affiliated hospitals, universities, and other organizations.

We have engaged and will continue to engage third parties for clinical trials and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals, and we can be held liable for the corrupt or other illegal activities of our personnel, agents, or partners, even if we do not explicitly authorize or have prior knowledge of such activities. If we further expand our operations outside of the United States, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The Foreign Corrupt Practices Act (the FCPA), prohibits any U.S. individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate and other related parties for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

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

If our procedures and controls to monitor anti-bribery compliance fail to protect us from reckless or criminal acts committed by our employees or agents or if we, or our employees, agents, contractors or other collaborators, fail to comply with applicable anti-bribery laws, our reputation could be harmed and we could incur criminal or civil penalties, other sanctions and/or significant expenses, which could have a material adverse effect on our business, including our financial condition, results of operations, cash flows and prospects. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. Our products may be subject to U.S. and foreign export controls, trade sanctions and import laws and regulations. Governmental regulation of the import or export of our products, or our failure to obtain any required import or export authorization for our products, when applicable, could harm our international or domestic sales and adversely affect our revenue. Compliance with applicable regulatory requirements regarding the export of our products may create delays in the introduction of our products in international markets or, in some cases, prevent the export of our products to some countries altogether. Furthermore, U.S. export control laws and economic sanctions prohibit the shipment of certain products and services to countries, governments and persons targeted by U.S. 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. Moreover, any new export or import restrictions, new legislation or shifting approaches in the enforcement or scope of existing regulations, or in the countries, persons or products targeted by such regulations, could result in decreased use of our products by, or in our decreased ability to export our products to, existing or potential customers with international operations. Any decreased use of our products or limitation on our ability to export or sell our products would likely adversely affect our business. If we expand our presence outside of the United States, it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our research and development costs.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We, and the third parties with whom we share our facilities, are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Each of our operations involves the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Each of our operations also produces hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. We could be held liable for any resulting damages in the event of contamination or injury resulting from the use of hazardous materials by us or the third parties with whom we share our facilities, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

We cannot guarantee that the safety procedures utilized by our third-party manufacturers and CROs for handling and disposing of these materials comply with the standards prescribed by these laws and regulations, nor can we eliminate the risk of accidental contamination or injury from these materials. Under certain environmental laws, we could be held responsible for costs relating to any contamination at our current or past facilities and at third-party facilities. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources, and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance.

Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our research and product development efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from hazardous materials or wastes. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not 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. Accordingly, in the event of contamination or injury, 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, which could have a material adverse effect on our business, results of operations and financial condition.

Even if we commercialize any product candidates, alone or with our partners, any such product may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which could adversely affect our business.

In some countries, 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 candidate. 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 coverage and reimbursement have been obtained. Reference pricing used by various countries and parallel distribution or arbitrage between low-priced and high-priced countries, can further reduce prices. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available products, which is time-consuming and costly. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay or limit our commercial launch of the product, possibly for lengthy time periods, which could negatively impact the revenue we generate from the sale of the product in that particular country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing approval. If coverage and reimbursement of our product candidates are unavailable or limited in scope or amount, our business could be materially harmed.

Risks Related to the Operation of Our Business

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

Prior to the completion of our IPO, we were a private company with limited accounting personnel to adequately execute our accounting processes and limited supervisory resources with which to address our internal control over financial reporting. In connection with the preparation of our consolidated financial statements for the year ended December 31, 2024, a material weakness was identified in the design and operating effectiveness of our internal control over financial reporting. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim consolidated financial statements will not be prevented or detected on a timely basis.

As of December 31, 2025, we have remediated the previously identified material weakness in our internal control over financial reporting. See Part II, Item 9A, "Item 9A. Controls and Procedures", of this Annual Report for additional detail. However, our internal control over financial reporting may not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected. If we identify additional material weaknesses or deficiencies in internal controls in the future and we are unable to correct them in a timely manner, our ability to record, process, summarize and report financial information accurately and within the time periods specified in the rules and forms of the SEC, will be adversely affected. Any such failure could negatively affect the market price and trading liquidity of our common stock, lead to delisting, cause investors to lose confidence in our reported financial information, subject us to civil and criminal investigations and penalties, and generally materially and adversely impact our business and financial condition.

If, in the future, we identify material weaknesses in our internal controls over financial reporting or fail to meet the demands that are placed upon us as a public company, including the requirements of the Sarbanes-Oxley Act, we may be unable to accurately report our financial results or report them within the timeframes required by law or stock exchange regulations. Failure to comply with Section 404 of the Sarbanes-Oxley Act could also potentially subject us to sanctions or investigations by the SEC or other regulatory authorities. If additional material weaknesses exist or are discovered in the future, and we are unable to remediate any such material weakness, our business, financial condition and results of operations could suffer.

Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on our senior management team. The employment agreements we have with these officers do not prevent such persons from terminating their employment with us at any time. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives. In addition, we will need to attract, retain and motivate highly qualified additional medical, scientific, technical, commercial, business, regulatory and administrative personnel. If we are not able to retain our management and to attract, on terms acceptable to us, additional qualified personnel necessary for the continued development of our business, we may not be able to sustain our operations or grow.

We may not be able to attract or retain qualified personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses. Many of the other pharmaceutical companies that we compete against for qualified personnel and consultants have greater financial and other resources, different risk profiles and a longer operating history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates and consultants than what we have to offer. If we are unable to attract, retain and motivate high-quality personnel and consultants to accomplish our business objectives, the rate and success at which we can discover and develop product candidates and our business will be limited and we may experience constraints on our development objectives. Additionally, we do not currently maintain "key person" life insurance on the lives of our executives or any of our employees.

Our future performance will also depend, in part, on our ability to successfully integrate newly hired executive officers into our management team and our ability to develop an effective working relationship among senior management. Our failure to integrate these individuals and create effective working relationships among them and other members of management could result in inefficiencies in the development and commercialization of our product candidates, harming future marketing approvals, sales of our product candidates and our results of operations.

There is a scarcity of experienced professionals in our industry. If we are not able to retain and recruit personnel with the requisite technical skills, we may be unable to successfully execute our business strategy.

The specialized nature of our industry results in an inherent scarcity of experienced personnel in the field. Our future success depends upon our ability to attract and retain highly skilled personnel (including medical, scientific, technical, commercial, business, regulatory and administrative personnel) necessary to support our anticipated growth and develop our business. Given the scarcity of professionals with the scientific knowledge that we require and the competition for qualified personnel among biotechnology businesses, we may not succeed in attracting or retaining the personnel we require to continue and grow our operations. 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.

We have in the past acquired, and may in the future acquire other assets, businesses or form joint ventures or make investments in other companies or technologies that could harm our operating results, dilute our stockholders' ownership, increase our debt or cause us to incur significant expense.

As part of our business strategy, we may pursue acquisitions of assets or licenses of assets, including preclinical, clinical or commercial stage products or product candidates, businesses, strategic alliances, joint ventures and collaborations, to expand our existing technologies and operations.

Any potential acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness, contractual obligations or contingent liabilities;
- the issuance of our equity securities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party, their regulatory compliance status, and their existing products or product candidates and marketing approvals; and
- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

In the future, we may not be able to find suitable partners or acquisition candidates, and we may not be able to complete such transactions on favorable terms, if at all. If we make any acquisitions, we may not be able to integrate these acquisitions successfully into our existing business, and we could assume unknown or contingent liabilities. Any future acquisitions also could result in the

incurrence of debt, contingent liabilities or future write-offs of intangible assets or goodwill, any of which could have a negative impact on our cash flows, financial condition and results of operations. Integration of an acquired company also may disrupt ongoing operations and require management resources that we would otherwise focus on developing our existing business. We may experience losses related to investments in other companies, which could harm our financial condition and results of operations. We may not identify or complete these transactions in a timely manner, on a cost-effective basis or at all, and we may not realize the anticipated benefits of any acquisition, license, strategic alliance or joint venture.

To finance such a transaction, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant amortization expense. If the price of our common stock is low or volatile, we may not be able to acquire other companies or fund a joint venture project using our stock as consideration. Alternatively, it may be necessary for us to raise additional funds for these activities through public or private financings or through the issuance of debt. Additional funds may not be available on terms that are favorable to us, or at all, and any debt financing may involve covenants limiting or restricting our ability to take certain actions.

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

As of February 28, 2026, we had 40 employees and 39 full-time or part-time consultants. As our development progresses, we expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of clinical development, product development and manufacturing, regulatory affairs, quality assurance and, if any of our product candidates receives marketing approval, sales, marketing and distribution. To manage our anticipated future growth, we must:

- manage our preclinical studies and clinical trials effectively;
- identify, recruit, retain, incentivize and integrate additional employees, including additional clinical, manufacturing, regulatory, quality assurance, scientific development and sales personnel;
- manage our development efforts effectively, including the initiation and conduct of clinical trials for our product candidates; and
- improve our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to develop, manufacture and commercialize our product candidates, if approved, will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert financial and other resources, and a disproportionate amount of its attention away from day-to-day activities, to managing these growth activities. 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 ARD-101 or any other potential future product candidates that may receive regulatory approval in key territories. These efforts will require substantial additional resources.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services, including contract manufacturers and companies focused on research and development and discovery activities. There can be no assurance that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality, accuracy or quantity of the services provided is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain, or may be substantially delayed in obtaining, regulatory approval of our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize ARD-101 or any other product candidates and, accordingly, may not achieve our research, development and commercialization goals.

We may acquire additional technology and complementary businesses in the future. Acquisitions involve many risks, any of which could materially harm our business, including the diversion of management's attention from core business concerns, failure to effectively exploit acquired technologies, failure to successfully integrate the acquired business or realize expected synergies or the loss of key employees from either our business or the acquired businesses.

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our research, development and commercialization goals.

Our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, suppliers and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, suppliers and vendors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates FDA regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA, manufacturing standards, federal and state healthcare laws and regulations, and laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct by these parties could also involve the improper use of individually identifiable information, including, without limitation, information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, including, without limitation, damages, fines, disgorgement, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, 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 the curtailment or restructuring of our operations.

We enter into various contracts in the normal course of our business in which we indemnify the other party to the contract. In the event we have to perform under these indemnification provisions, it could have a material adverse effect on our business, financial condition and results of operations.

In the normal course of business, we periodically enter into commercial, service, collaboration, licensing, consulting and other agreements that contain indemnification provisions. For example, we have entered into agreements in which we agreed to indemnify an institution and related parties from any losses that may arise from claims relating to alleged infringement of intellectual property rights held by a third party and in which we agreed to indemnify a counterparty from third-party claims arising from the death of, injury to, or damage to property of any person resulting from the research, development or use of applicable rights or products under the agreement.

Should our obligation under an indemnification provision in any of our agreements exceed applicable insurance coverage or if we are denied insurance coverage, our business, financial condition and results of operations could be adversely affected. Similarly, if we are relying on a collaborator to indemnify us and the collaborator is denied insurance coverage or the indemnification obligation exceeds the applicable insurance coverage, and if the collaborator does not have other assets available to indemnify us, our business, financial condition and results of operations could be adversely affected.

Our ability to use our net operating loss (NOL) carryforwards and certain other tax attributes to offset taxable income or taxes may be limited.

We have incurred substantial losses during our history and do not expect to become profitable in the near future, and we may never achieve profitability. As of December 31, 2025, we had federal NOL carryforwards of $79.3 million and state NOL carryforwards of $96.5 million. Under the Internal Revenue Code of 1986, as amended (the Code), our U.S. federal NOLs will not expire and may be carried forward indefinitely but the deductibility of U.S. federal NOLs is limited to no more than 80% of current year taxable income (with certain adjustments), and the state loss carryforwards begin expiring in 2037 unless previously utilized. In addition, under Sections 382 and 383 of the Code, if a corporation undergoes an "ownership change," generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three-year period, the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. We have not completed a Section 382 study to assess whether an ownership change has occurred or whether there have been multiple ownership changes since our formation due to the complexity and cost associated with such a study; however, we have raised funds several times in recent years, increasing the likelihood there have been changes in ownership that would limit our ability to utilize tax attribute carryforwards. Furthermore, there may be additional ownership changes in the future or as a result of subsequent

changes in our stock ownership, some of which may be outside of our control. As a result, if we undergo an ownership change, and our ability to use our pre-change NOL carryforwards and other pre-change tax attributes (such as research tax credits) to offset our post-change income or taxes is limited, such an ownership change would harm our future results of operations by effectively increasing our future tax obligations. In addition, there is a risk that due to changes under the tax law, regulatory changes or other unforeseen reasons, our existing NOLs and other tax attributes could expire or otherwise be unavailable to offset future income tax liabilities. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, even if we attain profitability, we may be unable to use all or a material portion of our NOLs and other tax attributes, which could adversely affect our future cash flows. We have recorded a full valuation allowance related to our NOLs and other deferred tax assets due to the uncertainty of the ultimate realization of the future benefits of those assets.

Our operations are concentrated in one location, and we or the third parties upon whom we depend may be adversely affected by a wildfire and earthquake or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our current operations are predominantly located in California. Any unplanned event, such as a flood, wildfire, explosion, earthquake, extreme weather condition, epidemic or pandemic, power outage, telecommunications failure or other natural or manmade accidents or incidents that result in us being unable to fully utilize our facilities may have a material and adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Any similar impacts of natural or manmade disasters on our third-party CMOs and CROs, could cause delays in our clinical trials and may have a material and adverse effect on our ability to operate our business and have significant negative consequences on our financial and operating conditions. If a natural disaster, power outage or other event occurred that prevented us from using our clinical sites, impacted clinical supply or the conduct of our clinical trials, that damaged critical infrastructure, such as the manufacturing facilities of our third-party CMOs, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we and our CMOs and CROs have in place may prove inadequate in the event of a serious disaster or similar event. In the event of an accident or incident at these facilities, we cannot assure you that the amounts of insurance we currently carry will be sufficient to satisfy any damages and losses. If our facilities, or the manufacturing facilities of our CMOs or CROs, are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our development programs may be harmed. Any business interruption could adversely affect our business, financial condition, results of operations and prospects.

International expansion of our business will expose us to business, regulatory, political, operational, financial and economic risks associated with doing business outside of the United States.

Our business strategy contemplates international expansion, including partnering with distributors, and introducing our current products and other planned products outside the United States. Doing business internationally involves a number of risks, including:

- multiple, conflicting and changing laws and regulations such as tax laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses;
- potential failure by us or our distributors to obtain regulatory approvals for the sale or use of our current products and our planned future products in various countries;
- difficulties in managing foreign operations;
- complexities associated with managing government payer systems, multiple payer-reimbursement regimes or self-pay systems;
- logistics and regulations associated with shipping products, including infrastructure conditions and transportation delays;
- limits on our ability to penetrate international markets if our distributors do not execute successfully;
- financial risks, such as longer payment cycles, difficulties enforcing contracts and collecting accounts receivable, and exposure to foreign currency exchange rate fluctuations;
- reduced protection for intellectual property rights, or lack of them in certain jurisdictions, forcing more reliance on our trade secrets, if available;
- natural disasters, political and economic instability, including wars, terrorism and political unrest, including the outbreak of hostilities in Ukraine and the Middle East and potential destabilization in Venezuela, outbreak of disease, boycotts, curtailment of trade and other business restrictions; and

- failure to comply with the FCPA, including its books and records provisions and its anti-bribery provisions, by failing to maintain accurate information and control over sales activities and distributors' activities.

Any of these risks, if encountered, could significantly harm our future international expansion and operations and consequently, have a material adverse effect on our business, financial condition, results of operations and prospects.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the testing of our current and future product candidates in clinical trials and may face an even greater risk if we commercialize any product candidate that we may develop. For example, we may be sued if any drug we develop allegedly causes injury or is found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and breach of warranty. If we cannot successfully defend ourselves against claims that any such product candidates caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates that we may develop;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- a diversion of management's time and our resources;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant time and costs to defend the related litigation;
- substantial monetary awards paid to trial participants, subjects or patients;
- initiation of investigations by regulators;
- loss of revenue;
- a decline in our stock price; and
- the inability to commercialize any products that we may develop.

Although we maintain product liability insurance coverage, such insurance may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of our product candidates. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. Although we will maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies will also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

Significant disruptions of our information technology systems or data security incidents could result in significant financial, legal, regulatory, business and reputational harm to us.

We are increasingly dependent on information technology systems and infrastructure, including mobile and third-party, cloud-based technologies, to operate our business. In the ordinary course of our business, we may collect, store, process and transmit large amounts of sensitive information, including intellectual property, proprietary business information, and other confidential information. It is important that we do so in a secure manner to maintain the confidentiality, integrity and availability of such sensitive information. We have also outsourced elements of our operations (including elements of our information technology infrastructure) to third parties, and as a result, we manage a number of third-party vendors who may or could have access to our computer networks or our sensitive information. In addition, many of those third parties in turn subcontract or outsource some of their responsibilities to third parties. While all information technology operations are inherently vulnerable to inadvertent or intentional security breaches, incidents, attacks and exposures, the accessibility and distributed nature of our information technology systems, and the sensitive information stored on or transmitted between those systems, make such systems potentially vulnerable to unintentional or malicious, internal and external exploits of our technology environment. In addition, we may face increased risks of a security breach or disruption due to our reliance

on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities.

Cyber incidents are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by organized groups and individuals with a wide range of motives (including, but not limited to, industrial espionage) and expertise, including organized criminal groups, "hacktivists," nation states and others. In addition to the extraction of sensitive information, such attacks could include the deployment of harmful malware, ransomware, supply chain attacks, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information. Data security incidents and other inappropriate access can also be difficult to detect, and any delay in identifying them may lead to increased harm. In addition, the prevalent use of mobile devices increases the risk of data security incidents.

Significant disruptions of, or cyber incidents directed at, our or our third-party vendors' and/or business partners' information technology systems could adversely affect our business operations and/or result in the loss, misappropriation, and/or unauthorized access, use or disclosure of, or the prevention of access to, sensitive information, which could result in a variety of adverse effects, including financial, legal, regulatory, business and reputational harm to us. In addition, information technology system disruptions, whether from attacks on our technology environment or from computer viruses, natural disasters, terrorism, war and telecommunication and electrical failures, could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our marketing approval efforts and significantly increase our costs to recover or reproduce the data. Additionally, theft of our intellectual property or proprietary business information could require substantial expenditures to remedy. If we or our third-party collaborators, consultants, contractors, suppliers, vendors or service providers were to suffer an actual or likely attack or breach, for example, that involves the unauthorized access to or use or disclosure of personal or health information, we may have to notify consumers, partners, collaborators, government authorities, and the media, and may be subject to investigations, civil penalties, administrative and enforcement actions (including mandatory corrective action or requirements to verify the correctness of database contents), and consuming, distracting and expensive litigation, any of which could result in increased costs to us, and result in significant legal and financial exposure, or other harm to our business and reputation.

While we have no reason to believe that we have been subject to any material system failure, accident or security breach to date, we have experienced cybersecurity incidents in the past and expect that we will experience cybersecurity incidents in the future. In addition, attackers have become very sophisticated in the way they conceal access to systems, and many companies that have been attacked are not aware that they have been attacked. We may also experience security breaches 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. While we have implemented security measures intended to protect our information technology systems and infrastructure, such measures may not successfully prevent service interruptions or security incidents.

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. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

Failure to comply with data privacy and security laws, regulations and other obligations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation, negative publicity, and/or other adverse consequences that could negatively affect our operating results and business.

We and our partners and vendors may be subject to federal and state privacy and data protection laws and regulations as well as international laws that impose broad compliance obligations on the collection, possession, use, storage, access, disclosure, transfer, deletion and protection of personal data. In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws and regulations that govern the collection, use, disclosure, and protection of health-related and other personal data, could apply to our operations or the operations of our partners. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA. Depending on the facts and circumstances, we could be subject to penalties if we violate HIPAA. HIPAA mandates the adoption of uniform standards for the electronic exchange of information in common healthcare transactions, as well as standards relating to the privacy and security of individually identifiable health information, which require the adoption of administrative, physical and technical safeguards to protect such information. Depending on the facts and circumstances, we could be subject to criminal penalties if we knowingly obtain, use or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA. Requirements for compliance under HIPAA are also subject to change, as the U.S. Department of Health and

Human Services Office of Civil Rights issued a proposed rule that would amend certain security compliance requirements for covered entities and business associates.

Even when HIPAA does not apply, according to the FTC, failing to take appropriate steps to keep consumers' personal data secure may constitute unfair acts or practices in or affecting commerce in violation of the FTC Act. The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of personal data it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards. Additionally, the FTC Health Breach Notification Rule applies to health apps and other similar technologies and expanded breach notification requirements, which adds complexity to compliance obligations. Further, the SEC implemented rules around incident reporting, requiring cybersecurity incidents to be reported 4 business days after determining that an incident is material.

The U.S. Department of Justice issued a final rule entitled, "Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons," codified at 28 CFR part 202, or the Bulk Transfer Rule. The Bulk Transfer Rule prohibits and restricts bulk transfers of sensitive personal data (including genetic and health data) to countries of concern, such as China, Russia, and Iran to prevent access by foreign adversaries. It restricts our ability to engage in certain cross-border transactions involving genomic or biological samples and related data, which may increase compliance costs, lead to increased regulatory scrutiny or liability, and may require additional contractual negotiations, which may adversely impact our business, financial condition, and operating results.

Certain state laws govern the privacy and security of health-related and other personal information in certain circumstances, some of which may be more stringent, broader in scope or offer greater individual rights with respect to protected health information than HIPAA, many of which may differ from each other, 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. For example, the California Consumer Privacy Act (CCPA), revised and amended by the California Privacy Rights Act (CPRA), created new individual privacy rights for California residents, including the right to opt out of certain disclosures of their data, the right to limit the use and disclosure of sensitive personal information (including health information). The CCPA places increased privacy and security obligations on entities handling certain personal data of California residents or households, limits data use and mandates audit requirements for higher risk data. The CCPA also creates a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. Although there are limited exemptions for clinical trial data and some other health data under the CCPA, as currently written, the CCPA may impact our business activities and exemplifies the vulnerability of our business to the evolving regulatory environment related to personal data and PHI. The CCPA is enforced by the California Privacy Protection Agency, a data protection authority, which has the power to issue substantive regulations resulting in increased privacy and information security enforcement. Additional compliance investment and potential business process changes may be required.

While California was the first among the states to adopt comprehensive data privacy legislation similar to the GDPR, many other states are following suit, which could increase our potential liability and adversely affect our business. More than 20 states have adopted statewide comprehensive privacy laws and many other states have privacy legislation that is pending. Many of these new state laws contain some type of exemption for information collected under HIPAA and some data processed in the context of clinical trials, either at the entity level or the data level, so the impact might be limited particularly as it relates to PHI. Some states also have laws that specifically focus on the processing of personal data related to individuals' health, including California's Confidentiality of Medical Information Act and Washington's My Health My Data Act. Changes to federal and state privacy laws may add complexity, variation in requirements, restrictions and potential legal risk, require additional investment of resources in compliance programs, impact strategies and the availability of previously useful data and could result in increased compliance costs and/or changes in business practices and policies. The existence of comprehensive privacy laws in different states in the country would make our compliance obligations more complex and costly and may increase the likelihood that we may be subject to enforcement actions or otherwise incur liability for non-compliance.

In addition, all 50 U.S. states and territories and international jurisdictions have varying breach notification laws that may require us to notify patients, employees or regulators in the event of unauthorized access to or disclosure of personal or confidential data experienced by us or our service providers. These laws are not consistent, and compliance in the event of a widespread data breach is difficult and may be costly. We also may be contractually required to notify patients or other counterparties of a security breach. In addition to government regulation, privacy advocates and industry groups have and may in the future propose self-regulatory standards from time to time. These and other industry standards may legally or contractually apply to us, or we may elect to comply with such standards.

Foreign data protection laws, including the European Union's General Data Protection Regulation (the EU GDPR), and the United Kingdom's equivalent of the same (the UK GDPR), may also apply to our processing of health-related and other personal data regardless of where the processing in question is carried out.

The GDPR in the EEA and the UK GDPR in the United Kingdom (together, the GDPR) impose stringent requirements for controllers and processors of personal data of individuals within the EEA or the United Kingdom. The GDPR applies to any company established in the EEA or United Kingdom as well as to those outside the EEA or United Kingdom if they collect and use personal data in connection with the offering of goods or services to individuals in the EEA or United Kingdom or the monitoring of their behavior. The GDPR, together with national legislation, regulations and guidelines of the EEA Member States and the United Kingdom governing the processing of personal data, imposes strict obligations and restrictions on the ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting. In particular, these obligations and restrictions concern the consent of the individuals to whom the personal data relates, the information provided to the individuals, the transfer of personal data out of the EEA or the United Kingdom, security breach notifications, security and confidentiality of the personal data and imposition of substantial potential fines for breaches of the data protection obligations. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for non-compliance of up to €20 million (£17.5 million) or 4% of the annual global revenues of the non-compliant company, whichever is greater. Such requirements may be subject to change in the near future as the European Commission announced proposed amendments to the GDPR in November 2025. In addition, on June 19, 2025, the UK's Data (Use and Access) Act 2025, or the DUAA, was granted Royal Assent, implementing various measures concerning data usage in the UK and reforming data protection laws. It remains too soon to tell how the DUAA will be implemented and what impact it will have on our international activities. Further, other EU and member state laws and regulations may impose further obligations or restrictions on processing health information in the EEA, such as the European Health Data Space Regulation.

In the EEA, the NIS 2 Directive, or NIS 2, is replacing the cybersecurity legal framework under the current NIS framework, aiming to ensure a high level of cybersecurity in the region. NIS 2 brings new medium and large organizations providing services in the EEA within scope of the legal framework. It extends to additional sectors and expands the list of in-scope healthcare organizations, including to certain providers engaged in research and development of medicinal products. The new regime imposes direct obligations on management in respect of an in-scope organization's compliance with NIS 2, requires covered organizations to put in place certain cyber risk management measures, strengthens incident reporting requirements and provides supervisory authorities with greater oversight. The majority of obligations will come into force when national legislation implementing NIS 2 becomes effective in the relevant EU Member State. EU Member States had until October 17, 2024 to transpose NIS 2 into national legislation, although many countries have still not completed the transposition. As such, the cybersecurity regulatory landscape in the EU is currently fragmented and uncertain. To the extent that we become subject to NIS 2 in the future, we may require additional investment of our resources in compliance programs. Under NIS 2, companies may be subject to administrative fines of up to the higher amount of €10 million or 2% of worldwide turnover.

Certain jurisdictions, including the EEA, have enacted laws and regulations governing cross-border personal information transfer and providing for data localization in certain cases. For example, absent appropriate safeguards or other circumstances, the GDPR and laws in Switzerland and the UK generally restrict the transfer of personal information to countries outside the EEA, Switzerland and the UK, such as the United States. Such safeguards include the use of standard contractual clauses approved by the European Commission and the UK and Swiss Data Protection Authorities as well as the EU-U.S. Data Privacy Framework. If we are unable to implement a valid solution to transfer personal data from the EEA to the United States or other countries that have not been deemed to provide an essentially equivalent level of data protection, we may face increased exposure to regulatory action, substantial fines, or injunction orders to stop processing personal data from EEA, Swiss, or UK residents. Any inability to import personal data to the United States may also restrict our clinical trials activities in the EU; limit our ability to collaborate with CROs as well as other service providers, contractors and other companies subject to EU data privacy and security laws; and require us to increase our data processing capabilities in the EU and the UK at a significant expense. Additionally, other countries outside of the EU have enacted or are considering enacting similar cross-border data transfer restrictions and laws requiring local data residency, which could increase the cost and complexity of delivering our services and operating our business. The types of challenges we face in the EEA, Switzerland, and the UK will likely also arise in other jurisdictions that adopt laws similar to the GDPR or regulatory frameworks of equivalent complexity.

Implementing mechanisms to endeavor to ensure compliance with the GDPR and relevant local legislation in EEA Member States and the United Kingdom may be onerous and may interrupt or delay our development activities, and adversely affect our business, financial condition, results of operations, and prospects. In addition to the foregoing, a breach of the GDPR or other applicable privacy and data protection laws and regulations could result in regulatory investigations, reputational damage, and orders to cease/change our use of data, enforcement notices, or potential civil claims including class-action-type litigation. While we have taken steps to comply with the GDPR where applicable, including by reviewing our security procedures, engaging data protection

personnel, and entering into data processing agreements with relevant contractors, our efforts to achieve and remain in compliance may not be fully successful.

Compliance with U.S. and foreign privacy and security laws, rules and regulations could require us to take on more onerous obligations in our contracts, require us to engage in costly compliance exercises, restrict our ability to collect, use and disclose data, or, in some cases, impact our or our partners' or suppliers' ability to operate in certain jurisdictions. Each of these constantly evolving laws can be subject to varying interpretations. Failure to comply with U.S. and foreign data protection laws and regulations could result in government investigations and enforcement actions (which could include civil or criminal penalties), fines, private litigation, and/or adverse publicity and could negatively affect our operating results and business. Moreover, patients about whom we or our partners obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could adversely affect our business, operating results, prospects or financial condition.

Risks Related to Artificial Intelligence

We may use certain artificial intelligence (AI) technologies, which presents risks and challenges that could adversely impact our business. As with many innovations, ineffective or inadequate AI development or deployment practices could result in unintended consequences. For example, AI algorithms we use in connection with our operations may be flawed or based on datasets that are biased or insufficient, potentially leading to errors in our business processes. Disruption or failure in AI functionality could adversely affect our business, cause delays or inaccuracies in our offerings, or harm our reputation. Conversely, if we are unable to adopt and deploy AI effectively as quickly as our competitors, it may cause us to be relatively less productive or innovative, adversely impacting our competitiveness and requiring additional investments that increase our costs. AI technologies may increase cybersecurity, privacy and data protection risks, including the risk that employees, contractors or vendors inadvertently input, expose, or enable access to confidential, proprietary, or regulated information through AI tools or related integrations. In addition, AI systems may be vulnerable to novel attacks (such as prompt injection or data poisoning) and, if we deploy AI-enabled automation or systems that can take actions based on AI outputs, those systems could execute unintended, unauthorized, or harmful actions due to inaccurate, manipulated, or improperly reviewed outputs. Laws and regulations regarding AI technologies are rapidly evolving as well, including in the areas of intellectual property, cybersecurity, privacy and data protection. Compliance with new or changing laws, regulations, or industry standards relating to AI may impose significant operational and financial burdens and may limit our ability to develop, deploy, or use AI technologies in our business.

Risks Related to the Commercialization of Our Product Candidates

Even if any of our product candidates receive regulatory approval, they may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

If any of our product candidates receive regulatory approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. If our product candidates do not achieve an adequate level of acceptance, we may not generate significant revenue and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including but not limited to:

- the clinical indications for which the product candidate is approved;
- the efficacy, safety and potential advantages compared to alternative treatments;
- the timing of market introduction of the product candidate as well as competitive products;
- effectiveness of sales and marketing efforts;
- the cost of treatment in relation to alternative treatments and products;
- our ability to offer our products for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- product labeling requirements of the FDA or comparable foreign regulatory authorities, including any limitations or warnings contained in a product's approved labeling, including any black box warning or patient inserts;
- the availability of the approved product candidate for use as a combination therapy;
- the willingness of the target patient population to try new treatments and of physicians to prescribe these treatments;
- our ability to hire and retain a sales force in the United States;

- the strength of marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement for our product candidates, once approved;
- the willingness of patients to pay out-of-pocket in the absence of coverage and adequate reimbursement by third-party payors and government authorities;
- patient satisfaction with the results and administration of our product candidates and overall treatment experience;
- the prevalence and severity of any side effects; and
- any restrictions on the use of our products together with other medications (e.g., contraindications).

Our efforts to educate physicians, patients, third-party payors and others in the medical community on the benefits of our product candidates may require significant resources and may never be successful. Such efforts may require more resources than are typically required due to the complexity and uniqueness of our product candidates. Because we expect sales of our product candidates, if approved, to generate substantially all of our revenues for the foreseeable future, the failure of our product candidates, if approved, to find market acceptance, could adversely affect our business and could require us to seek additional financing.

If we are unable to establish sales, marketing and distribution capabilities for our product candidates that may receive regulatory approval, we may not be successful in commercializing those product candidates if and when they are approved.

We have no internal sales, marketing or distribution capabilities, nor have we as a company commercialized a product. If any of our product candidates ultimately receives marketing approval, we will be required to build a marketing and sales organization with technical expertise and supporting distribution capabilities to commercialize each such product in the markets that we target, which will be expensive and time-consuming, or collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of establishing our own sales force and distribution systems. We have no prior experience as a company in the marketing, sale and distribution of biopharmaceutical products and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these product candidates. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to market our products on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians in order to educate physicians about our product candidates, once approved;
- 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.

If we are unable to establish our own sales, marketing and distribution capabilities and are forced to enter into arrangements with, and rely on, third parties to perform these services, our revenue and our profitability, if any, are likely to be lower than if we had developed such capabilities ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute our product candidates or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our product candidates effectively. If we are not successful in commercializing our product candidates, either on our own or through arrangements with one or more third parties, we may not be able to generate any future product revenue and we would incur significant additional losses, which could adversely affect our business, operating results, prospects or financial condition.

We face substantial competition, which may result in a smaller than expected commercial opportunity and/or others discovering, developing or commercializing products before or more successfully than we do.

The biotechnology and pharmaceutical industries are characterized by rapid evolution of technologies, fierce competition and strong defense of intellectual property. We face competition from major pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions, among others.

If any of our product candidates are approved for the indications for which we expect to conduct clinical trials, we anticipate they will compete with the foregoing therapies and currently marketed drugs, as well as any drugs potentially in development. It is also possible that we will face competition from other pharmaceutical approaches as well as other types of therapies. The key competitive factors affecting the success of all our programs, if approved, are likely to be their potency, tolerability, convenience, price, level of generic competition, and availability of reimbursement.

With respect to ARD-101, Soleno Therapeutics' VYKAT XR is the only approved treatment for PWS-associated hyperphagia. We are also aware of therapeutic candidates in development programs with reported hyperphagia reducing activity in patients with PWS, including those from Rhythm Pharmaceuticals, Relmada Therapeutics and Bright Minds Biosciences Inc.

Many of our current or potential competitors, either alone or with their collaboration partners, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical studies, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and subject registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Mergers and acquisitions in the biopharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that have fewer or less severe side effects, are more potent, are more convenient, are less expensive or are sold more effectively than any products that we may develop. Our competitors also may obtain FDA or other applicable regulatory authority approval for their product candidates 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. 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. Competitive products may make any products we develop obsolete or noncompetitive before we recover the expense of developing and commercializing our product candidates. If we are unable to compete effectively, our opportunity to generate revenue from the sale of any product candidates we develop, if approved, could be adversely affected.

The success of our product candidates will depend significantly on coverage and adequate reimbursement or the willingness of patients to pay for these products.

The availability and adequacy of coverage and 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 our product candidates, assuming FDA approval. Our ability to achieve acceptable levels of coverage and reimbursement for products by governmental authorities, private health insurers and other organizations will have an effect on our ability to successfully commercialize our product candidates. Assuming we obtain coverage for our product candidates by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. We cannot be sure that coverage and reimbursement in the United States, the EEA or elsewhere will be available for our product candidates or any product that we may develop, and any reimbursement that may become available may be decreased or eliminated.

An increasing number of third-party payors are challenging prices charged for pharmaceutical products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs or biologics when an equivalent generic drug, biosimilar or a less expensive product is available. It is possible that a third-party payor may consider our product candidates as substitutable and only offer to reimburse patients for the less expensive drug. Even if we show more favorable efficacy or a more favorable convenience of administration with our product candidates, pricing of existing third-party therapeutics may limit the amount we will be able to charge for our product candidates. 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 our product candidates. For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because higher prices are 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. If reimbursement is not available or is available only at limited levels, we may not be able to

successfully commercialize our product candidates, if approved, and may not be able to obtain a satisfactory financial return on our product candidates.

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 product candidates 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, in some cases on short notice, and we believe that changes in these rules and regulations are likely.

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 have and will continue to put pressure on the pricing and usage of our product candidates. 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 product candidates. Accordingly, in markets outside the United States, the reimbursement for our product candidates may be reduced compared with the United States and may be insufficient to generate commercially-reasonable revenue and profits. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures within the United States, could further limit our net revenue and results. The IRA, for example, includes provisions that impose new manufacturer financial liability on certain drugs under Medicare Part D, allowing the U.S. government to negotiate Medicare Part B and Part D price caps for certain high-cost drugs and biologics without generic or biosimilar competition. Orphan drugs are exempted from the Medicare drug price negotiation program, but as described in CMS guidance, this exemption will apply only to products that have no more than one rare disease designation and for which the only approved indication is for that disease or condition. Decreases in third-party reimbursement for our drug product candidate or a decision by a third-party payor to not cover our drug product candidate could reduce physician usage of the drug product candidate and have a material adverse effect on our sales, results of operations and financial condition.

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 product candidates. We expect to experience pricing pressures in connection with the sale of our product candidates due to the trend toward managed health care, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and biologics and surgical procedures and other treatments, has become intense. As a result, increasingly high barriers are being erected to the entry of new products.

There can be no assurance that our product candidates, if approved for sale in the United States or in other countries, will be considered medically reasonable and necessary, that it will be considered cost-effective by third-party payors, that coverage or an adequate level of reimbursement will be available or that reimbursement policies and practices in the United States and in other countries where our products are sold will not adversely affect our ability to sell our product candidates profitably, if they are approved for sale.

If the market opportunities for any of our product candidates are smaller than we estimate, even assuming approval of a product candidate, 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 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 scientific literature, surveys of clinics, patient foundations or market research, and may prove to be incorrect. Further, new information may change the estimated incidence or prevalence of these diseases. For example, PWS is a rare disease, and as such, our projections of both the number of people who have this disease, as well as the subset of people with PWS who have the potential to benefit from treatment with our product candidate, are based on estimates. Currently, most reported estimates of the prevalence of PWS are based on studies of small subsets of the population of specific geographic areas, which are then extrapolated to estimate the prevalence of the disease in the broader world population. There can be no assurance that the prevalence of PWS in the study populations, particularly in these newer studies, accurately reflects the prevalence of this disease in the broader world population. If our estimates of the prevalence of PWS or of the number of patients who may benefit from treatment with our product candidates prove to be incorrect, the market opportunities for our product candidate may be smaller than we believe it is, our prospects for generating revenue may be adversely affected and our business may suffer.

The total addressable market across 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 availability of alternative treatments and the safety, convenience, cost and efficacy of our product candidates relative to such alternative treatments, acceptance by the medical community and patient access, 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.

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

Social media is increasingly being used to communicate about our clinical development programs and the diseases our therapeutics are being developed to treat, and we intend to utilize appropriate social media in connection with our commercialization efforts following approval of our product candidates, if any. Social media practices in the biopharmaceutical industry continue to evolve and regulations and regulatory guidance relating to such use are evolving and not always clear. This evolution creates uncertainty and risk of noncompliance with regulations applicable to our business, resulting in potential regulatory actions against us, along with the potential for litigation related to off-label marketing or other prohibited activities. For example, patients may use social media channels to comment on their experience in an ongoing blinded clinical trial or to report an alleged adverse event. When such disclosures occur, there is a risk that trial enrollment may be adversely impacted, that we fail to monitor and comply with applicable adverse event reporting obligations or that we may not be able to defend our business or the public's legitimate interests in the face of the political and market pressures generated by social media due to restrictions on what we may say about our product candidates. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us on any social networking website. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face regulatory actions or incur other harm to our business.

Risks Related to Ownership of Our Common Stock and Our Status as a Public Company

An active and liquid trading market for our common stock may not develop and you may not be able to resell your shares of common stock at or above the public offering price, if at all.

Our common stock began trading on the Nasdaq Global Select Market under the symbol "AARD" on February 13, 2025. We can provide no assurance that a more active or liquid trading market for our common stock will develop or 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.

Our stock price may be volatile, which could result in substantial losses for investors purchasing shares of our common stock.

The market price of our common stock is volatile and could fluctuate widely in response to many factors, including but not limited to:

- volatility and instability in the financial and capital markets;
- announcements relating to our product candidates, including the results of clinical trials by us or our collaborators;
- announcements by competitors that impact our competitive outlook;
- negative developments with respect to our product candidates, or similar products or product candidates with which we compete;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to pause or terminate an existing clinical trial;
- developments with respect to patents or intellectual property rights;
- announcements of technological innovations, new product candidates, new products or new contracts by us or our competitors;
- announcements relating to strategic transactions, including acquisitions, collaborations, licenses or similar arrangements;

- actual or anticipated variations in our operating results due to the level of development expenses and other factors;
- changes in financial estimates by equities research analysts and whether our earnings (or losses) meet or exceed such estimates;
- announcement or expectation of additional financing efforts and receipt, or lack of receipt, of funding in support of conducting our business;
- sales of our common stock by us, our insiders, or other stockholders, or issuances by us of shares of our common stock in connection with strategic transactions;
- conditions and trends in the pharmaceutical, biotechnology and other industries;
- regulatory developments within, and outside of, the United States, including changes in the structure of healthcare payment systems;
- litigation or arbitration;
- pandemics, natural disasters or major catastrophic events;
- general economic, political and market conditions and other factors; and
- the occurrence of any of the risks described in this Part I, Item 1A, "Risk Factors," of this Annual Report.

In recent years, the stock market in general, and the market for pharmaceutical and biotechnology companies in particular, has experienced significant price and volume fluctuations that have often been unrelated or disproportionate to changes in the operating performance of the companies whose stock is experiencing those price and volume fluctuations. Broad market and industry factors may seriously affect the market price of our common stock, regardless of our actual operating performance.

Since our IPO, we have experienced volatility in our stock price. For example, from February 13, 2025 (the date our common stock commenced trading on the Nasdaq Global Select Market) to March 6, 2026, our closing stock price ranged from $4.90 to $17.41 per share. In particular, following our announcement in February 2026 that we have voluntarily paused enrollment and dosing in the Phase 3 HERO trial, the open label extension trial for ARD-101, and the POWER and STRENGTH clinical trials for ARD-201 based on reversible cardiac observations in a healthy volunteer study of ARD-101, the trading price of our common stock declined significantly, closing at $12.49 per share prior to the announcement on February 27, 2026 and then closing at $5.47 per share on March 2, 2026, the next trading day thereafter. When the market price of a stock has been volatile, as our stock price has been, holders of that stock have occasionally brought securities class action litigation claims against the company that issued the stock. If any of our stockholders were to bring a lawsuit of this type against us, even if the lawsuit were without merit, we could incur substantial costs defending the lawsuit. The lawsuit could also divert the time and attention of our management.

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

We expect our operating results to be subject to quarterly and annual fluctuations which may, in turn, cause the price of our common stock to fluctuate significantly. Our net loss and other operating results will be affected by numerous factors, including:

- the timing and cost of, and level of investment in, research, development, pre-commercial and, if approved, commercialization activities relating to our product candidates, which may change from time to time;
- the timing and status of enrollment for our clinical trials;
- the cost of manufacturing our product candidates, as well as building out our supply chain, which may vary depending on the quantity of production and the terms of our agreements with manufacturers;
- expenditures that we may incur to acquire, develop or commercialize additional product candidates and technologies;
- the timing of payments we may make or receive under existing license and collaboration arrangements or the termination or modification thereof;
- our execution of any strategic transactions, including acquisitions, collaborations, licenses or similar arrangements, and the timing and amount of payments we may make or receive in connection with such transactions;
- future accounting pronouncements or changes in our accounting policies;

- the timing and success or failure of preclinical studies and clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners;
- any intellectual property infringement lawsuit or opposition, interference or cancellation proceeding in which we may become involved;
- recruitment and departures of key personnel;
- the timing of receipt of approvals for, and the scope of or limitation on the marketing authorizations received on, our product candidates from regulatory authorities in the United States and internationally;
- coverage and reimbursement policies with respect to our product candidates, if approved, and currently approved products or potential future drugs that compete or may compete with our product candidates;
- the level of demand for our product candidates, if approved, which may vary significantly over time;
- regulatory developments affecting our product candidates or those of our competitors;
- fluctuations in stock-based compensation expense;
- the impacts of inflation and rising interest rates on our business and operations; and
- changes in general market and economic conditions.

If our quarterly or annual operating results fall below the expectations of investors or securities analysts or any forecasts or guidance we may provide to the market, 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. We believe that quarterly or annual comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

Because we do not anticipate paying any dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

We have never declared nor paid dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development, operation and expansion of our business and we do not anticipate declaring or paying any dividends in the foreseeable future. In addition, any future debt agreements may preclude us from paying dividends. As a result, capital appreciation of our common stock, which may never occur, will be your sole source of gain on your investment for the foreseeable future.

Our board of directors is authorized to issue and designate shares of our preferred stock without stockholder approval.

Our Fourth Amended and Restated Certificate of Incorporation, as may be amended from time to time (Certificate of Incorporation), authorizes our board of directors, without the approval of our stockholders, to issue shares of preferred stock, subject to limitations prescribed by applicable law, rules and regulations and the provisions of our Certificate of Incorporation, and to establish from time to time the number of shares of preferred stock to be included in each such series and to fix the designation, powers, preferences and rights of the shares of each such series and the qualifications, limitations or restrictions thereof. The powers, preferences and rights of these additional series of convertible preferred stock may be senior to or on parity with our common stock, which may reduce our common stock's value.

Conflicts of interest may arise because some members of our board of directors are representatives of our principal stockholders.

Certain of our principal stockholders or their affiliates are venture capital funds or other investment vehicles that could invest in entities that directly or indirectly compete with us. As a result of these relationships, when conflicts arise between the interests of the principal stockholders or their affiliates and the interests of other stockholders, members of our board of directors that are representatives of the principal stockholders may not be disinterested.

Our principal stockholders and management own a significant percentage of our common stock and are able to control matters subject to stockholder approval.

As of February 28, 2026, our executive officers, directors and holders of 5% or more of our capital stock beneficially owned approximately 51.6% of the outstanding shares of our common stock. As a result, such stockholders, acting together, have the ability

to significantly influence all matters submitted to our board of directors or stockholders for approval, including the appointment of our management, amendments of our organizational documents, the election and removal of directors and approval of any major corporate transactions, as well as our management and business affairs. The interests of these stockholders may not be the same as or may even conflict with your interests. For example, these stockholders could delay, defer or prevent a change of control of our company, impede a merger, consolidation, takeover or other business combination involving us, or discouraging a potential acquirer from making a tender offer or otherwise attempt to obtain control of our business, even if such a transaction would benefit our other stockholders. This could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company or our assets and might affect the prevailing market price of our common stock. The significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise.

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

Our Certificate of Incorporation and Amended and Restated Bylaws (Bylaws) contain provisions that could delay or prevent a change in control of our company. These provisions could also make it difficult for stockholders to elect directors who are not nominated by current members of our board of directors or take other corporate actions, including effecting changes in our management. These provisions:

- establish a staggered board of directors divided into three classes serving staggered three-year terms, such that not all members of our board of directors will be elected at one time;
- authorize our board of directors to issue one or more new series of preferred stock without stockholder approval and create, subject to applicable law, one or more series of preferred stock with preferential rights to dividends or our assets upon liquidation, or with superior voting rights to our existing common stock;
- eliminate the ability of our stockholders to call special meetings of stockholders;
- eliminate the ability of our stockholders to fill vacancies on our board of directors;
- establish advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted upon by stockholders at our annual stockholder meetings;
- permit our board of directors to establish the number of directors;
- provide that our board of directors is expressly authorized to make, alter or repeal our Bylaws;
- provide that stockholders can remove directors only for cause and only upon the approval of not less than 66-2/3% of all outstanding shares of our capital stock;
- require the approval of not less than 66-2/3% of all outstanding shares of our capital stock to amend the Bylaws and specific provisions of the Certificate of Incorporation; and
- specify the jurisdictions in which certain stockholder litigation may be brought.

In addition, because we are incorporated in Delaware, we are governed by Section 203 of General Corporation Law of the State of Delaware (the DGCL), which may discourage, delay or prevent a change in control of our company. Section 203 imposes certain restrictions on mergers, business combinations and other transactions between us and holders of 15% or more of our common stock, unless the holder has held the stock for three years or, among other exceptions, our board of directors has approved the transaction. Any of the foregoing provisions could limit the price that investors might be willing to pay in the future for shares of our common stock, and they could deter potential acquirers of our company, thereby reducing the likelihood the holders of our common stock would receive a premium for their shares of our common stock in an acquisition.

The Certificate of Incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our Certificate of Incorporation, to the fullest extent permitted by law, provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or another state court or the federal court located within the State of Delaware if the Court of Chancery does not have or declines to accept jurisdiction) shall be the sole and exclusive forum, in all cases subject to the court's having jurisdiction over indispensable parties named as defendants, for: (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a breach of fiduciary duty owed to us or our stockholders by any director, officer or other employee; (iii) any action asserting a claim against us or any director, officer or other employee arising pursuant to the DGCL; (iv) any action to interpret, apply, enforce or determine the validity of the Certificate of Incorporation or the

Bylaws; or (v) any other action asserting a claim that is governed by the internal affairs doctrine. In addition, the Certificate of Incorporation provides that the federal district courts of the United States are the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act but that the exclusive forum provision does not apply to claims brought to enforce a duty or liability created by the Exchange Act.

Although we believe these provisions benefit us by providing increased consistency in the application of Delaware law for the specified types of actions and proceedings, the provisions may result in increased costs to stockholders to bring a claim for any such dispute and may have the effect of discouraging lawsuits against us or our directors and officers. Alternatively, if a court were to find the choice of forum provision contained in the 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, operating results, prospects or financial condition. For example, under the Securities Act, federal courts have concurrent jurisdiction over all suits brought to enforce any duty or liability created by the Securities Act, and investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and consented to this exclusive forum provision, but will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder.

General Risk Factors

Recent and future changes to tax laws could materially adversely affect our company.

The tax regimes we are subject to or operate under, including with respect to income and non-income taxes, are unsettled and may be subject to significant change. Changes in tax laws, regulations, or rulings, or changes in interpretations of existing laws and regulations, could materially adversely affect our company. For example, the Tax Cuts and Jobs Act, the Coronavirus Aid, Relief, and Economic Security Act, and the IRA enacted many significant changes to the U.S. tax laws. Future guidance from the U.S. Internal Revenue Service and other tax authorities with respect to such legislation may affect us, and certain aspects thereof could be repealed or modified in future legislation. For example, the IRA includes provisions that will impact the U.S. federal income taxation of certain corporations, including imposing a 15% minimum tax on the book income of certain large corporations and a 1% excise tax on certain corporate stock repurchases that would be imposed on the corporation repurchasing such stock. On July 4, 2025, legislation commonly referred to as the One Big Beautiful Bill Act was signed into law and extended many of the tax law provisions that were set to expire in 2025. Further changes to the tax laws or changes to the administrative or judicial interpretations of such laws are possible and may apply with retroactive effect. In addition, many countries in Europe, as well as a number of other countries and organizations (including the Organization for Economic Cooperation and Development and the European Commission), have proposed, recommended, or (in the case of countries) enacted or otherwise become subject to changes to existing tax laws or new tax laws that could significantly increase our tax obligations in the countries where we do business or require us to change the manner in which we operate our business.

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

We may be the target of securities litigation in the future, including based on volatility in the market price of our stock. The stock market in general, and Nasdaq and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of companies. The market price of our common stock is volatile. For example, following our announcement in February 2026 that we have voluntarily paused enrollment and dosing in the Phase 3 HERO trial, the open label extension trial for ARD-101, and the POWER and STRENGTH clinical trials for ARD-201 based on reversible cardiac observations in a healthy volunteer study of ARD-101, the trading price of our common stock declined significantly, closing at $12.49 per share prior to the announcement on February 27, 2026 and then closing at $5.47 per share on March 2, 2026, the next trading day thereafter. In the past, companies that have experienced volatility and/or declines in the market price of their stock have been subject to securities class action litigation. Securities litigation (including the cost to defend against, and any potential adverse outcome resulting from any such proceeding) can be expensive, time-consuming, damage our reputation and divert our management's and board of directors' attention from other business concerns, which could adversely affect our business, operating results, prospects or financial condition.

We will continue to incur significant increased costs as a result of operating as a public company, and our management is required to devote substantial time and resources to new compliance initiatives.

As a public company, we are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, Nasdaq listing requirements, and other applicable securities rules and regulations. Complying with these rules and regulations has increased and will increase our legal and financial compliance costs, make some activities more difficult, time-consuming or costly and increase demand on our systems and resources. The Exchange Act currently requires, among other things, that we file annual, quarterly and current reports with respect to our business and operating

results. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We are required to disclose changes made in our internal control and procedures on a quarterly basis. In order to maintain and, if required, improve our disclosure controls and procedures and internal control over financial reporting to meet this standard, significant resources and management oversight may be required. As a result, management's attention may be diverted from other business concerns, which could significantly harm our business, financial condition, results of operations and prospects. We may plan to hire additional support for financial reporting and internal controls and other finance personnel or consultants in order to improve and implement appropriate internal controls and reporting procedures, which will increase our costs and expenses.

In addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time-consuming. These laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to their application and practice, regulatory authorities may initiate legal proceedings against us and our business, financial condition, results of operations and prospects may be significantly harmed.

The future issuance of equity or of debt securities that are convertible into equity would dilute our share capital.

We may choose to raise additional capital in the future, depending on market conditions, strategic considerations and operational requirements. To the extent that additional capital is raised through the issuance of shares or other securities convertible into shares, our stockholders will be diluted. Future issuances of our common stock or other equity securities, or the perception that such sales may occur, could adversely affect the trading price of our common stock and impair our ability to raise capital through future offerings of shares or equity securities. No prediction can be made as to the effect, if any, that future sales of common stock or other equity securities or the availability of common stock for future sales will have on the trading price of our common stock.

Pursuant to our 2025 Equity Incentive Plan (2025 Plan), our management is authorized to grant equity awards to our employees, directors and consultants. Initially, the aggregate number of shares of our common stock that may be issued pursuant to equity awards under the 2025 Plan was 2,150,000 shares, which was automatically increased by 1,090,767 shares effective January 1, 2026. Additionally, the number of shares of our common stock reserved for issuance under the 2025 Plan will automatically increase on January 1st of each year, continuing through and including January 1, 2035, by 5% of the total number of shares of our capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by our board of directors. Unless our board of directors elects not to increase the number of shares available for future grant each year, our stockholders may experience additional dilution, which could cause our stock price to fall.

Further, in May 2025, the Compensation Committee of the board of directors (the Compensation Committee) approved the Company's 2025 Inducement Equity Incentive Plan (the 2025 Inducement Plan) and reserved 900,000 shares of common stock for issuance thereby. If the board of directors or Compensation Committee approves issuances under the 2025 Inducement Plan, our stockholders may experience additional dilution, which could cause our stock price to fall.

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.

The 777,912 shares of our common stock that are subject to outstanding options under the 2017 Equity Incentive Plan (2017 Plan) as of December 31, 2025 became eligible for sale in the public market after our IPO, to the extent permitted by the provisions of various vesting schedules and Rule 144 and Rule 701 under the Securities Act. If these additional shares of our 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.

The holders of 11,439,838 shares of our outstanding common stock, or approximately 52.4% of our total outstanding common stock as of February 28, 2026, are entitled to rights with respect to the registration of their shares under the Securities Act. 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 adversely affect the trading price of our common stock.

Techniques employed by short sellers may drive down the market price of our common stock.

Short selling is the practice of selling securities that the seller does not own, but rather has borrowed from a third-party with the intention of buying identical securities back at a later date to return to the lender. The short seller hopes to profit from a decline in the value of the securities between the sale of the borrowed securities and the purchase of the replacement shares, as the short seller expects to pay less in that purchase than it received in the sale. As it is in the short seller's best interests for the price of the stock to decline, many short sellers publish, or arrange for the publication of, negative opinions regarding the relevant issuer and its business prospects in order to create negative market momentum and generate profits for themselves after selling a stock short. These short attacks have, in the past, led to selling of shares in the market. While we would strongly defend against any such short seller attacks, we may be constrained in the manner in which we can proceed against the relevant short seller by applicable state law or issues of commercial confidentiality. Such a situation could be costly and time-consuming, and could be distracting for our management team. Additionally, such allegations against us could negatively impact our business operations and stockholders' equity, and the value of any investment in our stock could be reduced.

We are an "emerging growth company" and a "smaller reporting company" and our election of reduced reporting 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 JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a non-binding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. In addition, as an emerging growth company, we are only required to provide two years of audited financial statements. We have taken advantage of these reduced reporting burdens in our periodic reports. We could be an emerging growth company for up to five years following the completion of our IPO, although circumstances could cause us to lose that status earlier, including if we are deemed to be a "large accelerated filer," which occurs when the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30, or if we have total annual gross revenue of $1.235 billion or more during any fiscal year before that time, in which cases we would no longer be an emerging growth company as of the following December 31, or if we issue more than $1.0 billion in non-convertible debt during any three-year period before that time, in which case we would no longer be an emerging growth company immediately. Even after we no longer qualify as an emerging growth company, we could still qualify as a "smaller reporting company," which would allow us to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may 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 share price may be 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 until such time as those standards apply to private companies. We have elected to avail ourselves of this exemption from new or revised accounting standards, and therefore we are not subject to the same requirements to adopt new or revised accounting standards as other public companies that are not emerging growth companies.

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 are able to take advantage of these scaled disclosures for so long as our 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 common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

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

The trading market for our common stock may be influenced in part by the research and reports that industry or securities analysts publish about us or our business. We do not have any control over the industry or securities analysts, or the content and opinions included in their reports and may never obtain research coverage by securities and industry analysts. If no or few securities or industry analysts commence coverage of us, or if analysts cease coverage of us, we could lose visibility in the financial markets, and

the trading price for our common stock could be impacted negatively. If any of the analysts who cover us publish inaccurate or unfavorable research or opinions regarding us, our business model, our intellectual property or our stock performance, or if our preclinical studies and clinical trials and operating results fail to meet the expectations of analysts, our stock price would likely decline.

Our failure to meet Nasdaq's continued listing requirements could result in a delisting of our common stock.

If 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.

Unfavorable global economic or political conditions could adversely affect our business, financial condition or results of operations.

Our business is susceptible to general conditions in the global economy and in the global financial markets. A global financial crisis or a global or regional political disruption could cause extreme volatility in the capital and credit markets. A severe or prolonged economic downturn, including a recession or depression resulting from the political disruption, could result in a variety of risks to our business, including weakened demand for our current or future product candidates, if approved, and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy or political disruption could also strain our manufacturers or suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our potential drugs, if approved. The ongoing conflict between Russia and Ukraine and sanctions against Russia are causing disruptions to global economic conditions. The ongoing conflicts in the Middle East and instability in Venezuela could also cause disruptions to global economic conditions. Further, in recent years the global equity markets in general have experienced extreme price and volume fluctuations, including as a result of economic uncertainty and increased interest rates, inflation, the government closure of Silicon Valley Bank and Signature Bank, and liquidity concerns at other financial institutions that may be unrelated to our operating performance. Any of the foregoing could materially and adversely affect our business, financial condition, results of operations and prospects, and we cannot anticipate all of the ways in which the political or economic climate and financial market conditions could adversely impact our business.

Furthermore, the current U.S. administration has substantially departed from prior U.S. government international trade policy and has commenced activities to renegotiate, or potentially terminate, certain existing bilateral or multi-lateral trade agreements and treaties with foreign countries. In addition, the current U.S. administration has initiated and is considering imposing additional tariffs on certain foreign goods. Related to this action, certain foreign governments, including China, have instituted or are considering imposing reciprocal tariffs on certain U.S. goods. It remains unclear what the current U.S. administration or foreign governments will or will not do with respect to tariffs or other international trade agreements and policies. A trade war or other governmental action related to tariffs or international trade agreements or policies has the potential to disrupt our research activities, affect our suppliers, increase the cost of materials purchased to manufacture our product candidates and negatively impact the United States or global economy or certain sectors thereof and, thus, could adversely impact our business, financial condition or results of operations.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

(a) Cybersecurity Risk Management Strategy

We have developed our cybersecurity risk management program (Cybersecurity Framework), including a cybersecurity incident response plan, based on the National Institute of Standards and Technology Cybersecurity Framework's (NIST CSF) principles: Identify, Protect, Detect, Respond, and Recover, and our Cybersecurity Framework is intended to address current vulnerabilities and anticipate future cybersecurity threats and risks to our cyber ecosystem. This does not imply that we meet any particular technical standards, specifications, or requirements, only that we use the NIST CSF as a guide to help us identify, assess, and manage cybersecurity risks relevant to our business.

Our Cybersecurity Framework is integrated into our overall enterprise risk management program, and shares common methodologies, reporting channels and governance processes that apply across the enterprise risk management program to other legal, compliance, strategic, operational, and financial risk areas.

Our cybersecurity risk management program includes:

- assessments designed to help identify material cybersecurity risks to our critical systems, information, products, services, and our broader enterprise IT environment;
- a security team principally responsible for managing (1) our cybersecurity risk assessment processes, (2) our security controls, and (3) our response to cybersecurity incidents;
- the use of external service providers, where appropriate, to assess, test or otherwise assist with aspects of our security controls;
- cybersecurity awareness training for our employees, incident response personnel, and senior management;
- a cybersecurity incident response process that includes procedures for responding to cybersecurity incidents; and
- a risk evaluation of our service providers, suppliers, and vendors of critical systems during contracting.

We have not identified risks from known cybersecurity threats, including as a result of any prior cybersecurity incidents, that have materially affected or are reasonably likely to materially affect us, including our operations, business strategy, results of operations, or financial condition. There can be no assurance, however, 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 systems and information. For more information, see Part I, Item 1A, "Risk Factors—Risks Related to the Operation of Our Business—Significant disruptions of our information technology systems or data security incidents could result in significant financial, legal, regulatory, business and reputational harm to us" of this Annual Report.

(b) Cybersecurity Governance

Our board of directors considers cybersecurity risk as part of its risk oversight function and has delegated to the Audit Committee oversight of cybersecurity and other information technology risks. The Audit Committee oversees management's implementation of our cybersecurity risk management strategy.

The Audit Committee receives periodic reports from management, including our IT Governance Team, on our cybersecurity risks. In addition, management updates the Audit Committee, as necessary, regarding any material cybersecurity incidents, as well as any incidents with lesser impact potential.

Our cybersecurity risk management and strategy processes are overseen by our IT Governance Team, which includes senior leadership across Finance, Project Management and Information Technology, Regulatory and Quality, and Legal, supported by external technical advisors. The IT Governance Team is responsible for assessing and managing cybersecurity risks, overseeing the implementation of our information security policies and procedures, and supervising the prevention, detection, mitigation, and remediation of cybersecurity incidents in accordance with our IT governance framework.

Our Senior Vice President of Program Management and Head of Information Technology has over 25 years of experience leading technology-enabled programs and cross-functional teams in biotechnology and other regulated environments. He provides executive oversight of our enterprise information systems and IT governance activities, integrating cybersecurity considerations into broader operational risk management, compliance, and business continuity processes.

Our Chief Financial Officer and Chief Operating Officer has over 20 years of experience in financial management, business operations, and corporate strategy, with extensive experience overseeing internal controls and enterprise governance. As part of our enterprise risk management framework, our Chief Financial Officer and Chief Operating Officer provides executive oversight of the cybersecurity risk management program, including supervision of third-party service providers, escalation of cybersecurity matters to executive management, and reporting, as appropriate, to the Audit Committee.

To support execution of its cybersecurity program, we engage an outsourced managed service provider (the MSP) to provide day-to-day operational support for our information technology environment. The MSP operates under the direction of our management and supports the implementation of cybersecurity policies, controls, and incident response procedures, including ongoing monitoring, detection, remediation, and recovery activities consistent with our established cybersecurity framework. The MSP's personnel includes experienced information technology and cybersecurity professionals with relevant industry certifications and experience in enterprise systems administration, security operations, and business continuity support.

We maintain formal information security policies, an incident response plan, and a designated incident response team, which are overseen by the IT Governance Team. Cybersecurity incidents are escalated through management in accordance with these procedures and, where appropriate, reported to the Audit Committee for matters involving material cybersecurity risk.

Item 2. Properties.

We currently lease approximately 8,000 square feet of space as our primary headquarters in San Diego, California. The lease expires in December 2026. We believe that our existing facility is adequate to meet our current needs, although we may seek to negotiate new leases or evaluate additional or alternate spaces for our operations. We believe suitable additional alternative spaces will be available in the future on commercially reasonable terms.

Item 3. Legal Proceedings.

From time to time, we may be involved in legal proceedings arising in the ordinary course of our business. We are not presently a party to any legal proceedings that, in the opinion of management, would have a material adverse effect on our business, financial condition or results of operations. Regardless of outcome, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources, negative publicity, reputational harm and other factors.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our common stock has traded on the Nasdaq Global Select Market since February 13, 2025 under the symbol "AARD". Prior to February 13, 2025, there was no public market for our common stock.

Holders of Record

As of February 28, 2026, there were approximately 26 stockholders of record of our common stock. Certain shares are held in "street" name and accordingly, the number of beneficial owners of such shares is not known or included in the foregoing number.

Dividend Policy

We have never declared or paid any cash dividends on our common stock. We do not currently anticipate declaring or paying, in the foreseeable future, any cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings, if any, to finance the operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future. Any future determination to pay dividends will be made at the discretion of our board of directors or any authorized committee thereof, subject to applicable laws, after considering our financial condition, results of operations, capital requirements, business prospects and other factors our board of directors or such committee may deem relevant.

Stock Performance Graph

We are a smaller reporting company, as defined by Rule 12b-2 of the Exchange Act, and are not required to provide a performance graph.

Recent Sales of Unregistered Securities.

None.

Use of Proceeds

On February 12, 2025, our registration statement on Form S-1 (File No. 333-284440) was declared effective by the SEC for our IPO. We sold an aggregate of 6,120,661 shares of common stock in the IPO, which included the partial exercise by the underwriters to purchase 232,661 additional shares, at an initial public offering price of $16.00 per share for gross proceeds of $97.9 million. Morgan Stanley & Co. LLC, BofA Securities, Inc., Cantor Fitzgerald & Co. and RBC Capital Markets, LLC acted as joint book-running managers of our IPO, which has now terminated. After deducting underwriting discounts, commissions and offering costs paid by us totaling $10.4 million, the net proceeds from the offering were approximately $87.5 million. As of December 31, 2025, we estimate that we have used approximately $46.5 million of the proceeds from our IPO for general corporate purposes, including to fund the clinical development of ARD-101 and our other clinical and preclinical activities, as well as operating expenses. No offering expenses were paid or are payable, directly or indirectly, to our directors or officers, to persons owning 10% or more of any class of our equity securities, or to any of our affiliates.

There has been no material change in the expected use of the net proceeds from our initial public offering as described in our final prospectus filed with the SEC pursuant to Rule 424(b) on February 13, 2025.

Issuer Repurchases of Equity Securities

None.

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the consolidated financial statements and related notes thereto included elsewhere in this Annual Report. This discussion and other parts of this Annual Report contain forward-looking statements that involve risk, assumptions and uncertainties, such as statements of our plans, objectives, expectations, intentions, forecasts and projections. Our actual results and the timing of selected events could differ materially from those discussed in these forward-looking statements as a result of several factors, including those set forth under Part I, Item 1A, "Risk Factors", of this Annual Report and elsewhere in this Annual Report. You should carefully read Part I, Item 1A, "Risk Factors", of this Annual Report to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements. Please also see the section titled "Special Note Regarding Forward-Looking Statements."

Overview

We are a clinical-stage biopharmaceutical company focused on developing novel, small-molecule therapeutics to activate innate homeostatic pathways for the treatment of metabolic diseases. We target biological pathways associated with alleviating hunger that we believe have the potential to deliver transformative outcomes for patients. We have focused our efforts on developing selective compounds, targeting Bitter Taste Receptors (TAS2Rs) for hunger-associated conditions. Our initial compounds target TAS2Rs expressed in the gut lumen, which normally respond to the chemicals in food and participate in the gut-brain axis. Our research has shown that activating these receptors can induce the secretion of endogenous signaling molecules, including cholecystokinin (CCK), peptide YY (PYY) and glucagon-like peptide-1 (GLP-1).

TAS2Rs are a family of 26 different nutrient-sensing G protein-coupled receptors (GPCRs) that are broadly expressed among vertebrates. TAS2Rs are present in the oral cavity to convey bitter taste and are highly expressed in many other tissues throughout the body where they are key in regulating metabolic and inflammatory pathways. CCK has long been recognized as a promising pharmaceutical target because its release is triggered with food and it helps suppress hunger, which is the feeling of discomfort that comes from a perception of not having eaten recently. We believe suppression of hunger could be complementary to the suppression of appetite reported from patients on GLP-1 receptor targeted treatments, which reduce the desirability of food. Previous approaches to directly agonize CCK receptors through exogenous molecules have been limited by safety concerns driven by systemic exposure, resulting in on-target, off-tissue toxicity, and in turn leading to adverse effects, such as pancreatitis. Our wholly-owned lead product candidate, ARD-101, is an oral, largely gut-restricted small-molecule agonist of certain TAS2Rs expressed in the gut lumen. ARD-101, in contrast to previous approaches to directly agonize CCK receptors, elicits the endogenous release of CCK by leveraging the body's natural response to TAS2R agonism. Besides our product candidates, we are not aware of any approved or other clinical-stage candidates targeting certain TAS2Rs.

ARD-101 has limited systemic absorption, which we believe reduces the potential for systemic toxicity and has contributed to ARD-101 being well-tolerated in our Phase 1 and 2 trials. We have completed a Phase 1 clinical trial of ARD-101 in healthy volunteers and a Phase 2 clinical trial in subjects with hyperphagia associated with Prader-Willi Syndrome (PWS). The Phase 2 clinical trial in hyperphagia associated with PWS evaluated two dosing regimens over 28 days followed by a 14-day withdrawal period. In Part 1 of the trial, 12 subjects completed the treatment period at a fixed dose of 200 mg delivered orally twice daily (BID). These 12 subjects that completed treatment had no significant treatment-related adverse events and, of these subjects, eight completed the Hyperphagia for Clinical Trial Questionnaire-9 (HQ-CT 9), with seven having complete post–database lock datasets. In this subgroup of seven, the mean decline at day 28 was approximately 9 points. In Part 2 of the trial, four subjects were dosed under a revised protocol: 400 mg BID for seven days, followed by 600 mg BID for seven days and ending with 800 mg BID for 14 days. The four subjects that completed the trial per protocol had only grade 1 treatment-related adverse events and showed a decrease in HQ-CT 9 of approximately eight points at 28 days. In our completed Phase 2 clinical trial in subjects with hyperphagia associated with PWS, ARD-101 was shown to be well-tolerated and demonstrated clinical activity through a reduction in Hyperphagia Questionnaire for Clinical Trials (HQ-CT) scores.

In the second quarter of 2025, we initiated dosing for a Phase 3 clinical trial for hyperphagia associated with PWS, which we refer to as the HERO (**H**unger **E**limination or **R**eduction **O**bjective) trial. We previously reached alignment with the FDA on a protocol for a Phase 3 clinical trial, which we initiated in December 2024. In August 2025, we submitted a protocol amendment to remove the use of anti-psychotics and insulin-requiring type 2 diabetes as exclusion criteria for the clinical trial. In October 2025, we reached alignment with the FDA on a protocol amendment to lower the minimum age of eligibility to participate in the trial from 13 to 10 years of age. This change broadened the eligible trial population and expanded the potential addressable opportunity within PWS. In December 2025, we submitted an additional protocol amendment seeking to further lower the minimum age of eligibility to participate in the trial to 7 years of age. During the third quarter of 2025, we commenced enrollment for the HERO Open Label Extension (OLE) trial, which was available to patients completing the HERO trial and we initiated our first clinical sites in Australia. In January 2026, we announced over 50% completion of the target enrollment of 90 patients in the HERO trial and within the first quarter of 2026, we initiated clinical sites in the UK, South Korea and Canada.

On February 27, 2026, we voluntarily paused enrollment and dosing in the HERO and OLE trials following reversible cardiac observations in a healthy volunteer study and are currently reviewing the data and collaborating with the FDA to determine next steps.

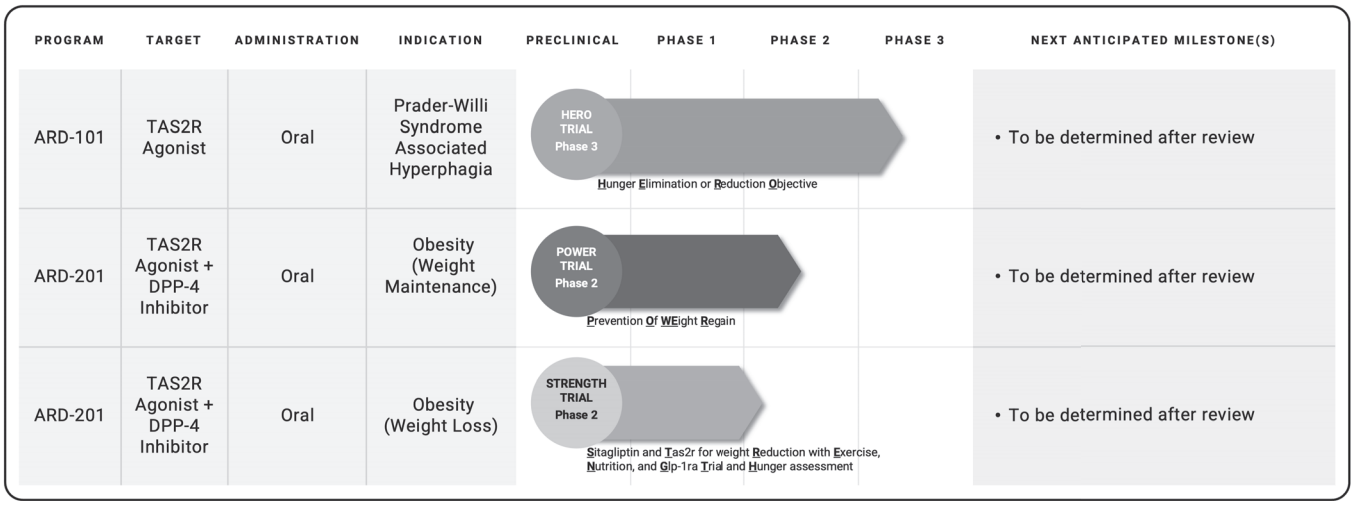
As a result, aspects of the trial design, development timeline and future clinical plans may change. Following the voluntary pause, we are reviewing the trial designs and protocols in collaboration with the FDA and the previously agreed protocol elements may be revisited.

Our second TAS2R program, ARD-201, was planned to be a fixed-dose combination of ARD-101 and a dipeptidyl peptidase-4 (DPP-4) inhibitor for the treatment of obesity and obesity-related conditions. We previously initiated a Phase 2 clinical trial, which we referred to as the POWER (Prevention Of WEight Regain) trial, in December 2025, to explore the efficacy of ARD-201 in the prevention of weight regain among patients who have successfully lost over 15% of body weight on GLP-1RA therapy. In addition, we previously planned to initiate a second Phase 2 trial for ARD-201 in the first half of 2026, which we referred to as the STRENGTH (Sitagliptin and TAS2R for weight Reduction with Exercise, Nutrition, and GLP-1RA Trial and Hunger assessment) trial. Because ARD-201 contains ARD-101 as a component of the planned combination therapy, we are assessing the potential implications of the voluntary pause of the HERO trial on the ARD-201 program. Following this assessment, we have voluntarily paused the STRENGTH and POWER clinical trials while we complete our ongoing evaluation of the safety observations identified in the healthy volunteer study of ARD-101 and continue discussions with the FDA regarding next steps for the ARD-101 program. We expect to provide further guidance in the second quarter of 2026.

In preparation for these trials, we expanded our clinical management and regulatory capabilities, including hiring clinical, regulatory and quality personnel, and we expect to continue to need to expand our clinical management and regulatory capabilities and to rely on third parties to conduct our later stage or pivotal clinical trials in the future. However, the timing of additional staffing and operational expansion may be delayed as we evaluate next steps following the voluntary pause of the HERO trial and related clinical programs.

Below is a summary of our portfolio of wholly-owned novel and proprietary small-molecule programs that we believe can induce satiety in patients with hunger-associated indications. As discussed above, certain clinical programs, including the HERO trial for ARD-101 and the POWER and STRENGTH trials for ARD-201, are currently paused while we evaluate safety observations and continue discussions with the FDA regarding next steps.

Our Hunger Associated TAS2R Pipeline



Beyond our lead product candidate, ARD-101, we are also developing other programs for the potential treatment of indications with high unmet need, including other indications mediated by TAS2R signaling.

Since we commenced operations in 2017, we have devoted substantially all of our resources to organizing and staffing our company, business planning, raising capital, discovering ARD-101, establishing and maintaining our intellectual property portfolio, conducting research, preclinical studies, and clinical trials, manufacturing of ARD-101 and related raw materials, and providing general and administrative support for these operations.

We have incurred significant net losses and negative cash flows from operations since our inception and, as of December 31, 2025, we had an accumulated deficit of $115.9 million. Our net losses for the years ended December 31, 2025 and 2024 were $57.6 million and $20.6 million, respectively. We expect our expenses and operating losses will increase substantially for the foreseeable future as we:

- continue our development of ARD-101 and evaluate next steps following the voluntary pause of the HERO and OLE trials;

- seek to discover and develop additional product candidates;
- conduct our ongoing and planned clinical trials and preclinical studies;
- continue our research and development activities;
- utilize third parties to manufacture ARD-101 and our other product candidates and related raw materials;
- hire additional personnel as our clinical programs advance and as we determine next steps following the voluntary pause of the HERO trial and related clinical programs;
- maintain, expand and protect our intellectual property;
- implement operational, financial and management information systems; and
- potentially experience any delays, challenges, or other issues associated with the clinical development of our product candidates, including with respect to our regulatory strategies.

If we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing, and distribution. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of and level of expense related to our clinical trials and preclinical studies and our other research and development activities and capital expenditures and the timing and amount of any milestone or royalty payments due under our existing or future license or collaboration agreements.

From inception and up to the date of our IPO in February 2025, we had raised a total of $129.1 million in gross proceeds to fund our operations from the sale and issuance of shares of our convertible preferred stock. In February 2025, we completed our IPO with the sale of 6,120,661 shares of common stock, which included the partial exercise by the underwriters of their option to purchase 232,661 additional shares, at a price of $16.00 per share and received net proceeds of approximately $87.5 million. As of December 31, 2025, we had cash, cash equivalents and short-term investments of $110.0 million. Based upon our current operating plans, we believe that our existing cash, cash equivalents and short-term investments will be sufficient to fund our projected operations into the second quarter of 2027. However, our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. In February 2026, we voluntarily paused enrollment and dosing in the Phase 3 HERO trial, the open label extension trial for ARD-101, and the POWER and STRENGTH clinical trials for ARD-201 based on reversible cardiac observations in a healthy volunteer study of ARD-101. The voluntary pause of these clinical trials may affect the timing and amount of our future expenditures and our need for additional capital, depending on the outcome of our ongoing data review and discussions with the FDA regarding next steps for our clinical programs.

We do not have any products approved for sale and have not generated any revenue to date. We do not expect to generate any revenue from product sales until we successfully complete development and obtain regulatory approval for one or more of our product candidates, which we expect will take a number of years and may never occur. We will need substantial additional funding in addition to the net proceeds of our IPO to support our continuing operations and pursue our long-term business plan, including to complete the development and commercialization of ARD-101 and our other product candidates, if approved. Accordingly, until such time as we can generate significant revenue from sales of ARD-101 or our other product candidates, if ever, we expect to finance our cash needs through equity offerings, debt financings, or other capital sources, including potential collaborations, licenses, and other similar arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. 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 our research and development programs or other operations, or grant rights to develop and market our product candidates that we would otherwise prefer to develop and market ourselves.

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We rely, and expect to continue to rely, on third parties for the manufacture of our ARD-101 and our other product candidates for preclinical and clinical testing, as well as for commercial manufacture if ARD-101 or any of our other product candidates obtain marketing approval. We are working with our current manufacturers to ensure that we will be able to scale up our manufacturing capabilities to support our clinical plans. In addition, we rely on third parties to package, label, store, and distribute ARD-101, and we intend to rely on third parties for our commercial products if marketing approval is obtained. We believe that this strategy allows us to maintain a more efficient infrastructure by eliminating the need for us to invest in our own manufacturing facilities, equipment, and personnel while also enabling us to focus our expertise and resources on the discovery and development of ARD-101 and our other product candidates.

Given our stage of development, we do not yet have a marketing or sales organization or commercial infrastructure; however, we intend to build the necessary sales, marketing and commercialization capabilities and infrastructure over time as our product candidates advance through clinical development if and when our product candidates advance through clinical development and

receive regulatory approval. We expect to spend a significant amount in commercial development and marketing costs prior to obtaining regulatory and marketing approval of one or more of our product candidates.

Macroeconomic Trends

We may be affected by unfavorable economic conditions and challenges in the United States and abroad, such as the effects of the ongoing conflicts in the Middle East and between Russia and Ukraine, sanctions against Russia, the instability in Venezuela, disruptions in the banking industry and inflationary trends. The fiscal years 2025 and 2024 were marked by significant market uncertainty and increasing inflationary pressures. These market dynamics are expected to continue into 2026, and these and similar adverse market conditions may negatively impact our business, financial position, results of operations and growth prospects. For further discussion of the potential impacts of macroeconomic events on us, refer to Part I, Item 1A, “Risk Factors”, of this Annual Report.

Components of Our Results of Operations

Revenue

To date, we have not generated any revenue from the sale of products. We do not expect to generate any such revenue unless and until such time as ARD-101 and our other product candidates have advanced through clinical development and regulatory approval, if ever. If we fail to complete preclinical and clinical development of any product candidates or obtain regulatory approval for them, our ability to generate future revenues, and our results of operations and financial position would be adversely affected.

Operating Expenses

Our operating expenses consist of (i) research and development expenses, (ii) general and administrative expenses and (iii) credit losses recorded on related party convertible promissory note and accounts receivable.

Research and Development

Our research and development (R&D) expenses consist primarily of external and internal costs incurred in performing preclinical and clinical development activities. Research and development expenses are recognized as incurred and payments made prior to the receipt of goods or services to be used in research and development are capitalized until the goods or services are received.

Our research and development expenses consist principally of:

- external costs, including:
- fees paid to CROs and consultants in connection with our preclinical studies, toxicology and clinical trials;
- costs related to manufacturing materials for our preclinical studies and clinical trials;
- costs related to compliance with regulatory requirements;
- license fees; and
- internal costs, including:
- personnel-related costs such as salaries, bonuses, payroll taxes, employee benefits, travel, and stock-based compensation expense for employees involved in research and development efforts; and
- facilities-related costs, depreciation and other allocated expenses, which include direct and allocated expenses for rent, maintenance of facilities, insurance, equipment, and other supplies and services.

We do not track our research and development expenses on a program-specific basis or allocate our internal costs associated with our discovery and development efforts because these costs are deployed across multiple programs and, as such, are not separately classified. Since our inception and through December 31, 2025, substantially all of our external costs have been related to the research and development of ARD-101.

Although R&D activities are central to our business model, the successful development of ARD-101 and our other product candidates is highly uncertain. We cannot determine with certainty the timing of initiation, the duration or the completion costs of current or future preclinical studies and clinical trials of ARD-101 or any other current or future product candidates due to the inherently unpredictable nature of preclinical and clinical development. There are numerous factors associated with the successful development of a product candidate, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. In addition, future regulatory factors beyond our control may impact our clinical development programs. Product candidates in later stages of development generally have higher development costs than those in earlier stages of development. As a result, we expect that our R&D expenses will increase substantially for the foreseeable future as we continue to conduct our ongoing R&D activities, advance preclinical research programs toward clinical development, conduct clinical trials, hire additional personnel, and maintain, expand, protect, and enforce our intellectual property portfolio.

At this time, we cannot accurately estimate or know the nature, timing and costs of the efforts that will be necessary to complete the preclinical and clinical development of any of our product candidates. Our future R&D expenses may vary significantly based on a wide variety of factors such as:

- the number and scope, rate of progress, expense and results of our discovery and preclinical activities and clinical trials;
- per patient trial costs;

- the number of trials required for approval;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- the number of patients that participate in the trials;
- the number of doses that patients receive;
- the drop-out or discontinuation rates of patients;
- the potential additional safety monitoring requested by regulatory agencies;
- the duration of patient participation in the trials and follow-up;
- the cost and timing of manufacturing our product candidates;
- the phase of development of our product candidates;
- the extent of changes in government regulation and regulatory guidance;
- the efficacy and safety profile of our product candidates;
- the timing, receipt, and terms of any approvals from applicable regulatory authorities; and
- the extent to which we establish collaboration, license, or other arrangements.

A change in the outcome of any of these variables with respect to development of any of our product candidates could significantly change the costs and timing associated with the development of that product candidate.

The process of conducting the necessary preclinical and clinical research to obtain regulatory approval is costly and time-consuming. The actual probability of success for ARD-101 or any other current or future product candidates may be affected by a variety of factors. We may never succeed in achieving regulatory approval for any of our product candidates. Preclinical and clinical development timelines, the probability of success, and total development costs can differ materially from expectations. We anticipate that we will make determinations as to which product candidates to pursue and how much funding to direct to each product candidate on an ongoing basis in response to the results of ongoing and future preclinical studies and clinical trials, regulatory developments, and our ongoing assessments as to each product candidates' commercial potential. We will need to raise substantial additional capital in the future. In addition, we cannot forecast which product candidate may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements.

General and Administrative

Our general and administrative (G&A) expenses consist primarily of personnel-related costs such as salaries, bonuses, payroll taxes, employee benefits, travel, and stock-based compensation expense for employees involved in executive, accounting and finance, legal, and other administrative functions. Other significant costs include allocated facility-related costs, legal fees relating to intellectual property and corporate matters, professional fees for accounting and consulting services, insurance costs, and business development expenses.

We expect that our G&A expenses will increase substantially for the foreseeable future as we continue to increase our general and administrative headcount to support our continued R&D activities and, if ARD-101 or our other product candidates receive marketing approval, commercialization activities, as well as to support our operations generally, although the timing of additional hiring may depend on the outcome of our evaluation of the voluntary pause of the HERO trial and related clinical programs. We also expect to incur increased expenses related to audit, legal, regulatory, and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance premiums, and investor relations costs associated with operating as a public company.

Credit Loss – Related Party Accounts Receivable

In connection with a Transition Services Agreement (the Transition Services Agreement) entered into with Aardwolf Therapeutics, Inc. (Aardwolf), which was effective through May 31, 2024, we performed certain services and billed Aardwolf monthly. As Aardwolf currently does not have the ability to repay the related party receivables, these amounts are deemed

uncollectible and have been written off until such time as Aardwolf has the ability to repay. In addition, in August 2022, we loaned Aardwolf $1.0 million in the form of a convertible promissory note, which, based on its current inability to repay, we also have written off as uncollectible. We will reassess the estimated recovery on previous written off balances at each reporting period.

Other Income (Expense), Net

Other income (expense), net consists primarily of interest income earned on our invested cash and cash equivalents, dividend income and changes in the fair value of equity securities held as investments.

Results of Operations

Comparison of the Year Ended December 31, 2025 and 2024

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

	Year Ended December 31,		
	2025	2024	Change
(in thousands)			
Operating expenses:			
Research and development	$ 48,936	$ 17,363	$ 31,573
General and administrative	13,789	5,305	8,484
Credit loss – related party accounts receivable	—	117	(117)
Total operating expenses	62,725	22,785	39,940
Loss from operations	(62,725)	(22,785)	(39,940)
Other income, net	5,134	2,197	2,937
Net loss	$ (57,591)	$ (20,588)	$ (37,003)

Research and Development Expenses

The following table summarizes our R&D expenses for each of the periods indicated:

	Year Ended December 31,		
	2025	2024	Change
(in thousands)			
External costs	$ 36,014	$ 12,659	$ 23,355
Internal costs:			
Personnel-related (including stock-based compensation expense)	11,965	4,272	7,693
Facilities-related (including depreciation) and other allocated costs	957	432	525
Total internal costs	12,922	4,704	8,218
Total R&D expenses	$ 48,936	$ 17,363	$ 31,573

R&D expenses were $48.9 million and $17.4 million for the year ended December 31, 2025 and 2024, respectively. The $31.6 million increase for the year ended December 31, 2025 as compared to the year ended December 31, 2024 resulted primarily from an increase of $23.4 million for external expenses incurred for chemistry, manufacturing and controls (CMC), clinical and toxicology studies primarily related to the development of ARD-101 and a $7.7 million increase in personnel-related costs due to increased headcount and bonuses.

General and Administrative (G&A) Expenses

G&A expenses were $13.8 million and $5.3 million for the year ended December 31, 2025 and 2024, respectively. The $8.5 million increase for the year ended December 31, 2025 as compared to the year ended December 31, 2024 resulted from a $4.5 million increase in personnel-related costs, a $2.4 million increase in legal, accounting and other professional services costs, a $0.7 million increase in facilities and other costs, a $0.6 million increase in insurance costs and a $0.2 million increase for fees paid to members of our board of directors.

Credit Loss – Related Party Accounts Receivable

Amounts written off as uncollectible related to the Transition Services Agreement with Aardwolf were zero and $0.1 million for the year ended December 31, 2025 and 2024, respectively. The $0.1 million decrease for the year ended December 31, 2025 as compared to the year ended December 31, 2024 was due to the expiration of the Transition Services Agreement in May 2024.

Other Income, Net

Other income, net was $5.1 million and $2.2 million for the year ended December 31, 2025 and 2024, respectively. The $2.9 million increase for the year ended December 31, 2025 as compared to the year ended December 31, 2024 resulted from higher interest income generated by our invested cash and lower unrealized losses recorded on the change in the fair value of our short-term investments, offset by lower dividend income.

Liquidity and Capital Resources

Sources of Liquidity

We have not generated any revenue from product sales and have incurred net losses and negative cash flows from operations since our inception and anticipate we will continue to incur net losses for the foreseeable future. From inception and up to the date of our IPO in February 2025, we had raised a total of $129.1 million in gross proceeds to fund our operations from the sale and issuance of shares of our convertible preferred stock. In February 2025, we completed our IPO with the sale of 6,120,661 shares of common stock, which included the partial exercise by the underwriters of their option to purchase 232,661 additional shares, at an initial public offering price of $16.00 per share and received net proceeds of $87.5 million.

Future Funding Requirements

As of December 31, 2025, we had cash, cash equivalents and short-term investments of $110.0 million. Based upon our current operating plans, we believe that our existing cash, cash equivalents and short-term investments will be sufficient to fund our projected operations into the second quarter of 2027. However, our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. We have based this estimate on assumptions that may prove to be wrong, and we could deplete our capital resources sooner than we expect. Additionally, the process of conducting preclinical studies, manufacturing and testing product candidates in clinical trials is costly, and the timing of progress and expenses in these studies and trials is uncertain. In February 2026, we voluntarily paused enrollment and dosing in our Phase 3 HERO trial, the open label extension trial for ARD-101, and the POWER and STRENGTH clinical trials for ARD-201. The voluntary pause of these clinical trials may affect the timing and amount of our future expenditures and our need for additional capital, depending on the outcome of our ongoing data review and discussions with the FDA regarding next steps for our clinical programs.

We have incurred significant operating losses since our inception and, as of December 31, 2025, we had an accumulated deficit of $115.9 million. We expect to continue to incur losses for the foreseeable future, and we anticipate these losses will increase substantially for the reasons described above.

Our future capital requirements are difficult to predict and depend on many factors, including but not limited to:

- the initiation, type, number, scope, progress, expansions, results, costs, and timing of clinical trials and preclinical studies of our current and future product candidates, including the costs of any third-party products used as combination agents in our combination clinical trials;
- the costs and timing of manufacturing for our product candidates, including commercial manufacture at sufficient scale, if any product candidate is approved;
- the costs, timing, and outcome of regulatory meetings and reviews of our product candidates;
- the costs of obtaining, maintaining, enforcing, and protecting our patents and other intellectual property and proprietary rights;
- our efforts to enhance operational systems and hire additional personnel to satisfy our obligations as a public company, including enhanced internal control over financial reporting;
- the costs associated with hiring additional personnel and consultants as our clinical and preclinical activities increase;
- the timing and payment of milestone, royalty or other payments we must make pursuant to our existing and potential future license or collaboration agreements with third parties;

- the costs and timing of establishing or securing sales and marketing capabilities if any product candidates is approved;
- our ability to achieve sufficient market acceptance, coverage, and adequate reimbursement from third-party payors and adequate market share and revenue for any approved products;
- patients' willingness to pay out-of-pocket for any approved products in the absence of coverage and/or adequate reimbursement from third-party payors;
- the terms and timing of establishing and maintaining collaborations, licenses, and other similar arrangements;
- costs associated with any products or technologies that we may in-license or acquire; and
- the effects of competing technological and market developments as well as disruptions to and volatility in the credit and financial markets.

We have no other committed sources of capital. Until we can generate a sufficient amount of product revenue to finance our cash requirements, if ever, we expect to finance our future cash needs primarily through equity offerings, debt financings, or other capital sources, including potential collaborations, licenses, and other similar arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. 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, 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 other collaborations or licensing arrangements with third parties, we may have to relinquish valuable rights to our future revenue streams, product candidates, research programs, intellectual property or proprietary technology, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, limit, reduce, or terminate our R&D programs or other operations, or grant rights to develop and market our product candidates to third parties that we would otherwise prefer to develop and market ourselves, or on less favorable terms than we would otherwise choose.

Cash Flows

The following table summarizes our cash flows for each of the periods indicated:

	Year Ended December 31,	
	2025	2024
(in thousands)		
Net cash used in operating activities	$ (54,172)	$ (18,087)
Net cash used in investing activities	(49,667)	(11,998)
Net cash provided by financing activities	89,249	81,991
(Decrease) increase in cash and cash equivalents	$ (14,590)	$ 51,906

Operating Activities

Net cash used in operating activities was $54.2 million and $18.1 million for the years ended December 31, 2025 and 2024, respectively. The net cash used in operating activities during the year ended December 31, 2025 was primarily due to our reported net loss of $57.6 million, net of non-cash items (including unrealized losses on short-term investments, credit losses, stock-based compensation expense and right-of-use asset amortization) totaling $3.1 million and a $0.4 million net increase of our net operating assets. The net cash used in operating activities during the year ended December 31, 2024 was primarily due to our reported net loss of $20.6 million, net of non-cash items (including unrealized losses on short-term investments, credit losses, stock-based compensation expense and right-of-use asset amortization) totaling $0.9 million and a $1.6 million net increase of our net operating assets. The increase in cash used in operations during the year ended December 31, 2025 in comparison to the year ended December 31, 2024 was primarily attributable to increased research and development activities.

Investing Activities

Net cash used in investing activities was $49.7 million and $12.0 million for the years ended December 31, 2025 and 2024, respectively, primarily as a result of the purchases of short-term investments offset by maturities/sales of short-term investments during the periods.

Financing Activities

Net cash provided by financing activities was $89.2 million and $82.0 million for the years ended December 31, 2025 and 2024, respectively. Net cash provided by financing activities for the year ended December 31, 2025 is primarily as a result of proceeds from the sale and issuance of shares of our common stock in our IPO in February 2025 for proceeds of $91.1 million, net of underwriting discounts, offset by payments for IPO costs of $2.4 million, and proceeds totaling $0.6 million from the issuance of shares of common stock under our equity plans. Net cash provided by financing activities for the year ended December 31, 2024 is primarily as a result of proceeds from the sale and issuance of shares of our Series C convertible preferred stock in May 2024 for net proceeds of $82.9 million, offset by payments for deferred IPO costs of $1.2 million.

Contractual Obligations and Other Commitments

We entered into a lease for office space commencing on August 1, 2024 and expiring on December 31, 2026. Total future aggregate operating lease commitments under the lease agreement is $0.4 million.

In August 2023, we acquired the rights to certain intellectual property, in connection with which we have payment obligations up to an aggregate of $118.5 million that are contingent upon our achievement of specified regulatory and commercial milestones. In addition, in October 2024, we acquired the rights to certain assets in exchange for an upfront cash payment of $0.6 million, in connection with which we have payment obligations up to an aggregate of $62.0 million that are contingent upon our achievement of specified regulatory and commercial milestones. As of December 31, 2025, we were unable to estimate the timing or likelihood of achieving the milestones or making future product sales. For additional information regarding this agreement, including our payment obligations thereunder, see Note 10 to our audited consolidated financial statements included elsewhere in this Annual Report.

During the normal course of our business, we enter into contracts for research and professional services, and for the purchase of lab supplies used in our research activities. These contracts generally provide for termination after a notice period, and, therefore, are cancelable contracts and not separately presented.

Off-Balance Sheet Arrangements

Since our inception, we have not had, and we do not currently have, any off-balance sheet arrangements as defined under the rules and regulations of the SEC.

Critical Accounting Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles (GAAP). The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, and expenses and the disclosure of contingent assets and liabilities in our consolidated financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses and stock-based compensation expense. 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. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 2 to our audited consolidated financial statements included elsewhere in this Annual Report, we believe the following accounting estimates to be most critical to the preparation of our consolidated financial statements.

Accrued R&D Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued R&D expenses as of each balance sheet date. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf, and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. We make estimates of our accrued R&D expenses as of each balance sheet date based on facts and circumstances known to us at that time. The significant estimates in our accrued R&D expenses include the costs incurred for services performed by our vendors in connection with services for which we have not yet been invoiced.

We base our expenses related to R&D activities on our estimates of the services received and efforts expended pursuant to quotes and contracts with vendors that conduct R&D on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract, and may result in uneven payment flows.

There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the R&D expense. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepaid expense accordingly. Advance payments for goods and services that will be used in future R&D activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made.

Although we do not expect our estimates to be materially different from amounts actually 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 actually incurred.

Recently Adopted Accounting Pronouncements

See Note 2 to our audited consolidated financial statements included elsewhere in this Annual Report for recently adopted accounting pronouncements.

Emerging Growth Company and Smaller Reporting Company Status

We qualify as an "emerging growth company," as defined in the JOBS Act. As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include: (i) being permitted to present only two years of audited financial statements, in addition to any required unaudited condensed financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure in this Annual Report; (ii) reduced disclosure about our executive compensation arrangements; (iii) not being required to hold advisory votes on executive compensation or to obtain stockholder approval of any golden parachute arrangements not previously approved; (iv) an exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act; and (v) 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 financial statements.

We may take advantage of these exemptions for up to five years or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company on the date that is the earliest of:

(i) the last day of the fiscal year in which we have total annual gross revenues of $1.235 billion or more;

(ii) December 31, 2030 (the last day of our fiscal year following the fifth anniversary of the date of the completion of our IPO);

(iii) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years; or

(iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

We may choose to take advantage of some but not all of these exemptions. We have elected to avail ourselves of this exemption and, therefore, while we are an emerging growth company we will not be subject to new or revised accounting standards at the same time that they become applicable to other public companies that are not emerging growth companies. As a result of this election, our financial statements may not be comparable to those of other public companies that comply with new or revised accounting pronouncements as of public company effective dates. We may choose to early adopt any new or revised accounting standards whenever such early adoption is permitted for private companies.

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 the market value of our shares of 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 the market value of our shares of common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Risk

Our cash and cash equivalents consist of cash held in readily available checking and money market accounts, as well as short-term debt securities. We are exposed to market risk related to fluctuations in interest rates and market prices. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. However, because of the short-term nature of the instruments in our portfolio, we do not believe a hypothetical 100 basis point increase or decrease in interest rates during any of the periods presented would have had a material impact on our audited consolidated financial statements included elsewhere in this Annual Report.

Foreign Currency

Net realized and unrealized gains and losses from foreign currency transactions are reported in other income (expense), net, in the consolidated statements of operations and comprehensive loss. All of our employees and our operations are currently located in the United States and our expenses are generally denominated in U.S. dollars. However, we have contracted with and may continue to contract with non-U.S. vendors who we may pay in local currency. To date, the impact of foreign currency costs on our operations has been negligible for all periods presented and we have not had a formal hedging program with respect to foreign currency. Therefore, we do not believe a hypothetical 100 basis point increase or decrease in exchange rates during any of the periods presented would have had a material impact on our audited consolidated financial statements included elsewhere in this Annual Report.

Inflation Risk

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation has had a material effect on our results of operations during the periods presented.

Item 8. Financial Statements and Supplementary Data.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Aardvark Therapeutics, Inc.

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Report of Independent Registered Public Accounting Firm

Stockholders and Board of Directors
Aardvark Therapeutics, Inc.
San Diego, California

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Aardvark Therapeutics, Inc. (the "Company") as of December 31, 2025 and 2024, the related consolidated statements of operations and comprehensive loss, convertible preferred stock and stockholders' equity (deficit), and cash flows for the years then ended, 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, 2025 and 2024, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

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

/s/ BDO USA, P.C.

We have served as the Company's auditor since 2021.

San Diego, California

March 23, 2026

AARDVARK THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS
(in thousands, except share and par value data)

	December 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 47,051	$ 61,641
Short-term investments	62,976	12,022
Prepaid expenses and other current assets	1,859	474
Total current assets	111,886	74,137
Operating lease right-of-use asset	355	735
Other assets	4,940	2,635
Total assets	$ 117,181	$ 77,507
Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 2,072	$ 2,298
Accrued liabilities	8,035	2,291
Operating lease liability, current portion	441	338
Total current liabilities	10,548	4,927
Operating lease liability, net of current portion	—	441
Other long-term liabilities	—	26
Total liabilities	10,548	5,394
Commitments and contingencies (Note 10)		
Convertible preferred stock, $0.00001 par value; no shares and 96,941,453 shares authorized at December 31, 2025 and 2024, respectively; no shares and 96,941,453 shares issued and outstanding at December 31, 2025 and 2024, respectively; liquidation preference of $0 and $129,135 at December 31, 2025 and 2024, respectively	—	126,756
Stockholders' equity (deficit):		
Preferred stock, $0.00001 par value; 10,000,000 and no shares authorized at December 31, 2025 and 2024, respectively; no shares issued and outstanding at December 31, 2025 and 2024	—	—
Common stock, $0.00001 par value; 490,000,000 and 157,230,354 shares authorized at December 31, 2025 and 2024, respectively; 21,815,353 and 4,075,386 shares issued at December 31, 2025 and 2024, respectively; 21,815,353 and 4,066,969 shares outstanding at December 31, 2025 and 2024, respectively	—	—
Additional paid-in capital	222,470	3,684
Accumulated other comprehensive income	81	—
Accumulated deficit	(115,918)	(58,327)
Total stockholders' equity (deficit)	106,633	(54,643)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 117,181	$ 77,507

See accompanying notes to consolidated financial statements.

AARDVARK THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except share and per share data)

	Year Ended December 31,	
	2025	2024
Operating expenses:		
Research and development	$ 48,936	$ 17,363
General and administrative	13,789	5,305
Credit loss—related party accounts receivable	—	117
Total operating expenses	62,725	22,785
Loss from operations	(62,725)	(22,785)
Other income (expense), net:		
Unrealized loss on short-term investments	(5)	(217)
Interest and dividend income	5,139	2,414
Total other income, net	5,134	2,197
Net loss	$ (57,591)	$ (20,588)
Net loss per share of common stock, basic and diluted (Note 3)	$ (2.93)	$ (5.15)
Weighted-average shares used in net loss per share calculation (Note 3)	19,624,626	3,996,376
Comprehensive loss:		
Net loss	$ (57,591)	$ (20,588)
Unrealized gain on short-term investments	81	—
Comprehensive loss	$ (57,510)	$ (20,588)

See accompanying notes to consolidated financial statements.

AARDVARK THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)
(in thousands, except share data)

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balance, December 31, 2023	48,910,723	$ 43,904	3,966,376	$ —	$ 2,937	$ —	$ (37,739)	$ (34,802)
Issuance of Series C convertible preferred stock for cash, net of issuance cost of $2,148	48,030,730	82,852	—	—	—	—	—	—
Exercise of common stock options	—	—	96,786	—	300	—	—	300
Vesting of restricted common stock	—	—	3,807	—	8	—	—	8
Stock-based compensation expense	—	—	—	—	439	—	—	439
Net loss	—	—	—	—	—	—	(20,588)	(20,588)
Balance, December 31, 2024	96,941,453	126,756	4,066,969	—	3,684	—	(58,327)	(54,643)
Issuance of common stock in initial public offering, net of discounts and issuance costs of $10.4 million	—	—	6,120,661	—	87,495	—	—	87,495
Conversion of convertible preferred stock into common stock upon initial public offering	(96,941,453)	(126,756)	11,439,838	—	126,756	—	—	126,756
Exercise of common stock options	—	—	146,926	—	355	—	—	355
Vesting of restricted common stock	—	—	11,367	—	37	—	—	37
Issuance of common stock under employee stock purchase plan	—	—	29,592	—	195	—	—	195
Stock-based compensation expense	—	—	—	—	3,948	—	—	3,948
Unrealized gain on short-term investments	—	—	—	—	—	81	—	81
Net loss	—	—	—	—	—	—	(57,591)	(57,591)
Balance, December 31, 2025	—	$ —	21,815,353	$ —	$ 222,470	$ 81	$ (115,918)	$ 106,633

See accompanying notes to consolidated financial statements.

AARDVARK THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Year Ended December 31,	
	2025	2024
Operating activities:		
Net loss	$ (57,591)	$ (20,588)
Adjustments to reconcile net loss to net cash used in operating activities:		
Credit loss—related party accounts receivables	—	117
Stock-based compensation expense	3,948	439
Non-cash lease expense	380	235
Unrealized loss on short-term investments	5	217
Amortization of discount on short-term investments	(1,306)	(96)
Depreciation expense	36	16
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(5,960)	(412)
Accounts payable	239	798
Accrued liabilities	6,415	1,385
Operating lease liability	(338)	(198)
Net cash used in operating activities	(54,172)	(18,087)
Investing activities:		
Purchases of short-term investments	(129,599)	(11,889)
Maturities/sales of short-term investments	80,027	—
Purchases of property and equipment	(95)	(109)
Net cash used in investing activities	(49,667)	(11,998)
Financing activities:		
Proceeds from sale and issuance of common stock in initial public offering, net of underwriting discounts	91,075	—
Financing costs paid in connection with initial public offering	(2,387)	—
Proceeds from sale and issuance of Series C convertible preferred stock	—	85,000
Financing costs paid in connection with issuance of Series C convertible preferred stock	—	(2,148)
Proceeds from exercises of common stock options	366	332
Proceeds from issuance of common stock under employee stock purchase plan	195	—
Costs paid in connection with deferred financing costs	—	(1,193)
Net cash provided by financing activities	89,249	81,991
Net (decrease) increase in cash and cash equivalents	(14,590)	51,906
Cash and cash equivalents at beginning of year	61,641	9,735
Cash and cash equivalents at end of year	$ 47,051	$ 61,641
Supplemental schedule of non-cash financing activity:		
Operating right-of-use assets in exchange for operating lease liability	$ —	$ 815
Early exercise options and unvested stock liability	$ 26	$ 8
Deferred financing costs included in accounts payable and accrued expenses	$ —	$ 1,136
Conversion of convertible preferred stock into common stock upon initial public offering	$ 126,756	$ —

See accompanying notes to consolidated financial statements.

1. Organization and Basis of Presentation

Description of Business

Aardvark Therapeutics, Inc. (“Aardvark” or the “Company”) was incorporated in the State of Delaware on May 17, 2017 and its principal offices are located in San Diego, California. The Company is a clinical-stage biopharmaceutical company focused on developing novel, small-molecule therapeutics to activate innate homeostatic pathways for the treatment of metabolic diseases. The Company targets biological pathways associated with alleviating hunger.

In October 2024, the Company incorporated a wholly-owned subsidiary, Artisan Therapeutics, Inc., in the State of Delaware and contributed certain assets to the new entity.

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary, Artisan Therapeutics, Inc., and have been prepared in conformity with U.S. generally accepted accounting principles (“GAAP”). All intercompany accounts and transactions have been eliminated in consolidation.

Reverse Stock Split

On February 5, 2025, the Company effected a one-for-8.474 reverse stock split of its common stock (the "Reverse Stock Split"). The par value and the authorized shares of the common stock were not adjusted as a result of the Reverse Stock Split. All issued and outstanding common stock and the conversion ratio of the redeemable convertible preferred stock have been retroactively adjusted to reflect the Reverse Stock Split for all periods presented.

Liquidity

As of December 31, 2025, the Company has devoted substantially all of its resources to organizing and staffing the Company, business planning, raising capital, discovering ARD-101, establishing and maintaining its intellectual property portfolio, conducting research, preclinical studies and clinical trials, manufacturing of ARD-101 and related raw materials, and providing general and administrative support for these operations. The Company does not have any products approved for sale and has not generated any revenue to date. In addition, the Company has a limited operating history, has incurred significant net losses and negative cash flows from operations since its inception and expects that its expenses and operating losses will increase substantially for the foreseeable future. As of December 31, 2025, the Company had an accumulated deficit of $115.9 million.

The Company believes its cash, cash equivalents and short-term investments of $110.0 million as of December 31, 2025 will be sufficient for the Company to continue as a going concern for at least one year following the date that the consolidated financial statements are available to be issued.

The Company will be required to raise additional capital and plans to finance its cash needs through public or private equity or debt financings or other capital sources, including potential collaborations, licenses and other similar arrangements. However, there can be no assurance that the Company will be able to obtain additional funding on acceptable terms, or at all. If the Company is not able to secure adequate additional funding, it may be forced to make reductions in spending, extend payment terms with suppliers, liquidate assets where possible, and/or delay or reduce the scope of its planned development programs. Any of these actions could materially harm the Company’s business, results of operations and future prospects.

Use of Estimates

The preparation of the Company’s consolidated financial statements requires the Company to make estimates and assumptions that impact the reported amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities in the consolidated financial statements and accompanying notes. Such estimates include the estimated incremental borrowing rate for the determination of the Company’s operating lease right-of-use (“ROU”) assets, valuation of stock-based awards, and the accrual of research and development expenses. Management evaluates its estimates on an ongoing basis. Although estimates are based on the Company’s historical experience, knowledge of current events, and actions it may undertake in the future, actual results may ultimately materially differ from these estimates and assumptions.

2. Summary of Significant Accounting Policies

Cash and Cash Equivalents

The Company considers all highly liquid investments that are readily convertible into cash, with original maturities of three months or less when purchased, to be cash equivalents and are stated at cost, which approximates fair value. Cash equivalents are comprised of money market mutual funds and short-term debt obligations of the U. S. Treasury.

Concentration of Credit Risk

Financial instruments which potentially subject the Company to significant concentration of credit risk consist of cash and cash equivalents and related party accounts and convertible promissory note receivable (Note 12). The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. The Company has not experienced any losses in such accounts, and management believes that the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held. The Company invests its excess cash in short-term debt obligations of the U. S. Treasury in order to mitigate credit risk and maintain principal and maximize liquidity.

Short-Term Investments

Short-term investments consist of investments in corporate equity securities with readily determinable fair values and short-term debt obligations of the U.S. Treasury with original maturities in excess of three months. The investments in corporate equity securities with readily determinable fair values are reported at fair value with changes in fair value recorded in the consolidated statements of operations and comprehensive loss. During the years ended December 31, 2025 and 2024, unrealized losses of $5,000 and $0.2 million, respectively, were reported in other income (expense), net in the accompanying consolidated statements of operations and comprehensive loss.

The Company obtains pricing information from its investment manager and generally determines the fair value of debt securities using standard observable inputs, including reported trades, broker/dealer quotes, and bid and/or offers. The Company classifies its investment securities as available-for-sale, as the sale of such securities may be required prior to maturity. Management determines the appropriate classification of its investments in debt securities at the time of purchase. Investments with original maturities beyond three months at the date of purchase and which mature at, or less than 12 months from, the balance sheet date are classified as short-term investments. Investments with contractual maturities beyond one year are also classified as short-term due to the Company's ability to liquidate the investment for use in operations within the next 12 months. Available-for-sale securities are carried at fair value, with the unrealized gains and losses reported as accumulated other comprehensive income (loss) until realized. The amortized cost of available-for-sale debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization and accretion are included in interest income. The cost of securities sold is based on the specific identification method. Interest and dividends on securities classified as available-for-sale are included in interest and dividend income in the accompanying consolidated statements of operations and comprehensive loss and accrued interest receivable is included in prepaid expenses and other current assets in the accompanying consolidated balance sheets.

At each balance sheet date, the Company reviews its available-for-sale debt securities that are in an unrealized loss position to determine whether the unrealized loss or any potential credit losses should be recognized in the consolidated statements of operations and comprehensive loss. For available-for-sale debt securities in an unrealized loss position, the Company first assesses 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. If either of the criteria regarding intent or requirement to sell is met, the security's amortized cost basis is written down to fair value through net income (loss). For available-for-sale securities that do not meet the aforementioned criteria, the Company 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, net through an allowance account. There have been no impairment or credit losses recognized during any of the periods presented related to investments in the Company's available-for-sale debt securities.

Deferred Financing Costs

Financing costs, consisting of legal, professional, accounting, and other third-party fees that are directly associated with in-process equity financings are deferred until such financings are consummated. After consummation of the equity financing, these costs are recorded in stockholders' equity (deficit) as a reduction of proceeds generated as a result of the offering. In the event a financing is terminated, the deferred financing costs will be expensed as a charge to operating expenses in the consolidated statements of operations and comprehensive loss. As of December 31, 2025 and 2024, capitalized deferred financing costs totaled zero and $2.3 million, respectively, and are included in other assets in the accompanying consolidated balance sheets.

Fair Value of Financial Instruments

The carrying amounts of cash equivalents, prepaid expenses and other current assets, accounts payable, and accrued expenses are considered to be representative of their respective fair values because of the short-term nature of those instruments.

Leases

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the unique facts and circumstances present, the existence of an identified asset(s), if any, and the Company's control over the use of the identified asset(s), if applicable.

Operating leases are included in operating lease right-of-use assets and in operating lease liabilities in the accompanying consolidated balance sheets. Operating lease assets represent the Company's right to use an underlying asset for the lease term, and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Operating lease liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term discounted based on the more readily determinable of (i) the rate implicit in the lease or (ii) the Company's incremental borrowing rate (which is the estimated rate the Company would be required to pay for a collateralized borrowing equal to the total lease payments over the term of the lease). Because the Company's operating leases do not provide an implicit rate, the Company estimates its incremental borrowing rate based on the information available at lease commencement date for borrowings with a similar term.

The Company's operating lease assets are measured based on the corresponding operating lease liability adjusted for (i) payments made to the lessor at or before the commencement date, (ii) initial direct costs incurred and (iii) tenant incentives under the lease. The Company does not assume renewals or early terminations unless it is reasonably certain to exercise such options at commencement. The Company has elected the practical expedient such that it does not recognize lease assets or lease liabilities for leases with a term of 12 months or less of all asset classes and to not allocate consideration between lease and non-lease components. Variable lease payments are recognized in the period in which the obligations for those payments are incurred. Operating lease expense is recognized on a straight-line basis over the lease term.

Convertible Preferred Stock

Prior to the completion of the Company's initial public offering ("IPO") in February 2025, the Company had outstanding convertible preferred stock which was classified as temporary equity in the accompanying consolidated balance sheets in accordance with authoritative guidance for the classification and measurement of potentially redeemable securities whose redemption is based upon certain change in control events outside of the Company's control, including liquidation, sale or transfer of control of the Company. Costs incurred in connection with the issuance of convertible preferred stock were recorded as a reduction of gross proceeds from issuance. The Company did not accrete the carrying values of the convertible preferred stock to the redemption values since the occurrence of any of these events was not considered probable as of December 31, 2024. Immediately prior to the closing of the IPO in February 2025, the Company's outstanding convertible preferred stock automatically converted into 11,439,838 shares of common stock. Following the closing of the IPO, no shares of convertible preferred stock were authorized or outstanding.

Research and Development Expenses

Research and development expenses are charged to expense as incurred. Research and development expenses consist primarily of external and internal costs incurred in performing preclinical and clinical development activities. External costs include fees paid to contract research organizations and consultants in connection with product development activities, including regulatory activities, costs related to manufacturing materials for preclinical studies and clinical trials and license fees. Internal costs include personnel-related costs such as salaries and related expenses for employees involved in research and development efforts, facilities-related costs, depreciation, and other allocated expenses. Non-refundable advance payments for goods and services for future research and development activities are deferred and included in other assets in the accompanying consolidated balance sheets and are expensed as the goods are delivered or the related services are performed.

The Company estimates its expenses resulting from its obligations under contracts with vendors, consultants, and contract research organizations in connection with the progress of research and development services performed. The financial terms of these contracts vary from contract to contract and may result in payment flows that do not match the periods over which the services are provided or goods delivered under such contracts. The Company reflects research and development expenses in its consolidated financial statements by matching those expenses with the period in which services are provided. The Company accounts for these expenses according to the progress of the preclinical or clinical study as measured by the timing of various aspects of the study or the progress of related activities. During the course of a study, the Company reassesses its estimate of performance prospectively based on

actual results or any modification to the agreements. Historically, there have been no material differences between the Company's estimates and the amounts actually incurred.

Patent Costs

Costs related to filing and pursuing patent applications are recorded as general and administrative expense and expensed as incurred since recoverability of such expenditures is uncertain.

Stock-Based Compensation Expense

Stock-based compensation expense represents the grant date fair value of employee and non-employee stock award grants recognized as expense over the requisite service period of the awards (usually the vesting period) on a straight-line basis, net of actual forfeitures during the period. The Company estimates the fair value of stock option grants using the Black-Scholes option pricing model.

For restricted stock awards, the fair value of the award is the estimated fair value of the Company's common stock on the grant date.

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, deferred tax assets and liabilities are determined on the basis of the differences between the consolidated financial statements and tax basis of assets and liabilities 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 the Company believes these assets are more likely than not to be realized. In making such a determination, management 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 management determines that the Company would be able to realize its deferred tax assets in the future in excess of their recorded amount, management 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 on the basis of a two-step process whereby (i) management 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 (ii) for those tax positions that meet the more-likely-than-not recognition threshold, management 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 within income tax expense. Any accrued interest and penalties are included within the related tax liability.

Comprehensive Loss

Comprehensive loss is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources, including unrealized gains and losses on certain investments. For the year ended December 31, 2025, comprehensive loss includes unrealized gains on short-term investments. Net loss and comprehensive loss were the same for the year ended December 31, 2024.

Recent Accounting Standards

From time to time, new accounting standards are issued by the Financial Accounting Standards Board ("FASB") or other standard setting bodies and adopted by the Company as of the specified effective date. Unless otherwise discussed, the impact of

recently issued standards that are not yet effective will not have a material impact on the Company's financial position or results of operations upon adoption.

Recently Adopted Accounting Standards

In December 2023, the FASB issued Accounting Standards Update ("ASU") No. 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures* ("ASU 2023-09"), which focuses on the rate reconciliation and income taxes paid. ASU 2023-09 requires public business entities to disclose, on an annual basis, specific categories in the effective tax rate reconciliation and provide additional information for reconciling items that meet a quantitative threshold. In addition, ASU 2023-09 requires companies to disclose further information about income taxes paid. The standard is effective for annual periods beginning after December 15, 2024, and may be applied prospectively or retrospectively. The Company adopted ASU 2023-09 retrospectively for the years ended December 31, 2025 and 2024, and it affects only the Company's disclosures and does not impact its results of operations or financial condition.

Recently Issued Accounting Standards Not Yet Adopted

In November 2024, the FASB issued ASU No. 2024-03, *Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40)* ("ASU 2024-03"), which requires new financial statement disclosures in tabular format, in the notes to the consolidated financial statements, of specified information about certain costs and expenses. This update is effective for all entities beginning after December 15, 2026 and interim periods within fiscal years beginning after December 15, 2027. ASU 2024-03 can be applied prospectively or retrospectively and early adoption is permitted. The Company is currently evaluating the impact of this guidance on its consolidated financial statements and related disclosures.

3. Net Loss Per Share

Basic net loss per share of common stock attributable to common stockholders is calculated by dividing the net loss by the weighted-average number of shares of common stock outstanding during the period, without consideration of potentially dilutive securities. Diluted net loss per share attributable to common stockholders is computed by dividing the net loss by the weighted-average number of shares of common stock and potentially dilutive securities outstanding for the period. The Company has excluded 4,040 and 2,548 weighted-average shares subject to repurchase or forfeiture from the weighted-average number of shares of common stock outstanding for the years ended December 31, 2025 and 2024, respectively.

Basic and diluted net loss attributable to common holders per share is presented in conformity with the two-class method required for participating securities as the convertible preferred stock were considered participating securities because they participated in dividends with the common stock. The Company also considers the shares issued upon the early exercise of stock options subject to repurchase to be participating securities because holders of such shares have non-forfeitable dividend rights in the event a dividend is paid on common stock. The holders of all series of convertible preferred stock and the holders of early exercised shares subject to repurchase do not have a contractual obligation to share in the Company's losses. As such, the net loss was attributed entirely to common stockholders. Because the Company has reported a net loss for all periods presented, diluted net loss per share is the same as basic net loss per share for those periods. Accordingly, for the years ended December 31, 2025 and 2024, there is no difference in the number of shares used to calculate basic and diluted shares outstanding.

The Company excluded the following potential shares of its common stock, presented based on amounts outstanding at each period end, from the computation of diluted net loss per share for the periods indicated because including them would have had an anti-dilutive effect:

	December 31,	
	2025	2024
Conversion of outstanding convertible preferred stock	—	11,439,841
Options to purchase common stock	3,038,413	991,058
Common stock subject to repurchase rights	—	8,417
Employee Stock Purchase Plan shares	7,244	—
Total	3,045,657	12,439,316

4. Fair Value Measurements

The accounting guidance defines fair value, establishes a consistent framework for measuring fair value and expands disclosure for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. Fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, the accounting guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1—Quoted prices in active markets for identical assets or liabilities.

Level 2—Observable inputs, 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 and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

As of December 31, 2025 and 2024, assets measured at fair value on a recurring basis were as follows (in thousands):

	December 31, 2025			
	Total	Level 1	Level 2	Level 3
Assets				
Cash equivalents				
Money market funds	$ 29,379	$ 29,379	$ —	$ —
U.S. Treasury bonds	4,999	—	4,999	—
Total cash equivalents	$ 34,378	$ 29,379	$ 4,999	$ —
Short-term investments				
Scilex Holding Company common stock	$ 30	$ 30	$ —	$ —
Sorrento Therapeutics, Inc. common stock	2	2	—	—
U.S. Treasury bonds	62,944	—	62,944	—
Total short-term investments	$ 62,976	$ 32	$ 62,944	$ —

	December 31, 2024			
	Total	Level 1	Level 2	Level 3
Assets				
Cash equivalents				
Money market mutual funds	$ 43,426	$ 43,426	$ —	$ —
Total cash equivalents	$ 43,426	$ 43,426	$ —	$ —
Short-term investments				
Scilex Holding Company common stock	$ 37	$ 37	$ —	$ —
Sorrento Therapeutics, Inc. common stock	—	—	—	—
U.S. Treasury bonds	11,985	—	11,985	—
Total short-term investments	$ 12,022	$ 37	$ 11,985	$ —

Cash Equivalents

There were no transfers in or out of Level 3 during the years ended December 31, 2025 and 2024.

The Company determines the fair value of its money market mutual funds and treasury bonds based upon quoted prices in active markets for identical and similar assets, as applicable. At December 31, 2025 and 2024, the Company did not hold any investments, within cash equivalents, that were in a material unrealized gain or loss position.

5. Short-Term Investments

The following tables summarize the available-for-sale investment debt securities held at December 31, 2025 and 2024 (in thousands):

	December 31, 2025			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Total Fair Value
U.S. Treasury bonds	$ 62,863	$ 81	$ —	$ 62,944
Total	$ 62,863	$ 81	$ —	$ 62,944

	December 31, 2024			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Total Fair Value
U.S. Treasury bonds	$ 11,985	$ —	$ —	$ 11,985
Total	$ 11,985	$ —	$ —	$ 11,985

As of December 31, 2025, the available-for-sale investment debt securities by contractual maturity were as follows (in thousands):

	Amortized Cost	Fair Value
Due in one year or less	$ 62,863	$ 62,944
Total	$ 62,863	$ 62,944

6. Balance Sheet Details

Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	December 31,	
	2025	2024
Research and development costs	$ 4,700	$ 1,222
Compensation-related expenses	2,913	225
Deferred offering costs	—	671
Other	422	173
Total accrued liabilities	$ 8,035	$ 2,291

7. Stockholders' Equity (Deficit)

Initial Public Offering and Related Transactions

In February 2025, the Company completed its IPO with the sale of 6,120,661 shares of common stock at an initial public offering price of $16.00 per share, which included the partial exercise by the underwriters of their option to purchase 232,661 additional shares, which resulted in net proceeds to the Company of approximately $87.5 million, after deducting underwriting discounts and commissions of approximately $6.9 million and offering-related transaction costs of approximately $3.5 million.

In addition, in connection with the completion of the IPO on February 14, 2025, all outstanding shares of convertible preferred stock were converted into 11,439,838 shares of the Company's common stock and the Company's certificate of incorporation was amended and restated to authorize 490,000,000 shares of common stock and 10,000,000 shares of undesignated preferred stock.

Convertible Preferred Stock

During 2024, the Company issued 48,030,730 shares of its Series C convertible preferred stock at a per share price of $1.7697, resulting in gross cash proceeds of $85.0 million.

At December 31, 2024, the Company's convertible preferred stock consisted of the following (in thousands, except share and per share amounts):

Series	Shares Authorized	Shares Outstanding	Per Share Original Issuance and Conversion Price	Liquidation Preference	Carrying Value
Series A	26,250,131	26,250,131	$ 0.5714	$ 15,000	$ 14,850
Series B	22,660,592	22,660,592	$ 1.2857	29,135	29,054
Series C	48,030,730	48,030,730	$ 1.7697	85,000	82,852
Total	96,941,453	96,941,453		$ 129,135	$ 126,756

At December 31, 2024, the Company's convertible preferred stock was classified as temporary equity in the accompanying consolidated balance sheets in accordance with authoritative guidance for the classification and measurement of potentially redeemable securities whose redemption is based upon certain change in control events outside of the Company's control, including liquidation, sale or transfer of control of the Company. Costs incurred in connection with the issuance of convertible preferred stock were recorded as a reduction of gross proceeds from issuance. The Company did not accrete the carrying values of the convertible preferred stock to the redemption values since the occurrence of any of these events was not considered probable as of December 31, 2024.

Equity Incentive Plans

In December 2024, the Company's board of directors adopted the 2025 Equity Incentive Plan (the "2025 Plan"), and the Company's stockholders approved the 2025 Plan in February 2025. The 2025 Plan, pursuant to which 2,150,000 shares were initially reserved for issuance, became effective on February 11, 2025. Upon the effectiveness of the 2025 Plan, no further grants will be made under the 2017 Stock Plan (as amended, the "Plan"). In May 2025, the Company adopted the 2025 Inducement Equity Incentive Plan (the "2025 Inducement Plan", and collectively with the 2025 Plan and the Plan, referred to as the "Plans") pursuant to which an additional 900,000 shares of common stock were reserved to be used exclusively for the grant of equity awards as a material inducement for individuals to commence employment at the Company in compliance with Nasdaq Listing Rule 5635(c)(4).

The maximum term of the options granted under the Plans is no more than ten years. Grants generally vest at 25% one year from the vesting commencement date and ratably each month thereafter for a period of 36 months, subject to continuous service. The Plans allow for the early exercise of all stock options granted if authorized by the board of directors at the time of grant. Any shares of common stock issued from the early exercise of stock options are restricted and vest over time. The Company has the option to repurchase any unvested shares at the lower of the original issue price or current fair value upon any voluntary or involuntary termination of such optionee.

Stock option activity for employee and nonemployee awards and related information is as follows:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding and expected to vest at December 31, 2024	991,058	$ 3.83	8.4	$ 3,175
Granted	2,315,283	$ 10.81		
Exercised	(149,876)	$ 2.43		
Canceled/forfeited	(118,052)	$ 7.44		
Outstanding and expected to vest at December 31, 2025	3,038,413	$ 9.08	9.0	$ 12,360
Exercisable at December 31, 2025	374,682	$ 3.44	6.9	$ 3,627

Aggregate intrinsic value in the above table is the difference between the estimated fair value of the Company's common stock as of either December 31, 2025 or 2024, and the exercise price of stock options that had exercise prices below that value. The aggregate intrinsic value of stock options exercised during the year ended December 31, 2025 and 2024 was $1.1 million and $0.1 million, respectively.

Employee Stock Purchase Plan

In January 2025, the Company's board of directors adopted the 2025 Employee Stock Purchase Plan (the "ESPP"), which became effective on February 11, 2025. The ESPP permits participants to purchase common stock through payroll deductions of up to 100% of their eligible compensation. Initially, a total of 215,000 shares of common stock was reserved for issuance under the ESPP. The first offering period under the ESPP commenced in April 2025. Stock compensation expense for the year ended December 31, 2025 related to the ESPP was immaterial. As of December 31, 2025, the unrecognized compensation cost related to current offering periods under the ESPP was $0.8 million and is expected to be recognized over a weighted-average period of 1.0 year.

Stock-Based Compensation Expense

The weighted-average assumptions used in the Black-Scholes option pricing model to determine the fair value of the stock options granted in the years ended December 31, 2025 and 2024 were as follows:

	Year Ended December 31,	
	2025	2024
Risk-free interest rate	4.09%	4.05%
Expected volatility	103.3%	101.7%
Expected term (in years)	6.0	6.0
Expected dividend yield	—	—

Risk-free interest rate. The Company based the risk-free interest rate assumption on the U.S. Treasury's rates for U.S. Treasury zero-coupon bonds with maturities similar to those of the expected term of the award being valued.

Expected volatility. Given the limited trading history for the Company's common stock, the expected volatility assumption is based on volatilities of a peer group of similar companies whose share prices are publicly available. The peer group was developed based on companies in the biotechnology industry.

Expected term. The expected term represents the period of time that options are expected to be outstanding. Because the Company does not have historical exercise behavior, it determines the expected life assumption using the "simplified" method, which is an average of the contractual term of the option and its vesting period.

Expected dividend yield. The Company used an expected dividend yield of zero, as it has never paid dividends on its common stock and has no present intention of doing so in the foreseeable future.

The weighted-average fair value of stock options granted during the years ended December 31, 2025 and 2024 was $8.84 and $3.67 per share, respectively.

The allocation of stock-based compensation expense was as follows (in thousands):

	Year Ended December 31,	
	2025	2024
Research and development expense	$ 1,731	$ 288
General and administrative expense	2,217	151
Total stock-based compensation expense	$ 3,948	$ 439

As of December 31, 2025, the unrecognized compensation cost related to outstanding time-based options was $18.4 million and is expected to be recognized over a weighted-average period of 3.2 years.

Early Exercise Liability

The right to repurchase shares that were exercised prior to the time the options have vested generally lapses over the four-year vesting period. As of December 31, 2025 and 2024, the early exercise liability was approximately zero and $26,000, respectively, and is included in other long-term liabilities. For accounting purposes, the early exercise of options is not considered to be a substantive exercise until the underlying awards vest and are not considered to be outstanding until those shares vest.

A summary of the unvested common stock issued pursuant to an early exercise of stock option awards is as follows:

	Number of Unvested Shares
Balance at January 1, 2025	8,417
Early-exercised stock options	2,950
Vested shares	(11,367)
Balance at December 31, 2025	—

Common Stock Reserved for Future Issuance

Common stock reserved for future issuance consisted of the following:

	December 31,	
	2025	2024
Conversion of outstanding convertible preferred stock	—	11,439,841
Outstanding stock options	3,038,413	991,058
Shares available for issuance under the Plans	849,328	1,164,562
Shares available for issuance under the ESPP	185,408	—
Total	4,073,149	13,595,461

8. Income Taxes

The Company's pretax loss for 2025 and 2024 was solely due to domestic operations.

For the years ended December 31, 2025, and 2024, due to the operating losses reported and the full valuation allowance recorded on the Company’s net deferred income tax assets, the Company recorded no provision for income taxes.

There were no federal or state payments for income taxes in 2025 or 2024.

A reconciliation of the Company’s income taxes to the amount computed by applying the statutory federal income tax rate to the pretax loss is summarized as follows (in thousands):

	Year Ended December 31,			
	2025		2024	
Tax at statutory rates	$ (12,094)	21.0%	$ (4,323)	21.0%
State and local income taxes, net of federal income tax effect*	(136)	0.2%	(50)	0.2%
Effects of changes in tax laws or rates in the current period	—	—	—	—
Tax credits:				
Research and development credits	(5,286)	9.2%	(2,986)	14.5%
Change in valuation allowance	15,766	(27.4)%	6,146	(29.8)%
Nontaxable or nondeductible items:				
Stock-based compensation expense	221	(0.4)%	84	(0.4)%
Research expenses	—	—	347	(1.7)%
Executive compensation	138	(0.2)%	—	—
Permanent differences	20	—	(14)	0.1%
Changes in unrecognized tax benefits	1,371	(2.4)%	796	(3.9)%
Other, net	—	—	—	—
Total income tax expense (benefit)	$ —	—	$ —	—

*State income taxes in California comprise the majority (greater than 50%) of the tax effect in this category.

Significant components of the Company's deferred income taxes were as follows (in thousands):

	December 31,	
	2025	2024
Deferred tax assets:		
Net operating loss carryforward	$ 23,497	$ 8,627
Capitalized R&D	3,731	4,202
Investment in securities	1,301	1,298
R&D tax credits	7,659	3,256
Allowance for receivables	711	696
Other, net	1,761	628
Total gross deferred tax assets	38,660	18,707
Deferred tax liabilities:		
Right-of-use asset	(99)	(206)
Cash to accrual method change	(32)	(63)
Other, net	(7)	(2)
Total gross deferred tax liabilities	(138)	(271)
Valuation allowance	(38,522)	(18,436)
Net deferred tax assets	$ —	$ —

The Company establishes a valuation allowance when it is more likely than not that the Company's recorded net deferred tax asset will not be realized. In determining whether a valuation allowance is required, the Company must take into account all positive and negative evidence with regard to the utilization of a deferred tax asset. As of December 31, 2025 and 2024, the valuation allowance for deferred tax assets totaled approximately $38.5 million and $18.4 million, respectively. The net change in the total valuation allowance for the years ended December 31, 2025 and 2024 was an increase of $20.1 million and $7.8 million, respectively.

As of December 31, 2025, the Company had federal and state net operating carryforwards of approximately $79.3 million and $96.5 million, respectively. The federal loss carryforwards will carryforward indefinitely and can be used to offset up to 80% of future annual taxable income. The state loss carryforwards begin expiring in 2037, unless previously utilized.

As of December 31, 2025, the Company had federal and state research and development credit carryforwards totaling $2.0 million and $1.4 million, respectively. As of December 31, 2025, the Company also had federal orphan drug credit carryovers of $7.1 million. The federal credits begin to expire in 2041, unless previously utilized. State credits of $0.2 million begin to expire in 2040, unless previously utilized, while the remainder of the credits will carryforward indefinitely.

Pursuant to Internal Revenue Code of 1986, as amended ("IRC"), Sections 382 and 383, annual use of the Company's federal and state net operating loss and research and development credit carryforwards may be limited in the event a cumulative change in ownership of more than 50% occurs within a three-year period. The Company has not completed an IRC Section 382 and 383 analysis regarding the limitation of net operating loss and research and development credit carryforwards. The deferred tax asset associated with the Company's federal and state net operating losses is fully offset by a valuation allowance. Due to the existence of the valuation allowance, future changes in the Company's unrecognized tax benefits will not impact its effective tax rate. Any carryforwards that will expire prior to utilization as a result of such limitations will be removed from deferred tax assets with a corresponding reduction of the valuation allowance. The Company intends to complete an IRC Section 382 study in the future, which could result in reductions to deferred tax assets and related valuation allowance disclosed above.

Uncertain tax positions are evaluated based upon the facts and circumstances that exist at each reporting period. Subsequent changes in judgment based upon new information may lead to changes in recognition, derecognition, and measurement. Adjustment may result, for example, upon resolution of an issue with the taxing authorities or expiration of a statute of limitations, barring an assessment for an issue. The Company recognizes a tax benefit from an uncertain tax position when it is more-likely-than-not that it will be sustained upon examination by tax authorities.

A reconciliation of the amount of unrecognized tax benefits is as follows (in thousands):

	Year Ended December 31,	
	2025	2024
Beginning balance	$ 1,104	$ 294
Additions related to current year positions	1,494	810
Additions (decreases) related to prior year positions	(86)	—
Additions (decreases) due to settlement	—	—
Expiration of unrecognized tax benefits	—	—
Ending balance	$ 2,512	$ 1,104

The Company's policy is to include interest and penalties related to unrecognized income tax benefits as a component of income tax expense. The Company has no accruals for interest or penalties in the accompanying consolidated balance sheet as of December 31, 2025 or 2024 and has not recognized interest or penalties in the accompanying consolidated statements of operations and comprehensive loss for the years then ended.

The Company is subject to taxation in the United States and various state jurisdictions. The Company is generally subject to examination by U.S. federal and state tax authorities from inception to date; however, to the extent allowed by law, the taxing authorities may have the right to examine periods where net operating losses were generated and carried forward and make adjustments to the amount of the net operating losses. The Company is not currently under examination by any jurisdictions.
On July 4, 2025, the One Big Beautiful Bill Act (the "Act") was signed into law. Among other changes, the Act reinstates and makes permanent 100% first-year bonus depreciation under Section 168(k) for qualified property acquired and placed in service after January 19, 2025. Additionally, the Act permanently allows immediate expensing of domestic research and experimentation expenditures under Section 174 for tax years beginning after December 31, 2024. The Company has reflected the effects of the Act in its income tax provision in accordance with authoritative guidance. Due to the full valuation allowance, the Act did not have a material impact on the Company's consolidated financial statements.

9. Leases

Commencing August 1, 2024, the Company leased office space in San Diego, California for a term of 29 months (the "2024 Lease"). Total payments under the lease of approximately $0.9 million will be paid in monthly payments through December 31, 2026. The lease includes an option to renew for 36 months; however, the Company has not included the optional renewal period in the measurement of the lease liability because it is not reasonably certain that the Company will exercise this renewal option.

The Company recognized an operating lease ROU asset and liability for the 2024 Lease based on the present value of the future minimum lease payments over the lease term at the commencement date, using the Company's assumed incremental borrowing rate and amortizes the ROU asset and liability over the lease term. As the 2024 Lease does not have an implicit interest rate, the present value reflects a 7.0% discount rate, which is the Company's estimated incremental borrowing rate. The weighted-average remaining lease term and discount rate related to the Company's operating lease liabilities as of December 31, 2025 was 1.0 year and 7.0%, respectively. The weighted-average remaining lease term and discount rate related to the Company's operating lease liabilities as of December 31, 2024 was 1.9 years and 7.0%, respectively.

Maturities of lease liabilities due under the operating lease agreements as of December 31, 2025 were as follows (in thousands):

Maturity of Lease Liability	Operating Lease
2026	$ 458
Total lease payments	458
Less imputed interest	(17)
Total operating lease liability	441
Less current portion of operating lease liability	(441)
Operating lease liability, net of current portion	$ —

Cash paid for amounts included in the measurement of lease liabilities for operating cash flow from operating leases during the years ended December 31, 2025 and 2024 totaled $0.3 million and $0.2 million, respectively.

10. Commitments and Contingencies

Acquisition-Related Liabilities

The Company has previously acquired the rights to certain intellectual property in exchange for an upfront cash payments and the sellers' right to receive additional consideration upon the achievement of specified regulatory and commercial milestones associated with products developed by the Company utilizing the acquired in-process research and development. At December 31, 2025, potential future regulatory and commercial milestone payments under these agreements totaled an aggregate of approximately $180.5 million.

Contingencies

From time to time, the Company may become subject to claims or suits arising in the ordinary course of business. The Company accrues a liability for such matters when it is probable that future expenditures will be made and such expenditures can be reasonably estimated. As of December 31, 2025, the Company's management is not aware of any legal proceedings or matters that could have a material adverse effect on the Company's financial position, results of operations or cash flows.

Indemnification Agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with officers and members of its board of directors that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. At December 31, 2025, no claims exist under indemnification arrangements and accordingly, no amounts have been accrued in its consolidated financial statements as of December 31, 2025.

11. Related Party Transactions

The Company's Chief Executive Officer is a member of the board of directors of Aardwolf Therapeutics, Inc. (Note 12).

12. Aardwolf Therapeutics, Inc.

In May 2022, through a series of transactions, the Company spun off certain assets of the Company ("the Spinoff") to Aardwolf Therapeutics, Inc. ("Aardwolf"). In accordance with authoritative guidance, the Company has determined that it holds a variable interest in Aardwolf and Aardwolf meets the definition of a variable interest entity ("VIE") as Aardwolf does not have the ability to finance its activities without additional subordinated financial support and its equity investors will not absorb their proportionate share of expected losses. However, as the Company does not have both (i) the power to direct the economically significant activities of Aardwolf and (ii) the obligation to absorb losses of, or the right to receive benefits from, Aardwolf, the Company is not considered the primary beneficiary of Aardwolf and has not consolidated the financial position or results of operations of Aardwolf in the accompanying consolidated financial statements, although Aardwolf is considered a related party of the Company. The Company will continuously perform this assessment, as changes to existing relationships or future transactions may result in the consolidation or deconsolidation of a VIE. At December 31, 2025 and 2024, the maximum exposure to loss was zero.

13. 401(k) Plan

The Company established a defined-contribution savings plan under Section 401(k) of the IRC (the "401(k) Plan"). The 401(k) Plan covers all employees who meet defined minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pretax basis. The Company's contributions to the 401(k) Plan in the years ended December 31, 2025 and 2024 totaled $0.2 million and $0.1 million, respectively.

14. Segment Reporting

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker ("CODM"), or decision-making group, in making decisions regarding resource allocation and assessing performance. The Company's CODM is its Chief Executive Officer. No product revenue has been generated since inception and all assets are held in the United States.

The Company views its operations and manages its business as one operating segment, focused on the discovery and development of novel therapies for the treatment of metabolic diseases. Segment profit or loss is measured as the Company's net loss as reported on the Company's consolidated statements of operations and comprehensive loss. The Company monitors its cash and cash equivalents and short-term investments as reported on the Company's consolidated balance sheets to determine funding for its research and development.

As the Company does not currently generate revenue, the CODM assesses Company performance through the achievement of pre-clinical and clinical research goals. In addition to the Company's consolidated statements of operations and comprehensive loss, the CODM is regularly provided with budgeted and forecasted expense information which is used to determine the Company's liquidity needs and cash allocation. The measure of segment assets is reported on the consolidated balance sheets as total assets.

Segment net loss, including significant segment expenses regularly provided to the CODM, are as follows (in thousands):

	Year Ended December 31,	
	2025	2024
Research and development expenses:		
Research expenses	$ 36,014	$ 12,659
Personnel-related (including stock-based compensation expense)	11,965	4,272
Facilities-related and other allocated costs	957	432
Total Research and development expenses	48,936	17,363
General and administrative expenses	13,789	5,305
Credit loss – related party accounts receivable	-	117
Interest and dividend income	(5,139)	(2,414)
Unrealized losses on short-term investments	5	217
Net Loss	$ (57,591)	$ (20,588)

15. Subsequent Events

Formation of Wholly-Owned Subsidiary

In February 2026, the Company incorporated a wholly-owned subsidiary, Ardia Therapeutics, Inc., in the State of Delaware and contributed certain assets to the new entity.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

We are responsible for maintaining disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Disclosure controls and procedures are controls and other procedures designed to ensure that the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and our principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

Based on our management's evaluation (with the participation of our principal executive officer and our principal financial officer) of our disclosure controls and procedures as required by Rule 13a-15 under the Exchange Act, our principal executive officer and our principal financial officer have concluded that our disclosure controls and procedures were effective at the reasonable level of assurance as of December 31, 2025, the end of the period covered by this Annual Report.

Remediation of the Material Weakness Identified as of December 31, 2024

In connection with the audit of our consolidated financial statements as of and for the year ended December 31, 2024, a material weakness was identified in our internal controls over financial reporting related to a lack of controls in the financial reporting process, including a lack of segregation of duties and the documentation and design of formalized processes and procedures. Specifically, we lacked a sufficient number of qualified resources to ensure adequate oversight and accountability over the performance of controls, including the retention of control evidence, while maintaining appropriate segregation of duties. Without such resources, we did not design and did not maintain effective general controls over information systems that supported the financial reporting process. This material weakness could have resulted in a misstatement of substantially all of our accounts or caused us to include disclosures that could have resulted in a material misstatement of our annual or interim consolidated financial statements that could not have been prevented or detected.

To remediate the deficiencies described above and prevent similar deficiencies in the future, in late 2024, we began to take steps to address the material weakness through our remediation plan, which included the hiring of additional experienced accounting and financial reporting personnel, formalizing the design and implementation of internal controls over the financial reporting process, including general controls over information systems, and implementing a new enterprise resource planning system. The improvements and enhancements made to our internal control environment were in place as of December 31, 2025, and based on the evaluation of relevant internal controls, management has concluded that the material weakness previously identified had been remediated as of December 31, 2025.

We cannot provide complete assurance that other material weaknesses or significant deficiencies will not occur in the future or that we will be able to remediate such weaknesses or deficiencies in a timely manner. The occurrence of such material weaknesses or our inability to remediate these deficiencies could impair our ability to accurately and timely report our financial position, results of operations or cash flows.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) and 15d-15(f) under the Exchange Act. Our management, including our Chief Executive Officer and Chief Financial Officer, conducted an evaluation of the effectiveness of our internal control over financial reporting based on the 2013 framework in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2025.

Inherent Limitations on Effectiveness of Controls

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls or our internal control over financial reporting will prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of a simple error or mistake.

Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the controls. The design of any system of controls is also based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Attestation Report of the Registered Public Accounting Firm

This Annual Report does not include an attestation report of our registered public accounting firm due to an exemption provided by the JOBS Act for "emerging growth companies."

Changes in Internal Control over Financial Reporting

As of December 31, 2025, we have remediated the material weakness in our internal controls over financial reporting identified as of December 31, 2024, as disclosed in Part II, Item 9A, "Item 9A. Controls and Procedures", of this Annual Report for additional detail. There were no other changes to our internal control over financial reporting that occurred during the quarter ended December 31, 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

Rule 10b5-1 Trading Arrangements

From time to time, our officers (as defined in Rule 16a–1(f)) and directors may enter into Rule 10b5-1 or non-Rule 10b5-1 trading arrangements (as each such term is defined in Item 408 of Regulation S-K). During the quarter ended December 31, 2025, none of our officers or directors adopted or terminated any such trading arrangements.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Executive Officers and Directors

Set forth below is certain biographical and other information regarding our directors and executive officers as of February 28, 2026.

Name	Age	Position(s)
Executive Officers and Employee Directors:		
Tien-Li Lee, M.D.	51	Chief Executive Officer and Director
Manasi Jaiman, M.D., M.P.H.	45	Chief Medical Officer
Nelson Sun	49	Chief Financial Officer and Chief Operating Officer
Non-Employee Directors:		
Jeffrey Chi, Ph.D.(1)(2)(3)	57	Lead Independent Director
Roy D. Baynes, M.D., Ph.D.(1)(2)	71	Director
Susan E. Graf(2)(3)	53	Director
Victor Tong, Jr.(1)(3)	42	Director

(1) Member of the Nominating and Corporate Governance Committee.
(2) Member of the Compensation Committee.
(3) Member of the Audit Committee.

Executive Officers and Employee Directors

Tien-Li Lee, M.D. is our founder and has served as our Chief Executive Officer since March 2017. Dr. Lee has over 20 years of experience as a biotechnology innovator and executive who has been integrally involved with the founding or advancement of several biopharmaceutical companies. Prior to founding our company, Dr. Lee joined NantKwest, Inc. (Nasdaq: NK), a publicly-traded immunotherapy company, in 2013 and served as its Chief Strategy Officer until March 2017. Prior to this, Dr. Lee served as the Director of Business Development at Simcere Pharmaceutical Group from 2011 to 2013 and as the co-founder and Vice President of Business Development of Onkor Pharma, Inc. from 2007 to 2011. His experience includes therapeutics for immunology, cardiovascular, oncology, neurology and infectious disease indications. Dr. Lee served as a director of Scilex Holding Company from March 2019 to August 2023. Dr. Lee is also an inventor or co-inventor of multiple biomedical and biotechnology innovations, licensed or assigned to several companies for development including NantKwest, Inc., Simcere Pharmaceutical Group, Cellics Therapeutics, Inc. and our company. Dr. Lee received his M.D. from the University of California, San Diego and his B.A. from the University of California, Berkeley in Molecular Biology where he was also a Regents and Alumni Scholar. Dr. Lee received post-graduate training in Internal Medicine at University of California Los Angeles and Physical Medicine and Rehabilitation at University of California Irvine.

We believe Dr. Lee's position as our Chief Executive Officer and founder of our company as well as his experience in management roles at life sciences companies and extensive academic and professional background in the field of biotechnology provide him with the qualifications and skills to serve on our board of directors.

Manasi Jaiman, M.D., M.P.H. has served as our Chief Medical Officer since September 2024. Prior to joining us, from October 2022 to March 2024, Dr. Jaiman was Vice President, Clinical Development and Platform Lead at Vertex Pharmaceuticals Incorporated (Nasdaq: VRTX), and from July 2020 to July 2023, she served in various roles at ViaCyte, Inc. (Nasdaq: VCYT), a biotechnology company, including as its Chief Medical Officer and Vice President of Clinical Development, where she developed novel approaches in cell therapy. Prior to that, she served as Senior Medical Director and Medical Director at Covance/LabCorp, a CRO. Previously, from July 2014 to September 2020, she was an attending physician at Harvard Medical School and Massachusetts General Hospital, where she was responsible for the clinical care of pediatric endocrinology patients, including those with diabetes, metabolic disease, obesity and Prader-Willi Syndrome. She also served as a co-investigator for several trials developing the bionic pancreas at Massachusetts General Hospital. Dr. Jaiman received her M.D. from Medical University of South Carolina, her M.P.H. from Tulane University School of Public Health and Tropical Medicine and her B.S. in Psychology from the University of South Carolina, Honors College. She completed her pediatric residency at Dartmouth-Hitchcock Medical Center and her pediatric endocrinology fellowship, which focused on type 1 diabetes research, at Massachusetts General Hospital.

Nelson Sun has served as our Chief Financial Officer since June 2019 and additionally as our Chief Operating Officer since February 2026. Mr. Sun has more than 20 years' experience in financial management, business operations, and corporate strategy, with various leadership roles at private equity firms. Prior to joining us, Mr. Sun served as an Operating Partner at Dubilier & Company from 2011 to 2019, where he assessed underperforming assets and strategic acquisition opportunities, alongside providing executive level oversight to portfolio companies spanning business operations, financial planning, and strategic exits. From 2005 to 2011, Mr. Sun served as a Vice President at Valor Equity Partners, where he worked on mergers and acquisitions, portfolio management, as well as provided executive level oversight to portfolio companies including operations leadership, corporate strategy, financial management, and operational scalability. Earlier in his career, he worked in financial valuation analysis and transaction support at Dubilier & Company, in product management at National Electronics Warranty, and in business development at Revbox.com. Mr. Sun received his M.B.A. in Finance from The Wharton School, his M.A. in International Studies from the School of Arts and Sciences at the University of Pennsylvania and his B.A. in Literature/Writing from the University of California, San Diego.

Non-Employee Directors

Jeffrey Chi, Ph.D. has served as a member of our board of directors since May 2019 and he has served as our Lead Independent Director since December 2024. Dr. Chi is a veteran in the venture capital industry and a strong advocate for the promotion of venture capital, entrepreneurship & socially responsible investing. Dr. Chi has served as the Chairman of the board of directors of Vickers Vantage Corp. I and its Chief Executive Officer from February 2020 to November 2022. Dr. Chi co-founded Vickers Ventures Partners in 2005, and served as its Vice Chairman and a member of its board of directors and Investment Committee until he transitioned into a senior consultant role in 2025. From 2013 to April 2017, Dr. Chi also served as the Chairman of the Singapore Venture Capital and Private Equity Association. From 2001 to 2005, Dr. Chi initially served as a Senior Consultant with the Monitor Group and later served as Executive Director with Pegasus Capital. Dr. Chi also sits on an advisory panel of the Monetary Authority of Singapore and previously sat on the board of SEEDS Capital (the investment arm of Enterprise Singapore) as well as on the advisory panels ETPL (the commercialization arm of A*Star) and the National University of Singapore Department of Industrial Systems Engineering and Management. Based out of Shanghai, Dr. Chi previously led Vickers Venture's investments in Asia and has investments in artificial intelligence, education, healthcare/wellness and financial services (including fintech) technology companies. Prior to managing venture capital funds, Dr. Chi managed advisory engagements for a wide range of clients in both the public and private sectors. Dr. Chi's operational background includes working on the management team of an engineering and construction group where he oversaw operations in Singapore, Malaysia, Taiwan and Indonesia. Dr. Chi also serves as a member of the board of directors of Vivance Pte Ltd (a renal care company), Jing-jin Electric Technologies Co., Ltd. (SH: 668280) and MatchMove Pay Pte. Ltd. Dr. Chi received his Ph.D. from the Massachusetts Institute of Technology in systems engineering, his M.A. from the University of Cambridge in engineering, his S.M. from the Massachusetts Institute of Technology in engineering and his B.A. from the University of Cambridge in engineering. He is also a C.F.A. charterholder, and is fluent in English and Mandarin.

We believe Dr. Chi is qualified to serve on our board of directors because of his experience, relationships and contacts, combined with his experience serving on the boards of directors of successful, high-growth public and private companies.

Roy D. Baynes, M.D., Ph.D. has served as a member of our board of directors since December 2024. Since July 2022, Dr. Baynes has served as Executive Vice President and Chief Medical Officer of Eikon Therapeutics, Inc. (Nasdaq: EIKN), a biotechnology company. Prior to Eikon Therapeutics, Inc., until April 2022, he served as Senior Vice President and Head of Global Clinical Development at Merck Research Laboratories, the research division of Merck and Co., Inc., commencing in December 2013, and as Chief Medical Officer of Merck and Co., Inc., a global healthcare company, commencing in July 2016. Prior to his roles at Merck and Co., Inc., Dr. Baynes served as Senior Vice President of Oncology, Inflammation and Respiratory Therapeutics at Gilead Sciences, Inc., a biopharmaceutical company, from January 2012 to December 2013. Prior to Gilead Sciences, Inc., Dr. Baynes held positions of increasing responsibility at Amgen Inc., a biotechnology company, including Vice President of Global Clinical Development and Therapeutic Area Head for Hematology/Oncology. Before joining Amgen Inc., Dr. Baynes was the Charles Martin Professor of Cancer Research at the Barbara Ann Karmanos Cancer Institute, a National Cancer Institute-designated Comprehensive Cancer Center, at Wayne State University. Dr. Baynes has authored more than 150 publications and is a member or fellow of several international medical societies. Dr. Baynes has served on the Boards of Directors of Natera, Inc. (Nasdaq: NTRA), a genetic testing and diagnostics company, since July 2018; Travere Therapeutics Inc. (formerly known as Retrophin, Inc.) (Nasdaq: TVTX), a biopharmaceutical company, since July 2016; CatalYm GmbH, a privately-held Germany-based biotechnology company, since January 2024; Nurix Therapeutics, Inc. (Nasdaq: NRIX), a biopharmaceutical company, since March 2025; and Adcendo ApS, a privately-held Danish-based antibody drug conjugate company, since February 2025. Previously, from September 2018 to December 2022, he served on the Board of Directors of Atara Biotherapeutics, Inc., a T-cell immunotherapy company. Dr. Baynes received his

medical degree and doctorate in philosophy from the University of the Witwatersrand in South Africa, and completed his medical training in the Department of Hematology and Oncology at Johannesburg Hospital.

We believe Dr. Baynes is qualified to serve on our board of directors because of his extensive experience in the life sciences and biopharmaceutical industry and his medical and drug development expertise.

Susan E. Graf has served as a member of our board of directors since November 2024. Since May 2021, Ms. Graf has served as a Senior Advisor and Entrepreneur in Residence at Locust Walk Partners, LLC, a global life science transaction firm. From August 2019 to May 2021, she served as the Chief Executive Officer of the biotechnology company, Akamara Therapeutics, Inc. Prior to Akamara Therapeutics, Inc., she was the Chief Business Officer at Epizyme, Inc., a biopharmaceutical company, from April 2016 to September 2018, where she also served as Principal Financial Officer from August 2017 to September 2018. Prior to Epizyme, Inc., Ms. Graf held the position of Vice President, Corporate Development and Strategy for NPS Pharma before it was acquired by Shire in 2015. Earlier in her career, Ms. Graf spent nearly 18 years at Roche in a number of leadership and executive positions. Ms. Graf currently serves on the boards of directors and as the chair of the audit committee of each of CG Oncology, Inc. (Nasdaq: CGON), a late-stage clinical biopharmaceutical company, and Kaléo, Inc., a privately held pharmaceutical company. She also currently serves on the compensation committee of Kaléo, Inc. From April 2021 to March 2024, she chaired the board of directors and the audit committee of Finch Therapeutics, Inc., which was a publicly-traded microbiome therapeutics company. Ms. Graf received her M.B.A. from the Stern School of Business at New York University and her B.Pharm. from Purdue University.

We believe Ms. Graf is qualified to serve on our board of directors because of her extensive experience in the life sciences industry and her financial expertise.

Victor Tong, Jr. has served as a member of our board of directors since May 2024. Mr. Tong is a Managing Director at Decheng Capital (Decheng), an investment firm, where he has worked since its inception in 2012 and focuses on investments in biotechnology and medical technology companies in China and the United States. Before joining Decheng, Mr. Tong was a Principal at Bay City Capital, a life sciences investment firm, and a member of the healthcare investment banking division at Morgan Stanley. Mr. Tong has served as a member of the board of directors of CG Oncology, Inc. (Nasdaq: CGON) since July 2023. He also serves on the board of directors of multiple privately held biotechnology and biopharmaceutical companies including Baylor Genetics, Cellares Corp., Harton Therapeutics, Hummingbird Bioscience, LevitasBio, Take2, and Watchmaker Genomics. Mr. Tong received his B.A. in Molecular and Cell Biology and his B.S. in Business Administration from the University of California, Berkeley.

We believe Mr. Tong is qualified to serve as our director because of his investment and board experience in the biopharmaceutical industry.

Family Relationships

There are no family relationships between any of our executive officers, directors or director nominees.

Board Composition

Our business and affairs are managed under the direction of our board of directors. The Bylaws provide that the number of directors that shall constitute the whole board of directors shall be determined by resolution of our board of directors. Currently our board of directors consists of five members: Tien-Li Lee, M.D., Roy D. Baynes, M.D., Ph.D., Jeffrey Chi, Ph.D., Susan E. Graf and Victor Tong, Jr.

Certain members of our board of directors were elected under the provisions of our Second Amended and Restated Voting Agreement entered into on May 1, 2024 (the Voting Agreement). Under the terms of the Voting Agreement, the stockholders who are party to the Voting Agreement have agreed to vote their respective shares to elect: (i) one director designated by the holders of a majority of the shares of Series A preferred stock and Series B preferred stock, currently Jeffrey Chi, Ph.D.; (ii) one director designated by Decheng Capital, LLC, currently Victor Tong, Jr. and (iii) our Chief Executive Officer, Tien-Li Lee, M.D. The Voting Agreement terminated upon the completion of our IPO, and currently no stockholders have any special rights regarding the election or designation of the members of our board of directors. The number of directors is fixed by our board of directors, subject to the terms of our Certificate of Incorporation and Bylaws. Our current directors elected to our board of directors pursuant to the Voting Agreement will continue to serve as directors until their successors are duly elected and qualified, or until their earlier resignation or removal.

In accordance with our Certificate of Incorporation, our board of directors is divided into three classes with staggered three-year terms. At each annual meeting of stockholders after the initial classification, the successors to the directors whose terms will then

expire will be elected to serve from the time of election and qualification until the third annual meeting of stockholders following their election. Our directors will be divided among the three classes as follows:

- the Class I directors are Victor Tong, Jr. and Jeffrey Chi, Ph.D., and their terms will expire at the annual meeting of stockholders to be held in 2026;
- the Class II director is Susan E. Graf, and her term will expire at the annual meeting of stockholders to be held in 2027; and
- the Class III directors are Tien-Li Lee, M.D. and Roy D. Baynes, M.D., Ph.D., and their terms will expire at the annual meeting of stockholders to be held in 2028.

Any increase or decrease in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors. This classification of our board of directors may have the effect of delaying or preventing a change of our management or a change in control of our company.

Board Leadership Structure

Our board of directors recognizes that one of its key responsibilities is to evaluate and determine its optimal leadership structure so as to provide effective oversight of management. The Bylaws and corporate governance guidelines provide our board of directors with flexibility to combine or separate the positions of Chairperson of our board of directors and Chief Executive Officer. Our board of directors currently believes that our Chief Executive Officer is best situated to serve as Chairperson because he is the director who is most familiar with our business and industry, possesses detailed and in-depth knowledge of the issues, opportunities and challenges facing us and is therefore best positioned to ensure that the board of directors' time and attention are focused on the most critical matters. Our independent directors bring experience, oversight and expertise from outside the company and industry, while the Chief Executive Officer brings company-specific experience and expertise. Our board of directors believes that the combined role of Chairperson and Chief Executive Officer facilitates information flow between management and the board of directors, which is essential to effective governance. Effective December 2024, Jeffrey Chi, Ph.D. was appointed as our Lead Independent Director. The duties of our Lead Independent Director include (i) presiding at all meetings of our board of directors at which the Chairperson of our board of directors is not present and leading executive sessions of the independent directors; (ii) providing input on board of directors agendas and materials in advance of meetings of our board of directors; (iii) if requested by stockholders, ensuring that our Lead Independent Director is available for consultation and direct communication; and (iv) performing such other functions as our board of directors may delegate to our Lead Independent Director from time to time. Our board of directors will continue to periodically review our leadership structure and may make such changes in the future as it deems appropriate.

Board Oversight of Risk

Although management is responsible for the day-to-day management of the risks our company faces, our board of directors and its committees take an active role in overseeing management of our risks and have the ultimate responsibility for the oversight of risk management. Our board of directors regularly reviews information regarding our operational, financial, legal and strategic risks. Specifically, senior management attends quarterly meetings of our board of directors, provides presentations on operations including significant risks, and is available to address any questions or concerns raised by our board of directors.

In addition, our three committees will assist our board of directors in fulfilling its oversight responsibilities regarding risk. The Audit Committee will coordinate our board of directors' oversight of our internal control over financial reporting, communication with our external auditors, disclosure controls and procedures, related party transactions and code of conduct and management will regularly report to the Audit Committee on these areas. The Compensation Committee will assist our board of directors in fulfilling its oversight responsibilities with respect to the management of risks arising from our compensation policies and programs as well as succession planning as it relates to our Chief Executive Officer. The Nominating and Corporate Governance Committee will assist our board of directors in fulfilling its oversight responsibilities with respect to the management of risks associated with board organization, membership and structure, succession planning for our directors, maintaining our corporate governance guidelines and our corporate governance. When any of the committees receives a report related to material risk oversight, the chairperson of the relevant committee will report on the discussion to our full board of directors. Matters of significant strategic risk are considered by our board of directors as a whole.

Board Committees

Our board of directors currently has three standing committees: an audit committee (Audit Committee), a compensation committee (Compensation Committee) and a nominating and corporate governance committee (Nominating and Corporate Governance Committee). The composition and responsibilities of each of the committees of our board of directors are described

below. Members will serve on these committees until their resignation or removal or until otherwise determined by our board of directors.

Audit Committee

Our Audit Committee is comprised of Susan E. Graf, Victor Tong, Jr. and Jeffrey Chi, Ph.D., with Ms. Graf serving as Chairperson of the committee. Each member of the Audit Committee must be independent as defined under the applicable Nasdaq and SEC rules and financially literate under the Nasdaq rules and listing standards (the Nasdaq Rules). Our board of directors has determined that each member of the Audit Committee is "independent" and "financially literate" under the Nasdaq Rules and the rules of the SEC and that Ms. Graf is an "audit committee financial expert" under the rules of the SEC.

The responsibilities of the Audit Committee are included in a written charter. The Audit Committee acts on behalf of our board of directors in fulfilling our board of directors' oversight responsibilities with respect to our corporate accounting and financial reporting processes, the systems of internal control over financial reporting and audits of financial statements, and also assists our board of directors in its oversight of the quality and integrity of our financial statements and reports and the qualifications, independence and performance of our independent registered public accounting firm. For this purpose, the Audit Committee performs several functions. The Audit Committee's responsibilities include, among others:

- appointing, determining the compensation of, retaining, overseeing and evaluating our independent registered public accounting firm and any other registered public accounting firm engaged for the purpose of performing other review or attest services for us;
- prior to commencement of the audit engagement, reviewing and discussing with the independent registered public accounting firm a written disclosure by the prospective independent registered public accounting firm of all relationships between us, or persons in financial oversight roles with us, and such independent registered public accounting firm or their affiliates;
- determining and approving engagements of the independent registered public accounting firm, prior to commencement of the engagement, and the scope of and plans for the audit;
- monitoring the rotation of partners of the independent registered public accounting firm on our audit engagement;
- reviewing with management and the independent registered public accounting firm any fraud that includes management or other employees who have a significant role in our internal control over financial reporting and any significant changes in internal controls;
- establishing and overseeing procedures for the receipt, retention and treatment of complaints regarding accounting, internal accounting controls or auditing matters and the confidential and anonymous submission by employees of concerns regarding questionable accounting or auditing matters;
- reviewing the results of management's efforts to monitor compliance with our programs and policies designed to ensure compliance with laws and rules;
- assisting our board of directors in overseeing our risk management, including with respect to enterprise, financial and legal risk assessment, risk exposures and risk management;
- overseeing our programs, policies, and procedures related to our information technology systems, including information asset security, data protection, data privacy, cybersecurity and back-up of information systems, and steps taken to monitor, mitigate and control such exposures;
- reviewing and establishing appropriate insurance coverage for our directors and executive officers; and
- reviewing and discussing with management and the independent registered public accounting firm the results of the annual audit and the independent registered public accounting firm's assessment of the quality and acceptability of our accounting principles and practices and all other matters required to be communicated to the Audit Committee by the independent registered public accounting firm under generally accepted accounting standards, the results of the independent registered public accounting firm's review of our quarterly financial information prior to public disclosure and our disclosures in our periodic reports filed with the SEC.

The Audit Committee will review, discuss and assess its own performance and composition at least annually. The Audit Committee will also periodically review and assesses the adequacy of its charter, including its role and responsibilities as outlined in its charter, and recommend any proposed changes to our board of directors for its consideration and approval.

Compensation Committee

Our Compensation Committee is comprised of Jeffrey Chi, Ph.D., Roy D. Baynes, M.D., Ph.D. and Susan E. Graf, with Dr. Chi serving as Chairperson of the committee. Our board of directors has determined that each member of the committee is "independent" under the Nasdaq Rules and all applicable laws. Each of the members of this committee is also a "non-employee director" as that term is defined under Rule 16b-3 of the Exchange Act and an "outside director" as that term is defined in Treasury Regulation Section 1.162-27(3). The Compensation Committee acts on behalf of our board of directors to fulfill our board of directors' responsibilities in overseeing our compensation policies, plans and programs; and in reviewing and determining the compensation to be paid to our executive officers and non-employee directors. The responsibilities of the Compensation Committee are included in its written charter. The Compensation Committee's responsibilities include, among others:

- reviewing the effectiveness of our overall compensation strategy to assure that it promotes stockholder interests and supports our strategic and tactical objectives, and that it provides appropriate rewards and incentives for our management and employees, taking into account whether such rewards and incentives encourage undue or inappropriate risk-taking by such personnel;
- reviewing, modifying and approving (or, if it deems appropriate, making recommendations to our board of directors regarding) our overall compensation strategy and policies, and reviewing, modifying and approving corporate performance goals and objectives relevant to the compensation of our executive officers and other senior management;
- determining and approving (or, if it deems appropriate, recommending to our board of directors for determination and approval) the compensation and terms of employment of our Chief Executive Officer, including seeking to achieve an appropriate level of risk and reward in determining the long-term incentive component of our Chief Executive Officer's compensation;
- determining and approving (or, if it deems appropriate, recommending to our board of directors for determination and approval) the compensation and terms of employment of our executive officers and other members of senior management;
- reviewing and approving (or, if it deems appropriate, making recommendations to our board of directors regarding) the terms of employment agreements, severance agreements, change-of-control protections and other compensatory arrangements for our executive officers and other senior management;
- conducting periodic reviews of the base compensation levels of all of our employees generally;
- reviewing and approving the type and amount of compensation to be paid or awarded to non-employee directors;
- reviewing and approving the adoption, amendment and termination of our stock option plans, stock appreciation rights plans, pension and profit sharing plans, incentive plans, stock bonus plans, stock purchase plans, bonus plans, deferred compensation plans, 401(k) plans, supplemental retirement plans and similar programs, if any; and administering all such plans, establishing guidelines, interpreting plan documents, selecting participants, approving grants and awards and exercising such other power and authority as may be permitted or required under such plans;
- reviewing our incentive compensation arrangements to determine whether such arrangements encourage excessive risk-taking, reviewing and discussing at least annually the relationship between our risk management policies and practices and compensation and evaluating compensation policies and practices that could mitigate any such risk; and
- reviewing human capital management strategies, programs and policies, including, but not limited to, those regarding recruitment, retention, career development, diversity, equity and inclusion, pay equity, workplace culture and employee engagement.

In addition, once we cease to be an "emerging growth company," as defined in JOBS Act, the responsibilities of the Compensation Committee will also include:

- reviewing and recommending to our board of directors for approval the frequency with which we conduct an advisory vote on executive compensation, taking into account the results of the most recent stockholder advisory vote on the frequency of the advisory vote on executive compensation, and reviewing and approving the proposals regarding the frequency of the advisory vote on executive compensation to be included in our annual meeting proxy statements; and

- reviewing and discussing with management our Compensation Discussion and Analysis, and recommending to our board of directors that the Compensation Discussion and Analysis be approved for inclusion in our Annual Reports on Form 10-K, registration statements and our annual meeting proxy statements.

Under its charter, the Compensation Committee may form, and delegate authority to, subcommittees as appropriate, including to delegate authority to our Chief Executive Officer to grant rights in, or options to purchase, shares of our common stock to eligible employees and consultants who are not executive officers, subject to certain limitations. The Compensation Committee will review, discuss and assess its own performance and composition at least annually. The Compensation Committee will also periodically review and assess the adequacy of its charter, including its role and responsibilities as outlined in its charter, and recommend any proposed changes to our board of directors for its consideration and approval.

Nominating and Corporate Governance Committee

Our Nominating and Corporate Governance Committee is comprised of Victor Tong, Jr., Roy D. Baynes, M.D., Ph.D. and Jeffrey Chi, Ph.D., with Mr. Tong serving as Chairperson of the committee. Our board of directors has determined that each member of the committee is "independent" under the Nasdaq Rules and all applicable laws. The Nominating and Corporate Governance Committee acts on behalf of our board of directors to fulfill our board of directors' responsibilities in overseeing all aspects of our nominating and corporate governance functions. The responsibilities of the Nominating and Corporate Governance Committee are included in its written charter. The Nominating and Corporate Governance Committee's responsibilities include, among others:

- evaluating composition, size, organization and governance of our board of directors and its committees to ensure that they appropriately reflect the knowledge, skills, integrity, ethics, diversity (including that of gender, sexual orientation, disability, age, race, ethnicity or national origin, global perspective and experience, business experience, functional expertise, stakeholder expectations, culture and geography), and other characteristics required to fulfill their respective duties, and determine future requirements;
- making recommendations to our board of directors regarding corporate governance issues;
- identifying, reviewing and evaluating candidates to serve as directors (consistent with criteria approved by our board of directors);
- determining the minimum qualifications for service on our board of directors;
- reviewing and evaluating incumbent directors;
- instituting and overseeing director orientation and director continuing education programs;
- serving as a focal point for communication between candidates, non-committee directors and our management;
- recommending to our board of directors for selection candidates to serve as nominees for director for the annual meeting of stockholders;
- making other recommendations to our board of directors regarding matters relating to the directors;
- reviewing succession plans for our Chief Executive Officer and our other executive officers;
- reviewing and overseeing matters of corporate responsibility and sustainability, including potential long- and short-term trends and impacts to our business of environmental, social and governance issues, and our public reporting on these topics;
- overseeing our environmental, social and governance programs and strategies;
- monitoring, and making recommendations to our board of directors regarding, our insider trading policy; and
- considering any recommendations for director nominees and proposals submitted by stockholders.

The Nominating and Corporate Governance Committee will periodically review, discuss and assess the performance of our board of directors and the committees of our board of directors. In fulfilling this responsibility, the Nominating and Corporate Governance Committee will seek input from senior management, our board of directors and others. In assessing our board of directors, the Nominating and Corporate Governance Committee will evaluate the overall composition of our board of directors, our board of directors' contribution as a whole and its effectiveness in serving our best interests and the best interests of our stockholders. The Nominating and Corporate Governance Committee will review, discuss and assess its own performance and composition at least annually. The Nominating and Corporate Governance Committee will also periodically review and assess the adequacy of its charter, including its role and responsibilities as outlined in its charter, and recommend any proposed changes to our board of directors for its consideration and approval.

Insider Trading Policy; Prohibition Against Hedging and Pledging Policy

Our board of directors has adopted an insider trading policy, which provides guidelines to our employees, directors, officers and consultants with respect to transactions in our securities, including the purchase, sale and/or other disposition of our securities. We adopted the insider trading policy and the procedures set forth therein to help avoid inadvertent instances of improper insider trading. We believe the insider trading policy is reasonably designed to promote compliance with insider trading laws, rules and regulations and listing standards applicable to Aardvark. In addition, with regard to any trading in our own securities, it is our policy to comply with the federal securities laws and the applicable exchange listing requirements.

Our insider trading policy prohibits our officers, directors and employees from engaging in hedging transactions, including zero-cost collars, prepaid variable forwards, equity swaps, puts, calls, collars and forwards. It further prohibits holding our stock in a margin account, short sales of our stock, and any transactions in puts, calls or other derivative securities involving our stock. Additionally, our insider trading policy generally prohibits our officers, directors and employees from pledging our stock as collateral to secure loans; however, the Audit Committee, the Compensation Committee or the Nominating and Corporate Governance Committee may approve an exception to this general prohibition where a person wishes to pledge securities as collateral for a loan (not including margin debt) and clearly demonstrates the financial capacity to repay the loan without resort to the pledged securities.

Attendance by Members of the Board of Directors at Meetings

There were five meetings of our board of directors during the fiscal year ended December 31, 2025. During the fiscal year ended December 31, 2025, each director attended at least 75% of the aggregate of all meetings of our board of directors, and each director attended at least 75% of meetings of the committees on which such director served during the period in which he or she served as a director.

Director Nominations

No material changes have been made to the procedures by which security holders may recommend nominees to our board of directors from those that were described in our final prospectus filed pursuant to Rule 424(b)(4) under the Securities Act with the SEC on February 13, 2025.

Communications from Stockholders

Our board of directors will give appropriate attention to written communications that are submitted by stockholders, and will respond if and as appropriate. Our Secretary is primarily responsible for monitoring communications from stockholders and for providing copies or summaries to the directors as he considers appropriate.

Communications are forwarded to all directors if they relate to important substantive matters and include suggestions or comments that our Secretary and Chairperson of our board of directors consider to be important for the directors to know. In general, communications relating to corporate governance and long-term corporate strategy are more likely to be forwarded than communications relating to ordinary business affairs, personal grievances and matters as to which we tend to receive repetitive or duplicative communications. Stockholders who wish to send communications on any topic to our board of directors should address such communications to our board of directors in writing: c/o Secretary, Aardvark Therapeutics, Inc., 4370 La Jolla Village Drive, Suite 1050, San Diego, California 92122.

Code of Business Conduct and Ethics

We have adopted a written code of business conduct and ethics which applies to all of our employees, officers and directors, including our principal executive officer, principal financial officer, principal accounting officer or controller and those officers responsible for financial reporting. The code of business conduct and ethics is available on our website at https://aardvarktherapeutics.com/. We intend to disclose any amendments to the code, or any waivers of its requirements, on our website to the extent required by the applicable rules and exchange requirements. The inclusion of our website address in this Annual Report does not incorporate by reference the information on or accessible through our website into this Annual Report. We have included our website in this Annual Report solely as an inactive textual reference.

Item 11. Executive Compensation.

Our named executive officers for the year ended December 31, 2025, are:

- Tien-Li Lee, M.D., our Chief Executive Officer;
- Nelson Sun, our Chief Financial Officer (note that Mr. Sun was appointed as our Chief Operating Officer as well effective February 2026); and

- Manasi Jaiman, M.D., M.P.H., our Chief Medical Officer.

Summary Compensation Table

The following table sets forth certain information with respect to the compensation for services rendered in all capacities that was awarded to, earned by or paid to our named executive officers for the fiscal years ended December 31, 2025 and 2024:

Name and principal position	Year	Salary ($)	Bonus ($)	Option Awards ($)(1)	Non-Equity Incentive Plan Compensation ($)(2)	All Other Compensation ($)	Total ($)
Tien-Li Lee, M.D.	2025	630,788	—	5,093,026	342,870	—	6,066,684
Chief Executive Officer	2024	422,989	111,000	203,223	167,976	1,134	906,322
Nelson Sun[3]	2025	432,654	—	1,944,646	170,646	—	2,547,946
Chief Financial Officer and Chief Operating Officer							
Manasi Jaiman, M.D., M.P.H.[4]	2025	495,962	—	1,177,014	197,077	—	1,870,053
Chief Medical Officer	2024	150,577	—	609,668	52,212	—	812,457

(1) The amounts reported in the "Option Awards" column represent the aggregate grant date fair value of the stock options awarded to our named executive officers during the applicable fiscal year, calculated in accordance with Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) Topic 718. The assumptions used in calculating the grant date fair value of the awards reported in this column are set forth in Note 7 to our audited consolidated financial statements included elsewhere in this Annual Report. The amounts reported in this column reflect the accounting cost for the stock options and do not reflect the actual economic value that will be realized by the individual upon the vesting of the stock options, the exercise of the stock options or the sale of the common stock underlying such awards. See the subsection titled "—Narrative Disclosure to Summary Compensation Table—Equity-Based Incentive Awards" below for additional detail.

(2) The amounts reported in the "Non-Equity Incentive Plan Compensation" column represent annual performance-based cash bonuses (see the subsection titled "—Narrative Disclosure to Summary Compensation Table—Annual Bonuses" below for additional detail).

(3) In accordance with SEC guidance, compensation information for Mr. Sun for fiscal year 2024 has not been included in this table because Mr. Sun was not a named executive officer for fiscal year 2024.

(4) Dr. Jaiman was appointed and joined our company as our Chief Medical Officer in September 2024.

Narrative Disclosure to Summary Compensation Table

Arrangements with Executive Officers

We have entered into offer letters with each of our named executive officers. The material terms of the offer letters are described below.

Lee Offer Letter and Compensation

We entered into an offer letter with Dr. Lee (the Lee Offer Letter) dated July 24, 2019, pursuant to which Dr. Lee serves as our Chief Executive Officer and President. Under the Lee Offer Letter, Dr. Lee's annual base salary was initially set at $300,000, which was increased to $370,000 in 2023 and was further increased to $468,000 effective June 28, 2024. Dr. Lee's employment with us is at-will, and either we or Dr. Lee may terminate the terms and conditions of the employment relationship at any time, with or without cause and with or without notice.

The Lee Offer Letter also provides for reimbursement of reasonable, actual and documented out-of-pocket expenses incurred in connection with Dr. Lee's employment.

Effective June 28, 2024, Dr. Lee's discretionary annual target bonus was established at 40% of his annual base salary.

Effective upon the completion of our IPO, Dr. Lee's base salary was increased to $650,000 per year and his discretionary annual target bonus was increased to 55% of his annual base salary.

Sun Offer Letter and Compensation

We entered into an offer letter with Mr. Sun (the Sun Offer Letter) dated August 23, 2021, pursuant to which Mr. Sun serves as our Chief Financial Officer. Under the Sun Offer Letter, Mr. Sun's annual base salary was set at $240,000, which was increased to $290,000 effective June 28, 2024. Mr. Sun's employment with us is at-will, and either we or Mr. Sun may terminate the terms and conditions of the employment relationship at any time, with or without cause and with or without notice.

In accordance with the Sun Offer Letter, on September 1, 2021, we issued Mr. Sun an option to purchase an aggregate of 44,253 shares of our common stock, with an exercise price equal to $3.06 per share. The shares of common stock subject to such option vest in equal monthly installments over a period of 48 months from the vesting commencement date of September 1, 2021, subject to Mr. Sun providing continuous service (as defined in the 2017 Plan) to our company on each such vesting date, inclusive.

The Sun Offer Letter also provides for reimbursement of reasonable, actual and documented out-of-pocket expenses incurred in connection with Mr. Sun's employment.

Effective June 28, 2024, Mr. Sun's discretionary annual target bonus was established at 30% of his annual base salary.

Effective upon the completion of our IPO, Mr. Sun's base salary was increased to $450,000 per year and his discretionary annual target bonus was increased to 40% of his annual base salary.

Jaiman Offer Letter and Compensation

We entered into an offer letter with Dr. Jaiman (the Jaiman Offer Letter) dated August 23, 2024, pursuant to which Dr. Jaiman serves as our Chief Medical Officer. Under the Jaiman Offer Letter, Dr. Jaiman's annual base salary was set at $450,000 and her annual target bonus was set at 35% of her annual base salary. Dr. Jaiman's employment with us is at-will, and either we or Dr. Jaiman may terminate the terms and conditions of the employment relationship at any time, with or without cause and with or without notice.

In accordance with the Jaiman Offer Letter, on September 1, 2024, we issued Dr. Jaiman an option to purchase an aggregate of 177,012 shares of our common stock, with an exercise price equal to $4.24 per share (the Jaiman Initial Option). 25% of the shares of common stock subject to the Jaiman Initial Option will vest on the one year anniversary of the vesting commencement date of September 1, 2024, and 1/48th of the shares subject to the Jaiman Initial Option will vest in equal monthly installments thereafter, in each case subject to Dr. Jaiman providing continuous service (as defined in the 2017 Plan) to our company on each such vesting date, inclusive.

The Jaiman Offer Letter also provides that, in the event we terminate Dr. Jaiman's employment other than for "Cause" (as defined in the Jaiman Offer Letter) or Dr. Jaiman resigns from her employment with us for "Good Reason" (as defined in the Jaiman Offer Letter), subject to Dr. Jaiman executing and delivering a customary release of claims in our favor, Dr. Jaiman will be entitled to severance consisting of (i) an amount equal to six months of her then-current base salary, and (ii) 100% of the premium cost of continued group health coverage for a period of up to six months following her termination date. In addition, if such termination or resignation occurs within three months prior to or 12 months following a "Change in Control" (as defined in the 2017 Plan), any unvested portion of the Jaiman Initial Option will be accelerated and the Jaiman Initial Option will be fully vested as of the date of such termination or resignation, as applicable. The severance provisions included in the Jaiman Offer Letter and described in this paragraph will be superseded by the Severance Plan, which became effective in connection with the completion of our IPO and is described in the subsection "—Potential Payments Upon Termination or Change in Control—Severance Plan" below.

Effective upon the completion of our IPO, Dr. Jaiman's base salary was increased to $500,000 per year and her discretionary annual target bonus was increased to 40% of her annual base salary.

Annual Bonuses

Our named executive officers are eligible to receive annual performance-based cash bonuses, which are designed to provide appropriate incentives to our executives to achieve corporate milestones and to reward our executives for individual achievement towards these milestones. The annual performance-based bonus that each named executive officer is eligible to receive is based on the extent to which we achieve corporate milestones, as well as the applicable named executive officer's discretionary annual target bonus percentage. In February 2026, the board of directors, upon the recommendation of the compensation committee, determined that we

had achieved 100% of the 2025 corporate goals for purposes of the 2025 annual performance-based bonuses. Based on the determination of 100% corporate goal achievement, our named executive officers were awarded the following bonuses for achievement at their respective target bonus, as follows:

	2025 Compensation ($)	Bonus Target Percentage	Bonus ($)
Tien-Li Lee, M.D.	630,788	55%	342,870
Nelson Sun	432,654	40%	170,646
Manasi Jaiman, M.D., M.P.H.	495,962	40%	197,077

Equity-Based Incentive Awards

On June 11, 2025, our board of directors approved the following stock option grants to our named executive officers under the 2025 Plan with a grant date of June 11, 2025, which grants are subject to the terms and conditions of the 2025 Plan and the applicable form of stock option agreement approved for use thereunder. The exercise price of the following stock option grants is $11.29 per share, with 1/48th of the total amount of the shares vesting each month after the grant date, subject to the executive officer's providing continuous service (as defined in the 2025 Plan) through the applicable vesting date (each inclusive); *provided that* the vesting of the options shall be accelerated in full contingent upon, and effective as of, a change in control (as defined in the 2025 Plan) during such named executive officer's continuous service.

	Shares Subject to Stock Options
Tien-Li Lee, M.D.	549,534
Nelson Sun	209,826
Manasi Jaiman, M.D., M.P.H.	126,999

Potential Payments Upon Termination or Change in Control

As of December 31, 2025, other than as described under the subsection "—Narrative Disclosure to Summary Compensation Table—Arrangements with Executive Officers—Jaiman Offer Letter and Compensation" above with respect to Dr. Jaiman and the Severance Plan (described below), we did not, and we currently do not, have any arrangements or agreements with any of our named executive officers that provide for payments to any of our named executive officers upon termination or change in control. The Severance Plan will supersede the severance provisions included in the Jaiman Offer Letter.

Severance Plan

Each of our current executive officers are eligible to receive benefits under the terms of the Aardvark Therapeutics, Inc. Severance Plan (Severance Plan) adopted by our board of directors in December 2024. The Severance Plan provides that upon (i) a termination of an eligible participant's employment with us that is effected by us without "cause," as defined in the Severance Plan (and other than due to death or disability), or (ii) a resignation by an eligible participant for "good reason," as defined in the Severance Plan, in each case outside of the time period beginning with the date three months prior to the date on which a change in control (as defined in the Severance Plan) occurs and ending 12 months following the change in control, or the "change in control period," an eligible participant will be entitled to receive, subject to, among other things, the execution, delivery and effectiveness of a customary release of claims in our favor, (a) continued base salary for a period of nine months at the rate in effect on the date of such participant's termination, and (b) reimbursement of premiums for the eligible participant's continued coverage under our health insurance plans for up to nine months.

The Severance Plan also provides that upon (i) a termination of an eligible participant's employment with us that is effected by us without "cause" (and other than due to death or disability) or (ii) a resignation by an eligible participant for "good reason," in each case within the change in control period, the eligible participant will be entitled to receive, subject to, among other things, the execution, delivery and effectiveness of a customary release of claims in our favor, (a) continued base salary for a period of 12 months at the rate in effect on the date of such participant's termination, (b) an additional cash lump sum payment equal to the participant's target annual bonus for the year of termination, (c) reimbursement of premiums for the eligible participant's continued coverage under our health insurance plans for up to 12 months, and (d) accelerated vesting of outstanding and unvested equity awards held by such

participant (with performance-based awards vesting at the higher of target (100%) level of performance or actual achievement measured as of the date of the change in control).

The payments and benefits provided under the Severance Plan in connection with a change in control may not be eligible for a federal income tax deduction by us pursuant to Section 280G of the Code. These payments and benefits may also subject an eligible participant, including our current executive officers, to an excise tax under Section 4999 of the Code. If the payments or benefits payable in connection with a change in control would be subject to the excise tax imposed under Section 4999 of the Code, then those payments or benefits will be reduced if such reduction would result in a higher net after-tax benefit to the recipient.

Perquisites, Health, Welfare and Retirement Plans and Benefits

All of our named executive officers are eligible to participate in our employee benefit plans offered to similarly situated employees, including medical, dental, vision, disability, life insurance and 401(k) plans. We generally do not provide perquisites or personal benefits to our named executive officers, except in limited circumstances. Our board of directors may elect to adopt qualified or non-qualified benefit plans in the future if it determines that doing so is in the best interests of our company and our stockholders.

Clawback Policy

Our board of directors has adopted a clawback policy that complies with recently enacted SEC rules and Nasdaq Rules. Our clawback policy provides for our recovery of erroneously awarded incentive-based compensation from our current and former executive officers (as defined in Rule 10D-1 promulgated under the Exchange Act and Nasdaq Rule 5608) who were employed by us during the applicable recovery period. Under the policy, if we are required to prepare an accounting restatement of our financial statements due to our material noncompliance with any financial reporting requirement under the securities laws, we shall promptly demand in writing and recoup the amount of any incentive-based compensation received by the applicable executive during the three completed fiscal years immediately preceding the date on which we are required to prepare such accounting restatement. The amount to be recouped is that which exceeds the amount of incentive-based compensation that otherwise would have been received by the applicable executive had such compensation been determined based on the restated amounts in the accounting restatement. Incentive-based compensation includes any compensation that is granted, earned or vested based wholly or in part upon the attainment of one or more measures derived from our financial statements. Our Compensation Committee will administer our clawback policy and will have the authority to determine the amount of recoverable compensation and manner of recovery.

Outstanding Equity Awards at Fiscal Year-End 2025

The following table presents certain information concerning outstanding equity awards held by each of our named executive officers at December 31, 2025:

			Option Awards[1]			
Name	Grant Date	Vesting Commencement Date	Number of Securities Underlying Unexercised Options Exercisable (#)	Number of Securities Underlying Unexercised Options Unexercisable (#)	Option Exercise Price ($)	Option Expiration Date
Tien-Li Lee, M.D.	7/21/2024[1]	6/27/2024	3,688	36,878	$ 4.24	7/20/2034
	6/11/2025[2]	6/11/2025	—	549,534	$ 11.29	6/10/2035
Nelson Sun	7/21/2024[1]	6/27/2024	7,170	16,549	$ 4.24	7/20/2034
	6/11/2025[2]	6/11/2025	—	209,826	$ 11.29	6/10/2035
Manasi Jaiman, M.D., M.P.H.	9/1/2024[2]	9/1/2024	55,316	121,696	$ 4.24	8/31/2034
	6/11/2025[2]	6/11/2025	—	126,999	$ 11.29	6/10/2035

(1) 1/48th of the shares subject to the options vested on the date that is one month following the vesting commencement date and an additional 1/48th of the shares subject to the options shall vest on the same date of each month thereafter, subject to the named executive officer's continued service to us through each vesting date.

(2) 25% of the shares subject to the option vested or vest one year after the vesting commencement date, and 1/48th of the shares subject to the option vested or vest monthly thereafter subject to the executive's continued service to us through each vesting date.

Non-Employee Director Compensation

Non-Employee Director Compensation Policy

Effective upon the completion of our IPO, our non-employee directors are compensated in accordance with our non-employee director compensation program (the Director Compensation Program). Pursuant to the Director Compensation Program, our non-employee directors receive cash compensation, paid quarterly in arrears, as follows:

- each non-employee director receives a cash retainer in the amount of $40,000 per year;
- the independent Chairperson of our board of directors or Lead Independent Director, as applicable, receives an additional cash retainer of $30,000 per year;
- the Chairperson of the Audit Committee receives a cash retainer in the amount of $20,000 per year for such Chairperson's service on the Audit Committee;
- each non-Chairperson member of the Audit Committee receives a cash retainer in the amount of $10,000 per year for such member's service on the Audit Committee;
- the Chairperson of the Compensation Committee receives a cash retainer in the amount of $12,000 per year for such Chairperson's service on the Compensation Committee;
- each non-Chairperson member of the Compensation Committee receives a cash retainer in the amount of $6,000 per year for such member's service on the Compensation Committee;
- the Chairperson of the Nominating and Corporate Governance Committee receives a cash retainer in the amount of $10,000 per year for such Chairperson's service on the Nominating and Corporate Governance Committee; and
- each non-Chairperson member of the Nominating and Corporate Governance Committee receives a cash retainer in the amount of $5,000 per year for such member's service on the Nominating and Corporate Governance Committee.

Each non-employee director may elect, on an annual basis, to convert all or a portion of such non-employee director's annual retainer into a number of restricted stock units granted under the 2025 Plan, which will be fully vested on the date of grant, and settlement of the restricted stock units may be deferred at the election of the non-employee director.

Pursuant to the Director Compensation Program, each non-employee director who is initially elected or appointed to our board of directors following the completion of our IPO will automatically be granted an option (Initial Grant) under the 2025 Plan to purchase that number of shares of our common stock equal to (i) $500,000, divided by (ii) the per share grant date fair value of the option award. Each Initial Grant will vest as to 1/36th of the underlying shares on a monthly basis over three years, subject to continued service through the applicable vesting date. In addition, on the date of each annual meeting of our stockholders following the completion of our IPO, each non-employee director, other than a non-employee director receiving an Initial Grant at such annual meeting, who will continue to serve as a non-employee director immediately following such annual meeting will automatically be granted an option (Full Annual Grant) under the 2025 Plan to purchase that number of shares of our common stock equal to (i) $250,000, divided by (ii) the per share grant date fair value of the option award. Notwithstanding the foregoing, if a non-employee director is first elected or appointed to our board of directors on a date other than the date of an annual meeting, then, at the next annual meeting following such non-employee director's election or appointment, in lieu of a Full Annual Grant, such non-employee director will be granted a pro-rata portion of such Full Annual Grant based on the number of full months between such non-employee director's initial election or appointment to our board of directors and the date of the first annual meeting immediately following such initial election or appointment to our board of directors (Partial Annual Grant). Each Full Annual Grant and each Partial Annual Grant will vest in full on the earlier of (i) the first anniversary of the grant date and (ii) immediately prior to the annual meeting of our stockholders following the date of grant, subject to continued service through the applicable vesting date. In addition, upon a Change in Control (as defined in the 2025 Plan), all outstanding equity awards granted under the 2025 Plan (or any other equity incentive plan maintained by us) that are held by a non-employee director will become fully vested and/or exercisable irrespective of any other provisions of such non-employee director's award agreements.

The Director Compensation Program also provides that we reimburse each non-employee director for all reasonable, documented, out-of-pocket travel and other business expenses incurred by such non-employee director in the performance of such non-employee director's duties to us in accordance with our applicable expense reimbursement policies and procedures in effect from time to time.

The following table sets forth information for the year ended December 31, 2025 regarding the compensation awarded to, earned by or paid to persons who served as our directors during 2025 who are not named executive officers.

Name[(1)]	Fees Earned or Paid in Cash ($)	Option Awards ($)	All Other Compensation ($)	Total ($)
Jeffrey Chi, Ph.D.	72,750	536,120	—	608,870
Roy D. Baynes, M.D., Ph.D.	48,374	277,568	—	325,942
Susan E. Graf	61,562	277,568		339,130
Victor Tong, Jr.	52,753	536,120	—	588,873

(1) As of December 31, 2025, our then-serving non-employee directors held unexercised stock options with respect to the following number of shares of our common stock: Dr. Chi: 61,017 shares, Dr. Baynes: 60,010 shares, Ms. Graf: 60,010 shares and Mr. Tong: 61,017 shares.

Equity Compensation Plans

2025 Equity Incentive Plan

In connection with the IPO, our board of directors adopted, and our stockholders approved, the 2025 Plan, which went into effect on February 11, 2025. The purpose of the 2025 Plan is to provide incentives for our employees, directors and consultants to exert maximum efforts for the success of our company and our affiliates and to provide a means by which such persons may be given an opportunity to benefit from increases in value of our common stock through the granting of awards. At the time the 2025 Plan became effective, no further grants may be made under the 2017 Plan.

2025 Inducement Equity Incentive Plan

In May 2025, we adopted the Aardvark Therapeutics, Inc. 2025 Inducement Equity Incentive Plan (2025 Inducement Plan), which will be used exclusively for the grant of equity awards as a material inducement for individuals to commence employment at the Company in compliance with Nasdaq Listing Rule 5635(c)(4).

2025 Employee Stock Purchase Plan

In connection with the IPO, our board of directors adopted, and our stockholders approved, the Aardvark Therapeutics, Inc. 2024 Employee Stock Purchase Plan, which went into effect on February 11, 2025, and which we refer to as the ESPP. The purpose of the ESPP is to secure the services of new employees, to retain the services of existing employees, and to provide incentives for such individuals to exert maximum efforts toward our success and that of our related corporations. The ESPP includes two components. One component is designed to allow eligible U.S. employees to purchase our common stock in a manner that may qualify for favorable tax treatment under Section 423 of the Code (the 423 Component), and accordingly, it will be construed in a manner that is consistent with the requirements of Section 423 of the Code. We intend (but make no undertaking or representation to maintain) the 423 Component to qualify as an employee stock purchase plan, as that term is defined in Section 423(b) of the Code. The other component permits the grant of purchase rights that do not qualify for such favorable tax treatment (the Non-423 Component), in order to allow deviations necessary to permit participation by eligible employees who are foreign nationals or employed outside of the United States while complying with applicable foreign laws, and except as otherwise provided in the ESPP or determined by our board of directors, it will operate and be administered in the same manner as the 423 Component.

Equity Award Timing Procedures

In accordance with Item 402(x) of Regulation S-K under the Securities Act, we are providing information regarding our procedures related to the grant of certain equity awards close in time to the release of material non-public information (MNPI). Although we do not have a formal policy, program or plan that requires us to award equity or equity-based compensation on specific dates, we generally expect our Compensation Committee to approve and grant equity awards to our executive officers annually. Additionally, our insider trading policy prohibits directors, officers and employees from trading in our common stock while in possession of or on the basis of MNPI about us. We have not timed, and do not plan to time, the disclosure of MNPI for the purpose of affecting the value of executive compensation.

During the year ended December 31, 2025, no options were granted to our named executive officers within four business days prior to, or one business day following, the filing or furnishing of a periodic or current report by us that disclosed MNPI.

Limitations on Liability and Indemnification

The Certificate of Incorporation and the Bylaws provide that, to the fullest extent permitted by law, we will indemnify any officer or director of our company against all damages, claims and liabilities arising out of the fact that the person is or was our officer or director, or served any other enterprise at our request as an officer or director. Amending this provision will not reduce our indemnification obligations relating to actions taken before an amendment. Delaware law provides that directors and officers of a corporation will not be personally liable for monetary damages for any breach of fiduciary duties as directors or officers, except liability for:

- any breach of the director's or officer's duty of loyalty to the corporation or its stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- as a director, unlawful payments of dividends or unlawful stock repurchases or redemptions;
- as an officer, derivative claims brought on behalf of the corporation by a stockholder; or
- any transaction from which the director or officer derived an improper personal benefit.

We have entered and expect to continue to enter into agreements to indemnify our directors, executive officers and other employees as determined by our board of directors. With certain exceptions, these agreements provide for indemnification for related expenses including attorneys' fees, judgments, fines and settlement amounts incurred by any of these individuals in any action or proceeding.

We believe that the Certificate of Incorporation and the Bylaws provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers. We also maintain customary directors' and officers' liability insurance.

The limitation of liability and indemnification provisions in the Certificate of Incorporation and the Bylaws may discourage stockholders from bringing a lawsuit against our directors for breach of their fiduciary duty. They may also reduce the likelihood of derivative litigation against our directors and officers, even though an action, if successful, might benefit us and other stockholders. Further, a stockholder's investment may be adversely affected to the extent that we pay the costs of settlement and damage awards against directors and officers as required by these indemnification provisions.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted for directors, executive officers, or persons controlling us, we have been informed that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

Compensation Committee Interlocks

None of the members of our Compensation Committee has at any time been one of our officers or employees. None of our executive officers currently serves, or in the past fiscal year has served, as a member of the board of directors or the compensation committee of any entity that has one or more executive officers on our board of directors or the Compensation Committee.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

Security Ownership of Certain Beneficial Owners and Management.

The following table sets forth information with respect to the beneficial ownership of our common stock as of February 28, 2026, by:

- each of our named executive officers;
- each of our directors;
- all of our executive officers and directors as a group; and
- each person or group of affiliated persons known by us to beneficially own more than 5% of our common stock.

The number of shares beneficially owned by each stockholder is determined under rules issued by the SEC. Under these rules, beneficial ownership includes any shares as to which a person has sole or shared voting power or investment power. Applicable percentage ownership is based on 21,816,041 shares of common stock outstanding on February 28, 2026. In computing the number of

shares beneficially owned by a person and the percentage ownership of that person, shares of common stock subject to options or other rights held by such person that are currently exercisable or that will become exercisable or otherwise vest within 60 days of February 28, 2026 are considered outstanding, although these shares are not considered outstanding for purposes of computing the percentage ownership of any other person.

Unless otherwise indicated, the address of each beneficial owner listed in the table below is c/o Aardvark Therapeutics, Inc., 4370 La Jolla Village Drive, Suite 1050, San Diego, CA 92122.

Name of Beneficial Owner	Number of Shares Beneficially Owned	Percent of Shares Beneficially Owned (%)
5% or Greater Stockholders:		
Entities affiliated with Decheng Capital Global Life Sciences Fund IV, L.P[1]	3,917,299	18.0%
Vickers Venture Fund VI Pte. Ltd.[2]	2,050,902	9.4%
Dr. Finian Tan[3]	1,861,258	8.5%
Christopher Ho[4]	1,694,894	7.8%
Entities affiliated with Citadel Advisors LLC[5]	1,192,971	5.5%
Jane Wu Lee, M.D.[6]	3,034,246	13.9%
Named Executive Officers and Directors:		
Tien-Li Lee, M.D.[7]	3,034,246	13.9%
Nelson Sun[8]	471,885	2.2%
Manasi Jaiman, M.D., M.P.H.[9]	70,067	*
Jeffrey Chi, Ph.D.	—	—
Roy D. Baynes, M.D., Ph.D.[10]	9,833	*
Susan E. Graf[11]	10,448	*
Victor Tong, Jr.	—	—
All executive officers and directors as a group (7 persons)[12]	3,596,479	16.4%

* Represents beneficial ownership of less than 1%.

(1) Consists of (i) 2,958,887 shares of our common stock held by Decheng Capital Global Life Sciences Fund IV, L.P. (Fund IV), and (ii) 958,412 shares of our common stock held by Decheng Capital Global Healthcare Fund (Master), LP (Healthcare). Decheng Capital Management IV (Cayman), LLC (GP IV) is the general partner of Fund IV and shares voting and investment authority over the shares held by Fund IV. Decheng Capital Global Healthcare GP, LLC (Healthcare GP) is the general partner of Healthcare and shares voting and investment authority over the shares held by Healthcare. Dr. Xiangmin Cui is the manager of GP IV and the indirect managing member and ultimate beneficial owner of Healthcare GP. Dr. Cui shares voting and investment authority over the shares held by each of Fund IV and Healthcare. Dr. Xiangmin Cui shares voting and investment authority over the shares held by each of Fund IV and Healthcare. The address of Fund IV and Healthcare Fund is c/o Decheng Capital, 3000 Sand Hill Road, Building 2, Suite 110, Menlo Park, CA 94025. Information in this footnote is as of February 12, 2025, and is based solely on a Schedule 13G filed with the SEC by Fund IV, GP IV, Healthcare, Healthcare GP and Dr. Cui on February 24, 2025.

(2) Vickers Venture Fund VI Pte. Ltd. (Vickers Pte) has two shareholders that each control the voting and disposition of an allocable portion of its securities, one of which is Vickers Venture Global Deep-tech Fund II (CI) L.P., which is managed by its general partner Vickers Venture Partners VI (CI) Ltd., which is in turn managed by its directors, being Dr. Finian Tan and Christopher Ho. Each of Dr. Tan and Mr. Ho disclaims beneficial ownership of the securities held by Vickers Pte, except to the extent of his respective proportionate pecuniary interest therein. The address of Vickers Pte is 1 Harbourfront Avenue, #16-06, Keppel Bay Tower Singapore 098632. Information in this footnote is as of February 12, 2025, and is based solely on a Schedule 13G filed with the SEC by Dr. Finian Tan, Christopher Michael Ho and Vickers Pte on February 24, 2025.

(3) Consists of (i) 20,000 shares held directly by Dr. Tan, (ii) 13,000 shares held by Dr. Tan's wife, (iii) 247,818 shares held by Vickers Venture Global Deep-tech Fund I L.P. (Vickers Deep-tech), (iv) 225,354 shares held by Vickers Venture Fund VI (Plan) Pte. Ltd. (Vickers Plan), (iv) 1,221,722 shares held by Vickers Pte and (vi) 133,364 shares held by Vickers Venture Co-investment LLC (Vickers Co-investment). Vickers Deep-tech is managed by its general partner Vickers Venture Partners V Ltd. which is in turn managed by its directors, Dr. Tan and Mr. Ho. The sole shareholder of Vickers Plan is Vickers Venture Global Deep-tech Fund II (Plan) L.P. Vickers Venture Global Deep-tech Fund II (Plan) L.P. is managed by its general partner Vickers Venture Partners VI (CI) Ltd which is in turn managed by its directors, Dr. Tan and Mr. Ho. Vickers Pte has two shareholders that each control the voting and disposition of an allocable portion of its

securities, one of which is Vickers Venture Global Deep-tech Fund II (CI) L.P., which is managed by its general partner Vickers Venture Partners VI (CI) Ltd. which is in turn managed by its directors, being Dr. Tan and Mr. Ho. Vickers Co-investment is managed by Vickers Venture Partners (S) Pte. Ltd. which is in turn managed by its two directors, one of which is Dr. Tan. Each of Dr. Tan and Mr. Ho disclaims beneficial ownership of the securities held by such entities, except to the extent of his respective proportionate pecuniary interest therein. Dr. Tan's address is 1 Harbourfront Avenue, #16-06, Keppel Bay Tower Singapore 098632. Information in this footnote is as of February 12, 2025, and is based solely on a Schedule 13G filed with the SEC by Dr. Finian Tan, Christopher Michael Ho and Vickers Pte on February 24, 2025.

(4) Consists of (i) 247,818 shares held by Vickers Deep-tech, (ii) 225,354 shares held by Vickers Plan and (iii) 1,221,722 shares held by Vickers Pte. Vickers Deep-tech is managed by its general partner Vickers Venture Partners V Ltd. which is in turn managed by its directors, Dr. Tan and Mr. Ho. The sole shareholder of Vickers Plan is Vickers Venture Global Deep-tech Fund II (Plan) L.P. Vickers Venture Global Deep-tech Fund II (Plan) L.P. is managed by its general partner Vickers Venture Partners VI (CI) Ltd which is in turn managed by its directors, Dr. Tan and Mr. Ho. Vickers Pte has two shareholders that each control the voting and disposition of an allocable portion of its securities, one of which is Vickers Venture Global Deep-tech Fund II (CI) L.P., which is managed by its general partner Vickers Venture Partners VI (CI) Ltd. which is in turn managed by its directors, being Dr. Tan and Mr. Ho. Each of Dr. Tan and Mr. Ho disclaims beneficial ownership of the securities held by such entities, except to the extent of his respective proportionate pecuniary interest therein. Mr. Ho's address is 1 Harbourfront Avenue, #16-06, Keppel Bay Tower Singapore 098632. Information in this footnote is as of February 12, 2025, and is based solely on a Schedule 13G filed with the SEC by Dr. Finian Tan, Christopher Michael Ho and Vickers Pte on February 24, 2025.

(5) Consists of (i) 1,152,375 shares of our common stock held by Citadel Multi-Strategy Equities Master Fund Ltd. (CM), and (ii) 40,596 shares of our common stock held by Citadel Securities LLC (Citadel Securities). Citadel Advisors LLC (Citadel Advisors) is the portfolio manager for CM. Citadel Advisors Holdings LP (CAH) is the sole member of Citadel Advisors. Citadel GP LLC (CGP) is the general partner of CAH. Citadel Securities Group LP (CALC4) is the non-member manager of Citadel Securities. Citadel Securities GP LLC (CSGP) is the general partner of CALC4. Kenneth Griffin is the President and Chief Executive Officer of CGP and owns a controlling interest in CGP and CSGP. Each of Citadel Advisors, CAH and CGP may be deemed to beneficially own 1,152,375 shares of our common stock. Each of Citadel Securities, CALC4 and CSGP may be deemed to beneficially own 40,596 shares of our common stock. Mr. Griffin may be deemed to beneficially own 1,192,971 shares of our common stock. The address of Citadel Advisors, CAH, CGP, Citadel Securities, CALC4, CSGP and Mr. Griffin is Southeast Financial Center, 200 S. Biscayne Blvd., Suite 3300, Miami, Florida 33131. The information in this table and footnote shall not be construed as an admission that any of the persons listed in this footnote is the beneficial owner of any securities referenced herein other than the securities actually owned by such person (if any). Information in this footnote is as of February 12, 2025, and is based solely on a Schedule 13G filed with the SEC by Citadel Advisors, CAH, CGP, Citadel Securities, CALC4, CSGP and Mr. Griffin on February 24, 2025.

(6) Consists of (i) 1,474,028 shares of our common stock held directly, (ii) 1,551,613 shares of our common stock held directly held by Dr. Lee's spouse, Tien-Li Lee, M.D., our Chief Executive Officer, and (iii) 8,605 shares of our common stock subject to options held by Tien-Li Lee, M.D., that are exercisable within 60 days of February 28, 2026.

(7) Consists of (i) 1,551,613 shares of our common stock held directly, (ii) 1,474,028 shares of our common stock held directly by Dr. Lee's spouse, Jane Wu Lee, M.D., and (iii) 8,605 shares of our common stock subject to options that are exercisable within 60 days of February 28, 2026.

(8) Consists of (i) 108,484 shares of our common stock held directly, (ii) 354,024 shares of our common stock held by two trusts of which Mr. Sun is the sole trustee (iii) and 9,377 shares of our common stock subject to options that are exercisable within 60 days of February 28, 2026.

(9) Consists solely of 70,067 shares of our common stock subject to options that are exercisable within 60 days of February 28, 2026.

(10) Consists solely of 9,833 shares of our common stock subject to options that are exercisable within 60 days of February 28, 2026.

(11) Consists solely of 10,448 shares of our common stock subject to options that are exercisable within 60 days of February 28, 2026.

(12) Consists of the shares of our common stock beneficially owned by our current executive officers and directors shown as beneficially owned by our current executive officers and directors in the table above.

Equity Compensation Plan Information

The following table provides information on our equity compensation plans as of December 31, 2025:

Plan	Number of securities to be issued upon the exercise of outstanding options, warrants and rights (a)	Weighted average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plan (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders (1)(2)	2,798,430	$ 8.95	374,719
Equity compensation plans not approved by security holders (3)	239,983	$ 10.42	660,017
Total	3,038,413		1,034,736

(1) Includes the 2017 Plan, the 2025 Plan and our ESPP, the terms of each of which are described in more detail above under "—Equity Compensation Plans." 185,408 shares under column (c) are attributable to our ESPP.

(2) Under the terms of the 2025 Plan, the number of shares of our common stock reserved for issuance under the 2025 Plan will automatically increase on January 1 of each calendar year beginning on January 1, 2026 and ending on January 1, 2035, in an amount equal to 5.0% of the total number of shares of our capital stock outstanding on December 31st of the immediately preceding calendar year, or a lesser number of shares determined by our board of directors. Under the terms of our ESPP, the number of shares of our common stock reserved for issuance will automatically increase on January 1 of each calendar year beginning on January 1, 2026 and ending on January 1, 2035, by the lesser of (a) 1.0% of the total number of shares of our common stock outstanding on December 31st of the immediately preceding calendar year, and (b) 645,000 shares; provided that before the date of any such increase, our board of directors may determine that such increase will be less than the amount set forth in (a) and (b).

(3) Includes the 2025 Inducement Plan, the terms of which are described in more detail above under "—Equity Compensation Plans—2025 Inducement Equity Incentive Plan."

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The following is a summary of transactions since January 1, 2024 and any currently proposed transactions to which we have been a participant in which the amount involved exceeded or will exceed the lesser of $120,000 or 1% of the average of our total assets as of each of December 31, 2024 and 2025, and in which any of our then directors, executive officers or holders of more than 5% of any class of our capital stock at the time of such transaction, or any members of their immediate family, had or will have a direct or indirect material interest, other than compensation arrangements which are described in Part III, Item 11, "Executive Compensation", of this Annual Report.

Initial Public Offering

In February 2025, we completed our initial public offering pursuant to which we issued and sold an aggregate of 6,120,661 shares of common stock, which included the partial exercise by the underwriters to purchase 232,661 additional shares at a price to the public of $16.00 per share. The following table sets forth the number of shares of common stock purchased by our directors, executive officers or holders of more than 5% of our common stock or entities affiliated with them, including entities affiliated with certain of our directors at the closing of the initial public offering:

Name[(1)]	Shares of Common Stock	Purchase Price
Decheng Capital Global Life Sciences Fund IV, L.P.[(2)]	1,250,000	$ 20,000,000
Tien-Li Lee, M.D.	16,542	$ 264,672
Nelson Sun	10,000	$ 160,000

(1) Additional detail regarding these stockholders and their equity holdings is provided under Part III, Item 12, "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters", of this Annual Report.

(2) Comprised of 625,000 shares of our common stock purchased by Decheng Capital Global Life Sciences Fund IV, L.P. and 625,000 shares of our common stock purchased by Decheng Capital Global Healthcare Fund (Master), LP. Mr. Tong, a member of our board of directors, is an affiliate of Decheng Capital Global Life Sciences Fund IV, L.P.

Series C Convertible Preferred Stock Financing

In two closings held in May 2024, we issued and sold an aggregate of 48,030,730 shares of our Series C convertible preferred stock at a purchase price of $1.7697 per share for an aggregate purchase price of $85.0 million. All shares of our Series C convertible preferred stock automatically converted into shares of our common stock immediately prior to the completion of our IPO.

The following table summarizes the Series C convertible preferred stock purchased by holders of more than 5% of our capital stock as of the date of the closing of the Series C convertible preferred stock, and entities affiliated with certain of our executive officers and directors.

Participants[1]	Series C Preferred Stock Purchased (#)	Aggregate Purchase Price ($)
Decheng Capital Global Life Sciences Fund IV, L.P.[2]	22,602,700	39,999,998
Vickers Venture Fund VI Pte. Ltd.[3]	1,130,135	2,000,000

(1) Additional detail regarding these stockholders and their equity holdings is included in Part III, Item 12, "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters", of this Annual Report.

(2) Comprised of shares purchased by Decheng Capital Global Life Sciences Fund IV, L.P. and Decheng Capital Global Healthcare Fund (Master), LP. Mr. Tong, a member of our board of directors, is an affiliate of Decheng Capital Global Life Sciences Fund IV, L.P.

(3) Comprised solely of shares purchased by Vickers Venture Co-investment LLC, an affiliate of Vickers Venture Fund VI Pte. Ltd. Dr. Chi, a member of our board of directors, was formerly an affiliate of Vickers Venture Fund VI Pte. Ltd.

Aardwolf Spin-Off

On May 31, 2022, we entered into a Contribution Agreement and a Project Contribution Agreement in connection with a spin-off (the Spin-off) of certain of our early-stage, non-core assets, through a series of transactions, to a newly-formed company, Aardwolf Therapeutics, Inc. (Aardwolf). The assets spun off relate primarily to the data, ideas, patents and results relating to two of our product candidates, WOLF-201 and WOLF-301.

Tien-Li Lee, M.D., our Chief Executive Officer, also serves as the President and Secretary of Aardwolf. Nelson Sun, our Chief Financial Officer and Chief Operating Officer, also serves as the Chief Financial Officer and Treasurer of Aardwolf. Jeffrey Chi, Ph.D., a member of our board of directors, also serves as a director of Aardwolf.

In connection with the Spin-off, we also entered into a Transition Services Agreement (the Transition Services Agreement), dated as of May 31, 2022, pursuant to which we (or any person on our behalf) agreed to provide certain transition services to Aardwolf or its affiliates. As of December 31, 2024, we invoiced approximately $1.4 million to Aardwolf pursuant to the services provided by us under the Transition Services Agreement. As of December 31, 2025, all of such invoiced amount has been deemed uncollectible and has been written-off, and we will reassess the estimated recovery thereof in future periods. The Transition Services Agreement terminated on May 31, 2024.

Aardwolf Convertible Promissory Note

On August 1, 2022, Aardwolf issued a convertible promissory note in the aggregate principal amount of $1.0 million to Aardvark (the Convertible Promissory Note). The Convertible Promissory Note matures seven years from the date of issuance and bears interest at the rate of 5.0% per annum. Pursuant to the Convertible Promissory Note, in the event that Aardwolf issues and sells shares of its equity securities to investors in an equity financing with total proceeds of not less than $3.0 million (a Qualified Financing), then the outstanding principal amount of the Convertible Promissory Note and any unpaid accrued interest shall automatically convert in whole into equity securities sold in the Qualified Financing at a conversion price equal to the cash price paid per share for equity securities by the investors in the Qualified Financing multiplied by 70%. Aardvark has the option to treat certain other equity financing, including an equity financing pursuant to which Aardwolf sells shares of preferred stock, as a Qualified Financing on the same terms. All outstanding amounts under the Convertible Promissory Note have been, as of December 31, 2025, deemed uncollectible and written-off, and we will reassess the estimated recovery of such balances in future periods.

Investors' Rights Agreement

In May 2024, in connection with the issuance and sale of our Series C preferred stock, we entered into an Amended and Restated Investors' Rights Agreement (the Rights Agreement) with certain holders of our convertible preferred stock, including certain holders of 5% or more of our capital stock and entities affiliated with certain of our directors, as well as certain of our directors and executive officers.

The Rights Agreement granted certain rights to the holders of our then-outstanding convertible preferred stock, which automatically converted into shares of common stock immediately prior to the completion of our IPO, including certain registration rights with respect to the registrable securities held by them.

In addition, the Rights Agreement imposed certain affirmative obligations on us, including, among other things, our obligation to grant each investor who held shares of our convertible preferred stock a right of first refusal with respect to certain issuances of our capital stock, excluding the shares sold in our IPO, and granted certain information and inspection rights to such investors. Each of these other obligations terminated in connection with the completion of our IPO. We remain obligated to comply with reporting requirements under the Exchange Act.

Voting Agreement

In May 2024, in connection with the issuance and sale of our Series C preferred stock, we entered into the Voting Agreement under which certain holders of our capital stock, including certain holders of 5% or more of our capital stock, entities affiliated with certain of our directors and certain of our directors and executive officers, agreed to vote in a certain way on certain matters, including with respect to the election of directors.

Pursuant to the Voting Agreement, (i) Vickers Venture Fund VI (Plan) L.P. had the right to designate one member to be elected to our board of directors and (ii) Decheng Capital, LLC had the right to designate one member to be elected to our board of directors. The Voting Agreement terminated by its terms in connection with the completion of our IPO and none of our stockholders have any continuing rights regarding the election or designation of members of our board of directors.

Right of First Refusal and Co-Sale Agreement

In May 2024, in connection with the issuance and sale of our Series C preferred stock, we entered into an Amended and Restated Right of First Refusal and Co-Sale Agreement (the Co-Sale Agreement) with holders of our convertible preferred stock, including certain holders of 5% or more of our capital stock and entities affiliated with certain of our directors, pursuant to which we had a right of first refusal, and certain holders satisfying an ownership threshold of convertible preferred stock had a right of first refusal and co-sale, in respect of certain sales of securities by specified holders of convertible preferred stock. The Co-Sale Agreement terminated by its terms in connection with the completion of our IPO.

Management Rights Letters

In connection with the issuance and sale of our Series C preferred stock, we entered into a management rights letter with Decheng Capital Global Life Sciences Fund IV, L.P. and its affiliates, pursuant to which such entities were granted certain management rights, including the right to consult with and advise our management on significant business issues, review our annual operating plans, examine our books and records and inspect our facilities. Such management rights letter terminated by its terms in connection with the completion of our IPO.

Employment Arrangements

We have entered into employment agreements and offer letters with certain of our executive officers. For more information regarding these agreements with our executive officers, see Part III, Item 11, "Executive Compensation—Narrative Disclosure to Summary Compensation Table—Arrangements with Executive Officers", of this Annual Report.

Equity Grants

We have granted options to purchase shares of our common stock to certain of our executive officers and directors. For more information regarding the options granted to our executive officers and directors, see Part III, Item 11, "Executive Compensation—Non-Employee Director Compensation", of this Annual Report.

Indemnification Agreements

We have entered into indemnification agreements with certain of our current directors and executive officers. The indemnification agreements and the Certificate of Incorporation and the Bylaws require us to indemnify our directors and executive officers to the fullest extent permitted by Delaware law. For more information regarding these agreements, see Part III, Item 11, "Executive Compensation—Limitations on Liability and Indemnification", of this Annual Report.

Related Person Transaction Policy

Our board of directors has adopted a written related person transaction policy, which became effective upon the closing of our IPO, setting forth our procedures for the identification, review, consideration and approval or ratification of related person transactions. For purposes of our policy only, a related person transaction is a transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we and any related person are, were or will be participants and in which the amount involved exceeds $120,000. Transactions involving compensation for services provided to us as an employee or director are not covered by this policy. A related person is any officer, director (or nominee to become a director) or beneficial owner of more than 5% of any class of our voting securities, including any of their immediate family members. In reviewing and approving any such transactions, the 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 were entered into prior to the effectiveness of this written related person transaction policy, but all were approved by our board of directors considering similar factors to those described above.

Director Independence

Under the Nasdaq Rules, a majority of the members of our board of directors must satisfy the Nasdaq criteria for "independence." No director qualifies as independent under the Nasdaq Rules unless our board of directors affirmatively determines that the director does not have a relationship with us that would impair independence (directly or as a partner, stockholder or officer of an organization that has a relationship with us). Based upon information requested from and provided by each director concerning such director's background, employment and affiliations, including family relationships, our board of directors has determined that Jeffrey Chi, Ph.D., Roy D. Baynes, M.D., Ph.D., Susan E. Graf and Victor Tong, Jr. are independent directors as defined under the Nasdaq Rules. Dr. Lee is not independent under the Nasdaq Rules as a result of his position as our Chief Executive Officer. In making these determinations, our board of directors considered the current and prior relationships that each non-employee director has with our company, their ability to exert control over us and all other facts and circumstances our board of directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director and the transactions described in Part III, Item 13, "Certain Relationships and Related Transactions, and Director Independence" of this Annual Report.

Item 14. Principal Accounting Fees and Services.

Audit and All Other Fees

The following table presents fees for services rendered by BDO USA, P.C., our independent registered public accounting firm, for the years ended December 31, 2025 and 2024 in the following categories:

	Years ended December 31,	
	2025	2024
Audit Fees [1]	$ 943,666	$ 852,729
Audit-Related Fees	—	—
Tax Fees [2]	—	—
All Other Fees	—	—
	$ 943,666	$ 852,729

(1) Audit fees consist of fees billed for professional services by BDO USA, P.C. for audit and quarterly review of our consolidated financial statements and review of our registration statement on Form S-1, and related services that are normally provided in connection with statutory and regulatory filings or engagements.

(2) Tax fees consist of fees for professional services performed by BDO USA, P.C. with respect to tax compliance, tax advice and tax planning.

Audit Committee Pre-Approval of Audit and Non-Audit Services

The Audit Committee has established a policy that all audit and permissible non-audit services provided by our independent registered public accounting firm will be pre-approved by the Audit Committee. These services may include audit services, audit-related services, tax services and other services. The Audit Committee considers whether the provision of each non-audit service is compatible with maintaining the independence of our auditors. Pre-approval is detailed as to the particular service or category of services. Our Chief Financial Officer is required to periodically report to the Audit Committee regarding the extent of services provided by the independent registered public accounting firm in accordance with this pre-approval.

PART IV

Item 15. Exhibits, Financial Statement Schedules.
(a) Documents filed as part of this report.

1. Financial Statements

The consolidated financial statements of Aardvark Therapeutics, Inc. listed below are set forth in Part II, Item 8 of this Annual Report:

	Page
Report of Independent Registered Public Accounting Firm: BDO USA, P.C.; San Diego, California; (PCAOB ID # 243)	F-2
Consolidated Balance Sheets as of December 31, 2025 and 2024	F-3
Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2025 and 2024	F-4
Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit) for the years ended December 31, 2025 and 2024	F-5
Consolidated Statements of Cash Flows for the years ended December 31, 2025 and 2024	F-6
Notes to Consolidated Financial Statements	F-7

2. Financial Statement Schedules

These schedules have been omitted because the required information is included in the consolidated financial statements or notes thereto or because they are not applicable or not required.

3. Exhibits

Exhibit Number	Description of Document
3.1	Fourth Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 of our Current Report on Form 8-K (File No. 001-42513), filed on February 14, 2025).
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.4 of Amendment No. 1 of our Registration Statement on Form S-1/A (File No. 333-284440), filed on February 6, 2025).
4.1	Form of Common Stock Certificate (incorporated by reference to Exhibit 4.1 of Amendment No. 1 of our Registration Statement on Form S-1/A (File No. 333-284440), filed on February 6, 2025).
4.2	Description of Securities (incorporated by reference to Exhibit 4.2 of our Annual Report on Form 10-K, filed on March 31, 2025).
10.1+	2017 Equity Incentive Plan, as amended, and forms of agreement thereunder (incorporated by reference to Exhibit 10.1 of our Registration Statement on Form S-1 (File No. 333-284440), filed on January 23, 2025).
10.2+	2025 Equity Incentive Plan (incorporated by reference to Exhibit 10.2 of our Registration Statement on Form S-8 (File No. 333-284915), filed on February 13, 2025).
10.3+	2025 Equity Incentive Plan Form of Stock Option Agreement (incorporated by reference to Exhibit 10.3 of Amendment No. 1 of our Registration Statement on Form S-1/A (File No. 333-284440), filed on February 6, 2025).
10.4+	2025 Equity Incentive Plan Form of Restricted Stock Unit Award Agreement (incorporated by reference to Exhibit 10.4 of Amendment No. 1 of our Registration Statement on Form S-1/A (File No. 333-284440), filed on February 6, 2025).
10.5+	2025 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.5 of our Registration Statement on Form S-8 (File No. 333-284915), filed on February 13, 2025).
10.6+	2025 Inducement Equity Incentive Plan (incorporated by reference to Exhibit 10.1 of our Quarterly Report on Form 10-Q (File No. 001-42513), filed on August 13, 2025).
10.7+	2025 Inducement Equity Incentive Plan Form of Stock Option Agreement (incorporated by reference to Exhibit 10.2 of our Quarterly Report on Form 10-Q (File No. 001-42513), filed on August 13, 2025).
10.8+	2025 Inducement Equity Incentive Plan Form of Restricted Stock Unit Agreement (incorporated by reference to Exhibit 10.3 of our Quarterly Report on Form 10-Q (File No. 001-42513), filed on August 13, 2025).
10.9+	Form of Indemnification Agreement (incorporated by reference to Exhibit 10.6 of our Registration Statement on Form S-1 (File No. 333-284440), filed on January 23, 2025).
10.10+	Employment Offer Letter, dated July 24, 2019, between the Registrant and Tien-Li Lee, M.D. (incorporated by reference to Exhibit 10.7 of our Registration Statement on Form S-1 (File No. 333-284440), filed on January 23, 2025).
10.11+	Employment Offer Letter, dated August 23, 2021, between the Registrant and Nelson Sun (incorporated by reference to Exhibit 10.9 of our Registration Statement on Form S-1 (File No. 333-284440), filed on January 23, 2025).
10.12+	Employment Offer Letter, dated August 23, 2024, between the Registrant and Manasi Jaiman, M.D., M.P.H. (incorporated by reference to Exhibit 10.10 of our Registration Statement on Form S-1 (File No. 333-284440), filed on January 23, 2025).
10.13	Amended and Restated Investors' Rights Agreement, dated May 1, 2024 (incorporated by reference to Exhibit 10.11 of our Registration Statement on Form S-1 (File No. 333-284440), filed on January 23, 2025).
10.14+	Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.12 of our Registration Statement on Form S-1 (File No. 333-284440), filed on January 23, 2025).
10.15+	Aardvark Therapeutics, Inc. Severance Plan (incorporated by reference to Exhibit 10.13 of our Registration Statement on Form S-1 (File No. 333-284440), filed on January 23, 2025).

Exhibit Number	Description of Document
19.1*	Aardvark Therapeutics, Inc. Insider Trading Policy, as amended
21.1*	Subsidiaries of the Registrant.
23.1*	Consent of BDO USA, P.C. Independent Registered Public Accounting Firm.
24.1*	Power of Attorney. Reference is made to the signature page hereto.
31.1*	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.
31.2*	Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.
32.1†	Certification of the Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2†	Certification of the Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
97	Aardvark Therapeutics, Inc. Clawback Policy (incorporated by reference to Exhibit 97 of our Annual Report on Form 10-K (File No. 001-42513), filed on March 31, 2025).

* Filed herewith.
+ Indicates management contract or compensatory plan.
† Furnished herewith.

Item 16. Form 10-K Summary

None.

SIGNATURES

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

AARDVARK THERAPEUTICS, INC.

Date: March 23, 2026

By: /s/ Tien-Li Lee, M.D.
Tien-Li Lee, M.D.
Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Tien-Li Lee, M.D. and Nelson Sun, and each of them, as his or her true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution and full power to act without the other, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K and to file the same, with all exhibits thereto, and all other documents in connection therewith, with the Securities and Exchange Commission, granting unto each said attorney-in-fact and agents full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises hereby ratifying and confirming all that said attorneys-in-fact and agents, or his or their substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

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

Name	Title	Date
/s/ Tien-Li Lee, M.D. Tien-Li Lee, M.D.	Chief Executive Officer and Director *(Principal Executive Officer)*	March 23, 2026
/s/ Nelson Sun Nelson Sun	Chief Financial Officer and Chief Operating Officer *(Principal Financial and Accounting Officer)*	March 23, 2026
/s/ Jeffrey Chi, Ph.D. Jeffrey Chi, Ph.D.	Director	March 23, 2026
/s/ Roy D. Baynes, M.D., Ph.D. Roy D. Baynes, M.D., Ph.D.	Director	March 23, 2026
/s/ Susan E. Graf Susan E. Graf	Director	March 23, 2026
/s/ Victor Tong, Jr. Victor Tong, Jr.	Director	March 23, 2026